

**REGISTRATION REPORT
Part A**

Risk Management

Product code: Detia Mäuse Giftkörner
Active Substance: Zinc phosphide 25 g/kg

COUNTRY: Germany
Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant: Detia Freyberg GmbH
Submission Date: 22/12/2012
Date: 30/07/2018

Table of Contents

PART A – Risk Management	4
1 Details of the application	4
1.1 Application background	4
1.2 Annex I inclusion	4
1.3 Regulatory approach	5
1.4 Data protection claims	5
1.5 Letters of Access	5
2 Details of the authorisation	5
2.1 Product identity	5
2.2 Classification and labelling	6
2.2.2 Classification and labelling under Regulation (EC) No 1272/2008	6
2.2.3 R and S phrases under Regulation (EU) No 547/2011	7
2.2.3 Other phrases	7
2.2.3.2 Specific restrictions linked to the intended uses	8
2.3 Product uses	10
3 Risk management	16
3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles	16
3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)	16
3.1.2 Methods of analysis (Part B, Section 2, Point 5)	16
3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)	16
3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)	17
3.1.3.1 Acute Toxicity (Part B, Section 3, Point 7.1)	17
3.1.3.2 Operator Exposure (Part B, Section 3, Point 7.3)	17
3.1.3.3 Bystander Exposure (Part B, Section 3, Point 7.4)	17
3.1.3.4 Worker Exposure (Part B, Section 3, Point 7.5)	17
3.1.4 Residues and Consumer Exposure (Part B, Section 4, Point 8)	18
3.1.4.1 Residues (Part B, Section 4, Points 8.3 and 8.7)	18
3.1.4.2 Consumer exposure (Part B, Section 4, Point 8.10)	18
3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)	19
3.1.5.1 Predicted Environmental Concentration in Soil (PECsoil) (Part B, Section 5, Points 9.4 and 9.5)	19
3.1.5.2 Predicted Environmental Concentration in Ground Water (PECGW) (Part B, Section 5, Point 9.6)	19

3.1.5.3 Predicted Environmental Concentration in Surface Water (PEC_{SW}) (Part B, Section 5, Points 9.7 and 9.8)	20
3.1.5.4 Predicted Environmental Concentration in Air (PEC_{Air}) (Part B, Section 5, Point 9.9)	20
3.1.6 Ecotoxicology (Part B, Section 6, Point 10)	20
3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)	21
3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)	23
3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)	24
3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms (Part B, Section 6, Point 10.6)	24
3.1.6.5 Effects on organic matter breakdown (Part B, Section 6, Point 10.6)	24
3.1.6.6 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)	24
3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)	25
3.1.7 Efficacy (Part B, Section 7, Point 8)	26
3.3 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation	27
Appendix 1 – Copy of the product authorisation	28
Appendix 2 – Copy of the product label	29
Appendix 3 – Letter of Access	30

PART A – Risk Management

This document describes the acceptable use conditions required for the re-registration of Detia Mäuse Giftkörner containing zinc phosphide in Germany.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C and where appropriate the addendum for Germany. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national re-registration by the EU review. It also includes assessment of data and information relating to Detia Mäuse Giftkörner where that data has not been considered in the EU review. Otherwise assessments for the safe use of Detia Mäuse Giftkörner have been made using endpoints agreed in the EU review of zinc phosphide.

This document describes the specific conditions of use and labelling required for Germany for the re-registration of Detia Mäuse Giftkörner.

Appendix 1 of this document provides a copy of the final product authorisation Germany.

Appendix 2: The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions drawn by the competent authority. The final version of the label is not available, because the layout is the sole responsibility of the applicant and will not be checked again.

Appendix 3 of this document contains copies of the letters of access to the protected data / third party data that was needed for evaluation of the formulation.

1 Details of the application

1.1 Application background

This application was submitted by Detia Freyberg GmbH on 22 December 2012.

The application was for approval of Detia Mäuse Giftkörner, a bait ready for use, containing 25 g/kg zinc phosphide for use as a rodenticide for control of common voles (*Microtus arvalis*) in field crops, grassland, pasture and meadows, vegetables, fruit crops, grape vine, forest plants and ornamentals for professional use and amateur gardening, to be applied underground in the common voles' holes or in bait stations.

1.2 Annex I inclusion

Zinc phosphide was included on Annex I of Directive 91/414/EEC on 1 May 2011 under Inclusion Directive 2010/85/EU amending Decision 2008/941/EC and implemented under Regulation (EU) No 540/2011.

Zinc phosphide was included in annex I under provisions as use only as rodenticide in the form of ready-to-use baits placed in bait stations or target locations.

The approval of zinc phosphide (Inclusion Directive for zinc phosphide (2010/85/EU) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on zinc phosphide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010 shall be taken into account.

In this overall assessment Member States should pay particular attention to:

- the protection of non target organisms. Risk mitigation measures should be applied as appropriate in particular to avoid the spread of baits where only part of the content has been consumed.

1.3 Regulatory approach

To obtain re-approval the product Detia Mäuse Giftkörner must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

This application was submitted in order to allow the re-registration of an already approved product in Germany in accordance with the above.

1.4 Data protection claims

Where data protection is being claimed regarding information supporting registration of Detia Mäuse Giftkörner, it is indicated in the reference list in Appendix 1 of the respective documents of the Registration Report.

1.5 Letters of Access

Data access has been proven.

Detia Freyberg GmbH is the owner of all data. This point is not relevant.

2 Details of the authorisation

2.1 Product identity

Product Name	Detia Mäuse Giftkörner
Authorization Number (for re-registration)	007851-00
Function	Rodenticide
Applicant	Detia Freyberg GmbH
Composition	25 g/kg zinc phosphide
Formulation type	Ready for use Bait [Code: RB]

Packaging	<p>For non-professional users: 180 g box of polyethylene; 500 g bucket, polypropylene has been applied for but could <u>not</u> be approved based on concerns in the ecotox section.</p> <p>For professional users: 1 kg bucket, polypropylene; 5 kg bucket, polypropylene; 25 kg sack (PE or PP)</p>
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2.2 Classification and labelling

2.2.2 Classification and labelling under Regulation (EC) No 1272/2008

The following labelling is proposed in accordance with Regulation (EC) No 1272/2008:

<i>Hazard classes and categories:</i>	
Acute Tox. 4, Aquatic acute 1, Aquatic chronic 1	
<i>Hazard pictograms:</i>	
GHS07	exclamation mark
GHS09	environment
<i>Signal word:</i>	
Warning	
<i>Hazard statements:</i>	
H302	Harmful if swallowed.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
<i>Precautionary statements:</i>	
P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P264	Wash ... thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P391	Collect spillage.
P404	Store in a closed container.
P405	Store locked up.
P501	Dispose of contents/container to ...
<i>Additional labelling phrases:</i>	
EUH 401	To avoid risks to man and the environment, comply with the instructions for use.
EUH 032	Contact with acids liberates very toxic gas.

2.2.3 R and S phrases under Regulation (EU) No 547/2011

None.

2.2.3 Other phrases

2.2.3.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions (mandatory labelling):

Human health protection	
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
SB005	If medical advice is needed, have product container or label at hand.
SB010	Keep out of children´s reach.
SB011	Keep away from children.
SB111	Concerning the requirements for personal protective gear for handling the plant protection product the material safety data sheet and the instructions for use of the plant protection product as well as the guideline "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety (www.bvl.bund.de) must be observed.
SB166	Do not eat, drink or smoke when using this product.
SS1201-1	Protective gloves (plant protection) must be worn when handling/applying the product.
SS206	Working clothes (if no specific protective suit is required) and sturdy footwear (e.g. rubber boots) must be worn when applying/handling plant protection products.
NT660	Application of the product outside the forest is only permissible by subsurface placing (§ 2 Abs. 1 Pflanzenschutz-Anwendungsverordnung). Violations may be punished by fines of up to 50.000 Euro.
NT667	Place bait out of reach for children, domestic animals and animals living in the wild.
NT668	If dead or dying rats or mice are found during or after control measures, they must be

	cleared away immediately in order to avoid secondary poisoning.
Particular regulation for packages in the home and allotment garden area:	
VH298	The packaging/container must be provided with a warning which can be identified by touching for home and garden use.
Ecosystem protection	
NS648	Application only if sample trappings or other suitable prognosis methods have proven that control measures are necessary.
NT659	Do not put in exposed places.
NT671	The product is very toxic for birds and game.
NW262	The product is toxic for algae.
NW264	The product is toxic for fish and aquatic invertebrates
NW467	The product and its remains, empty containers and packaging and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.
Integrated Pest Management	
NB663	Due to the manner in which authorisation governs application of the product, bees are not endangered. (B3)
NN001	Due to the manner in which authorisation governs the application of the product, populations of beneficial organisms living on plants are not endangered.
	Mode of Action: rodenticide

2.2.3.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions (mandatory labelling):
See 2.3 (Product uses)

Human health protection

SS202 Wear protective gloves when handling the product.

SS205-1 Wear long-sleeved shirt, long trousers and sturdy footwear during handling and applying plant protection products.

Uses: 004, 007, 009, 014, 017, 019

Ecosystem protection

NW704 Due to the danger of run-off, there must be a buffer zone of at least 10 m between treated areas and surface waters - including periodically but excluding occasionally water-bearing surface waters - when applying the product.

Uses: 001 – 003, 005, 006, 008, 010 – 013, 015, 016, 018, 020

NT802 Not to be used in nature reserves and bird protection areas.

Uses: 001 – 003, 005, 006, 008, 010 – 013, 015, 016, 018, 020

- NT803 Not to be used in resting areas of migratory birds on their migratory routes.
Uses: 001 – 003, 005, 006, 008, 010 – 013, 015, 016, 018, 020
- NT820 Not to be used in areas inhabited by European hamster, hazel dormouse, northern birch mouse or Bavarian pine vole.
Uses: 001 – 003, 005, 006, 008, 010 – 013, 015, 016, 018, 020
- NT664 The bait must be placed deep down in the rodent burrows by using a commercially available bait dispenser to make it inaccessible for birds. There shall be no bait left on the surface.
Uses: 001 – 003, 005, 006, 008, 010
- NT680 Only bait stations may be used which are mechanically stable, weather-resistant and tamper-resistant. Both construction and installation have to ensure that bait stations are inaccessible to non-target organisms as possible. For control of common vole, field vole and bank vole the diameter of the opening may not exceed 6 cm. The bait stations have to be labelled legibly with the following safety phrase: „Caution rodenticide“, active substance(s), poison emergency number and note: „Keep away children and domestic animals“.
Uses: 011 – 013, 015, 016, 018, 020

2.3 Product uses

GAP rev. (No), date: 2013-08-15

- PPP (product name/code) active substance 1 **Detia Mäuse Giftkörner zinc phosphide**
 Formulation type: **bait (ready for use)**
 Conc. of as 1: **25 g/kg**

Applicant: Detia Fryberg GmbH
Zone(s): central

professional use x
non professional use x

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
001	DE	Field crops (NNNAC)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha		F *)	5 piece(s) per hole (hide), The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. *) The PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product

002	DE	Forest plants (NNNWW)	F	Common vole (MICRAR)	lay out poisoned cereal grams	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	N **)	and the use of the product (e.g. harvest) or the setting of a PHI in days is not required resp. NT664, NT802, NT803, NT820, NW704 5 piece(s) per hole (hide), The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. **) The setting of an PHI is without any relevance. NT664, NT802, NT803, NT820, NW704
003	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned cereal grams	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	F	5 piece(s) per hole (hide), The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. NT664, NT802, NT803, NT820, NW704
004	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned cereal grams	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	F	5 piece(s) per hole (hide), The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. Amateur gardening No authorisation possible since unacceptable effects on wildlife vertebrates cannot be excluded.
005	DE	Grassland, Pasture, Meadow (NNNFW)	F	Common vole (MICRAR)	lay out poisoned cereal	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	F	5 piece(s) per hole (hide), The application rate of 2 kg/ha per application can be

006	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	grains lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	F	5 piece(s) per hole (hide), The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.	NT664, NT802, NT803, NT820, NW704	divided into 3 single applications of 0.66 kg/ha.
007	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	F	5 piece(s) per hole (hide), The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. Amateur gardening	NT664, NT802, NT803, NT820, NW704	divided into 3 single applications of 0.66 kg/ha.
008	DE	Grape vine (VITVI)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	F	5 piece(s) per hole (hide), The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.	NT664, NT802, NT803, NT820, NW704	divided into 3 single applications of 0.66 kg/ha.
009	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	N	5 piece(s) per hole (hide), The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. Amateur gardening	NT664, NT802, NT803, NT820, NW704	divided into 3 single applications of 0.66 kg/ha.

010	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	N	No authorisation possible since unacceptable effects on wildlife vertebrates cannot be excluded. 5 piece(s) per hole (hide), The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. NT664, NT802, NT803, NT820, NW704
011	DE	Field crops (NNNAC)	F	Common vole (MICRAR)	lay out poisoned cereal grains in suitable bait stations	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	F	50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. NT680, NT802, NT803, NT820, NW704
012	DE	Forest plants (NNNWW)	F	Common vole (MICRAR)	lay out poisoned cereal grains in suitable bait stations	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	N	50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. NT680, NT802, NT803, NT820, NW704
013	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned cereal grains in suitable bait stations	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	F	50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. NT680, NT802, NT803, NT820, NW704
014	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned cereal grains in	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	F	50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. NT680, NT802, NT803, NT820, NW704

015	DE	Grassland, Pasture, Meadow (NNNFW)	F	Common vole (MICRAR)	suitable bait stations	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	F	50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. NT680, NT802, NT803, NT820, NW704	applications of 0.66 kg/ha. Amateur gardening No authorisation possible since unacceptable effects on wildlife vertebrates cannot be excluded..
016	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned cereal grains in suitable bait stations	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	F	50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. NT680, NT802, NT803, NT820, NW704	50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.
017	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned cereal grains in suitable bait stations	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	F	50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. Amateur gardening	No authorisation possible since unacceptable effects on wildlife vertebrates cannot be excluded..
018	DE	Grape vine (VITVI)	F	Common vole (MICRAR)	lay out poisoned cereal grains in suitable bait stations	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	F	50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.	50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.

019	DE	Ornamentals (NINZZ)	F	Common vole (MICRAR)	lay out poisoned cereal grains in suitable bait stations	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	N	NT680, NT802, NT803, NT820, NW704 50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. Amateur gardening No authorisation possible since unacceptable effects on wildlife vertebrates cannot be excluded..
020	DE	Ornamentals (NINZZ)	F	Common vole (MICRAR)	lay out poisoned cereal grains in suitable bait stations	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	N	NT680, NT802, NT803, NT820, NW704 50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.

Remarks:

- (1) Numeration of uses in accordance with the application/as verified by MS
- (2) Member State(s) or zone for which use is applied for
- (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
- (6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (7) Growth stage of treatment(s) (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

- (8) The maximum number of applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
- (8) Min. interval between applications (days) were relevant
- (10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
- (11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
- (12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
- (13) PHI - minimum pre-harvest interval
- (14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)

Overall Summary:

The product is a mid-brown to black metallic shiny grain bait with a garlic-like odour. It is not explosive, has no oxidising properties, is not highly flammable and shows no self-ignition. The stability data indicate a shelf life of at least two years at ambient temperature.

The technical characteristics are acceptable for a ready-for-use bait.

Implications for labelling: none

Compliance with FAO specifications:

There is no FAO specification for zinc phosphide.

Compliance with FAO guidelines:

The product Detia Mäuse Giftkörner complies with the general requirements according to the FAO/WHO manual (2016).

Compatibility of mixtures:

No mixtures are recommended on the label.

Nature and characteristics of the packaging:

Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment:

Information regarding the required protective clothing and equipment for the safe handling of Detia Mäuse Giftkörner has been provided and is considered to be acceptable.

3.1.2 Methods of analysis (Part B, Section 2, Point 5)

3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)

The phosphine of Detia Mäuse Giftkörner can be quantified using the titration method Detia SOP-025/2., although information on specificity and accuracy are missing.

There is no CIPAC method available for the determination of zinc phosphide in RB formulations like Detia Mäuse Giftkörner.

A routine analysis of zinc phosphide content was laid down in CIPAC 69, which however was not of accepted specificity. It is noted that CIPAC does not longer support this method (see DAR+AR for Zinc phosphide, point B.1.1)

Zinc phosphide does not contain any impurity of toxicological or ecotoxicological concern.

3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)

Analytical methods for soil and water are active substance data and were provided in the EU review of zinc phosphide and were considered adequate.

Methods for food of plant and animal origin are not required because it is not expected that the intended use (granular bait in special boxes) results in residues in food. No method for air is required, since exposure of operators, workers and bystanders can be excluded. An analytical method for body fluids and tissues is not required, since phosphine, the toxicologically active compound, will be quickly exhaled or metabolised to phosphates, which would not be found in analysis.

3.1.3 Mammalian Toxicology (Part B, Section 3, Point 7)

3.1.3.1 Acute Toxicity (Part B, Section 3, Point 7.1)

Detia Mäuse Giftköder, containing 25 g/kg Zinc phosphide has a low toxicity in respect to oral toxicity. Applying a waiving concept no further studies on the product were submitted nor deemed to be necessary. Therefore, sufficient data were provided and are considered adequate.

The details of the proposed labelling taking in to account the acute toxicity evaluation are given in chapter 2.2.

3.1.3.2 Operator Exposure (Part B, Section 3, Point 7.3)

Operator exposure was assessed against the AOEL systemic (0.042 mg/kg bw/d) applying an approach typically used for biocidal products. Dermal absorption data were based on EFSA Conclusion (EFSA Journal 2010; 8(7):1671). A detailed evaluation report is provided in Part B.

According to the model calculations, it can be concluded that the risk for operators using Detia Mäuse Giftköder is acceptable only with the use of personal protective equipment as described in 2.2.3.1.

3.1.3.3 Bystander Exposure (Part B, Section 3, Point 7.4)

In view of the low zinc phosphide content of the preparation and the application method, any quantitatively relevant exposure of bystanders to the active ingredient or the co-formulants is unlikely. The potential for dust exposure is considered negligible.

Exposure of residents (adults or children) to the product is also considered to be unlikely. Nevertheless, the product should be kept out of reach of children and applied in a way so as to minimize the risk of consumption by children.

According to the justifications and the assessment provided, it can be concluded that there is no undue risk to any bystander or resident (adult or child).

3.1.3.4 Worker Exposure (Part B, Section 3, Point 7.5)

Detia Mäuse Giftköder is ready-to-use rodenticide bait, which is laid out directly into vole holes or bait stations. Hence, worker exposure during re-entry activities is not considered to occur. The estimation of worker exposure during re-entry tasks is therefore not required for this product type.

Implications for labelling resulting from operator, worker, bystander assessments:

Please refer to chapter 2.2.

3.1.4 Residues and Consumer Exposure (Part B, Section 4, Point 8)

3.1.4.1 Residues (Part B, Section 4, Points 8.3 and 8.7)

The intended uses are not relevant in terms of consumer health protection. The submission of supervised residue trials is not necessary. Repeated application of baits will not alter the assessment.

3.1.4.2 Consumer exposure (Part B, Section 4, Point 8.10)

The envisaged uses are not relevant in terms of consumer health protection.

Thus, risk assessment is made for long term exposure only, applying the MRLs as laid down in EU residue legislation for “phosphines and phosphides” (Reg. (EC) No 149/2008). The calculated PRIMo results represent up to ca. 23% (WHO cluster diet) of the EU PRIMo diets and 22% (2-4 year old children) of German consumer group diets compared to the respective ADI.

Based on the calculations made to estimate the risk for consumer through diet it can be concluded that the use of product Detia Mäuse Giftkörner does not result in an unacceptable risk for consumers when applied according to the recommendations.

3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)

A full exposure assessment for the plant protection product Detia Mäuse Giftkörner in its intended uses in agriculture, orchard, vegetables, ornamentals, grassland, forestry and grape vine is documented in detail in the core assessment of the plant protection product Detia Mäuse Giftkörner performed by zRMS Germany.

The following chapters summarise the specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorisation of Detia Mäuse Giftkörner in Germany according to its intended uses in agriculture, orchard, vegetables, ornamentals, grassland, forestry, and grape vine (Use No. 001-020).

Metabolites

No new study on the fate and behaviour of zinc phosphide or Detia Mäuse Giftkörner has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

Zinc phosphide

The risk assessment for the metabolites of zinc phosphide has already been performed for EU approval (see SANCO/12548/2010). The metabolites are considered ecotoxicologically not relevant and did not penetrate into groundwater. Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.

For details see Part B, core assessment, section 5, chapter 5.3.1.3.

3.1.5.1 Predicted Environmental Concentration in Soil (PEC_{soil}) (Part B, Section 5, Points 9.4 and 9.5)

For the intended use of the plant protection product Detia Mäuse Giftkörner in all crops according to use No. 00-001 PEC_{soil} was calculated for the active substance zinc phosphide considering a soil depth of 5 cm. Due to the fast degradation of the active substance zinc phosphide in soil the accumulation potential of zinc phosphide was not considered.

Details are given in Part B core assessment, Section 5, chapter 5.5.

The results for PEC_{soil} for the active substance and its metabolites were used for the eco-toxicological risk assessment.

3.1.5.2 Predicted Environmental Concentration in Ground Water (PECGW) (Part B, Section 5, Point 9.6)

1. Direct leaching into groundwater

A risk assessment for PEC_{GW} is not considered to be required. For a justification of non-submission please see the Core Assessment, Part B, section 5, chapter 5.7.

Consequences for authorisation:

None.

2. Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

A risk assessment for PEC_{GW} is not considered to be required. For a justification of non-submission please see the Core Assessment, Part B, section 5, chapter 5.7.

Consequences for authorisation:

None.

3.1.5.3 Predicted Environmental Concentration in Surface Water (PEC_{SW}) (Part B, Section 5, Points 9.7 and 9.8)

A risk assessment for PEC_{SW} is not considered to be required. For a justification of non-submission please see the Core Assessment, Part B, section 5, chapter 5.6.

3.1.5.4 Predicted Environmental Concentration in Air (PEC_{Air}) (Part B, Section 5, Point 9.9)

Due to the properties of the active substance which is considered to be non-volatile the predicted environmental concentration in air is deemed to be negligible.

Implications for labelling resulting from environmental fate assessment:

Classification and labelling

Based on the data on the active substance zinc phosphide the plant protection product Detia Mäuse Giftkörner is considered to be not readily degradable in the sense of the CLP regulation.

Standard Phrases for special risks and safety precautions under Regulation (EU) 547/2011 Annex II and III / conditions of use

None.

Further data requirements:

None.

3.1.6 Ecotoxicology (Part B, Section 6, Point 10)

A full risk assessment according to Uniform Principles for the plant protection product Detia Mäuse Giftkörner in its intended uses is documented in detail in the core assessment performed by zRMS Germany. The intended uses of Detia Mäuse Giftkörner in Germany are generally covered by the uses evaluated in the course of the core assessment by zRMS Germany, however, the GAP table for Germany comprises more intended uses than the GAP table for the central zone as some uses according to the GAP for the central zone have been subdivided for the German GAP table.

The following chapters summarise the specific risk assessment for non-target organisms and hence risk mitigation measures for the authorisation of Detia Mäuse Giftkörner in Germany according to its intended uses.

For reasons of better readability the intended uses in of the plant protection product Detia Mäuse Giftkörner in Germany are summarised as follows:

Risk envelope approach for exposure assessment according to Section 5			
Group / use no.	Crop/growth stage/interception	Application method	Application rate, cumulative (g a.s./ha)
A (covers all intended uses in all use areas in the central zone)	Agriculture, Orchard, Vegetables, Ornamentals, Grassland, Forestry, grape vine / all stages	placing of baits in vole hole or placing of baits in bait stations	3 x 3 appl. per season , zinc phosphide max. 3 x 50, Soil effective application rate: Zinc phosphide max. 150
Grouping for overall environmental risk assessment (based on conditions of use, method/kind, crop/situation as stated above)			
Group	Crop/growth stage/interception	Application method/drift scenario	Application rate, cumulative (g a.s./ha)
A 1 / 001, 002, 003, 005, 006, 008, 010	Outdoor use in: field crops; forst plants; vegetables; grassland, pasture, meadows#; fruit crops; grape vine; ornamentals / if required	lay out poisoned cereal grains, 5 piece(s) per hole (hide)	Zinc phosphide Max. 3 x 50
A 2 / 011, 012, 013, 015, 016, 018, 020	Outdoor use in: field crops; forst plants; vegetables; grassland, pasture, meadows#; fruit crops; grape vine; ornamentals / if required	lay out poisoned cereal grains, 50 g per bait station (hide)	Zinc phosphide Max. 3 x 50
A 3 / 004, 007, 009	Home and garden use (non-professional): Vegetables; fruit crops; ornamentals / if required	lay out poisoned cereal grains, 5 piece(s) per hole (hide)	Zinc phosphide Max. 3 x 50
A 4 / 014, 017, 019	Home and garden use (non-professional): Vegetables; fruit crops; ornamentals / if required	lay out poisoned cereal grains, 50 g per bait station (hide)	Zinc phosphide Max. 3 x 50

3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)

The risk assessment for effects on birds and other terrestrial vertebrates was carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

Birds and non-target mammals

Zinc phosphide is hazardous towards birds and mammals. On individual level, risk cannot be excluded as in comparison to the representative use evaluated in the DAR, the intended uses of Detia Mäuse Giftkörner lack the combination of inherent risk mitigation by being generally provided in foliated bags and the hidden placement of the bait.

In conclusion, acceptable acute risk can only be approved when risk mitigation that ensures hidden application is considered.

For intended use group A1 (intended use loose provision in vole holes) hidden application deep in the vole holes by using application technique (Legeflinte) is feasible.

For intended use groups A 2 (for use in bait stations) approval can be supported when suitable bait stations are used. Criteria for suitable bait stations (e.g. tamper-proof, mechanically stable, resistance to weathering) have to be defined.

In agreement with the DAR evaluation and the applicant's argumentation a lack of systematic continuous ingestion is presumed and thus the risk of short- and long-term exposure was not calculated.

For non-professional use (intended use groups A 3 to A 4), approval cannot be supported, due the following reasons: According to § 2 of PflSchG plant protection measures are bound to the principles of good agricultural practice. For any approval of products for non-professional use it has to be considered that for non-professional users not the same level of expertise can be presumed. In order to minimise the risk for non-target species a high standard in expertise is requested for safe usage of chemical rodent control in terms of risk mitigation (i.e. bait placement), control and documentation of density in pest infestation and success of pest control that cannot be granted for non-professional users. Being a product that is designed to kill vertebrates with risk to harm or kill non-target vertebrates safe usage of Detia Mäuse Giftkörner carried out by non-professional users therefore cannot be approved from an environmental risk assessment perspective as in contrast to the intended uses for professional users the benefits do not prevail in this case. When following the principle of integrated pest management, however, non-professional users in amateur gardening should not reach a density in pest infestation that require chemical pest control of rodents as there are non-chemical measures that can be applied from an early stage on (consulting information e.g. available via www.biozid.info).

For details see Part B, Core Assessment and National Addendum-Germany, Section 6, chapters 6.2 and 6.3.

Other terrestrial vertebrates (reptiles and amphibians)

Reptiles and amphibians are not yet considered explicitly in standard risk assessments thus far and have not been considered explicitly in the review process for Annex I inclusion of zinc phosphide either. Traditionally it has been assumed that reptiles and amphibians would be covered by the regular birds and mammals risk assessment. Research results recently questioned this assumption (Brühl et al. 2011; Fryday and Thompson, 2012; Brühl et al., 2013). In the case of zinc phosphide, an open literature search reveals that zinc phosphide bears potential to act especially toxic to lizards (Avery et al., 2011) with respect to primary poisoning. Moreover, the risk from secondary poisoning for snakes differs from other predators. In contrast to many other predators, snakes follow their prey into the pathways and hence can easily prey on poisoned voles where other predators would not have access. Also, they consume the whole animal and do not reject the gastrointestinal tract of their prey.

The applicant was therefore asked to compile current knowledge on the risk for reptiles considering likelihood of exposure by crop culture, effects and possible risk mitigation for reptiles.

For details see Part B, National Addendum-(Germany) and the Core Assessment, Section 6, chapter 6.4.

Even though the overall risk is considered acceptable, some uncertainties remain. These uncertainties, however, are considered to be addressed by the risk mitigation measures deduced for prevention of unacceptable effects on mammals (see below).

Consequences for authorisation:

No authorisation for intended use groups A 3 and A 4 (non-professional user).

For the authorisation of the plant protection product Detia Mäuse Giftkörner the following labelling and conditions of use are mandatory:

- NS648 Application only if sample trappings or other suitable prognosis methods have proven that control measures are necessary.
- NT659 Do not put in exposed places.
- NT671 The product is very toxic for birds and game.

Additionally for intended use group A 1:

- NT664 The bait must be placed deep down in the rodent burrows by using a commercially available bait dispenser to make it inaccessible for birds. There shall be no bait left on the surface.
- NT802 Not to be used in nature reserves and bird protection areas.
- NT803 Not to be used in resting areas of migratory birds on their migratory routes.
- NT820 Not to be used in areas inhabited by European hamster, hazel dormouse, northern birch mouse or Bavarian pine vole.

Additionally for intended use group A 2:

- NT680 Only bait stations may be used which are mechanically stable, weather-resistant and tamper-resistant. Both construction and installation have to ensure that bait stations are inaccessible to non-target organisms as possible. For control of common vole, field vole and bank vole the diameter of the opening may not exceed 6 cm. The bait stations have to be labelled legibly with the following safety phrase: „Caution rodenticide“, active substance(s), poison emergency number and note: „Keep away children and domestic animals“.
- NT802 Not to be used in nature reserves and bird protection areas.
- NT803 Not to be used in resting areas of migratory birds on their migratory routes.
- NT820 Not to be used in areas inhabited by European hamster, hazel dormouse, northern birch mouse or Bavarian pine vole.

3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)

The overall risk for the aquatic biocenosis is expected to be low due to specific mode of application and the thereby limited exposure, yet it has to be pointed out, that acute toxicity of zinc phosphide technical for fish, *Daphnia* and algae indicates labelling as “very toxic for aquatic organisms, may cause long-term adverse effects in the aquatic environment” (relevant endpoint *Desmodesmus subspicatus* $E_rC_{50} = 3.75 \mu\text{g/L}$).

In order to prevent exposure incidents via run-off or wash out after rainfall, there must be a buffer zone of at least 10 m between treated areas and surface waters - including periodically but excluding occasionally water-bearing surface waters - when applying the product.

For details see Part B, National Addendum-Germany, Section 6, chapter 6.5.

Consequences for authorisation:

For the authorisation of the plant protection product Detia Mäuse Giftkörner the following labelling and conditions of use are mandatory:

Required Labelling

- NW262 zinc phosphide: *Desmodesmus subspicatus* NOE_rC 0.00140 mg/L
- NW264 zinc phosphide: *Daphnia magna* $EC_{50} = 0.114 \text{ mg/L}$; *Leuciscus idus*
 $LC_{50} > 0.0217 \text{ mg/L}$

Safety precautions / Conditions of use

- All uses NW467
NW704 (10 m)

3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)

Bees

The risk to bees can be considered negligible since no exposure is expected from the use of zinc phosphide containing rodenticide baits such as Detia Mäuse Giftkörner.

Other non-target arthropods

Due to the discrete placement and the limited exposure (the zRMS wants to point out that exposure for ground-living arthropods is not excluded but presumably limited in cases where the bait is not fully consumed by target species), no unacceptable risk for non-target arthropods is expected.

For details please refer to the core assessment Part B, section 6, chapter 6.7.

Specific additional risk mitigation measures are not required.

Consequences for authorisation:

None.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms (Part B, Section 6, Point 10.6)

Based on the predicted concentrations of zinc phosphide in soils, the TER values describing the acute risk for earthworms following exposure to zinc phosphide according to the GAP of the formulation Detia Mäuse Giftkörner achieve the acceptability criteria $TER \geq 10$ according to Commission Regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The assessment of TER values for other soil non-target macro-organisms is not triggered.

The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of Detia Mäuse Giftkörner according to the label.

For details please refer to the core assessment Part B, section 6, chapter 6.8.

Specific additional risk mitigation measures are not required.

Consequences for authorisation:

None.

3.1.6.5 Effects on organic matter breakdown (Part B, Section 6, Point 10.6)

Evaluation not triggered.

Specific additional risk mitigation measures are not required.

Consequences for authorisation:

None.

3.1.6.6 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)

Based on the predicted concentrations of zinc phosphide in soils, the risk to soil microbial processes

following exposure to zinc phosphide according to the GAP of the formulation Detia Mäuse Giftkörner is considered to be acceptable according to Commission Regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

For details please refer to the core assessment Part B, section 6, chapter 6.8.

Specific additional risk mitigation measures are not required.

Consequences for authorisation:

None.

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

Non-Target Plants

As shown in the EU DAR, adverse effects on plants due to the zinc content of the baits are not expected. The mode of application at discrete sites prevents extensive contamination. Additionally, the area of influence can be assumed to be low due to the moderate release of zinc phosphide from remaining bait and the rapid degradation and low mobility of released zinc phosphide in soils (for details on the behaviour in soils please refer to Section 5 of the Core Assessment). Thus the risk is considered to be acceptable.

For details please refer to the core assessment Part B, section 6, chapter 6.10.

Specific additional risk mitigation measures are not required.

Consequences for authorisation:

None.

Implications for labelling resulting from ecotoxicological assessment:

For the authorisation of the plant protection product Detia Mäuse Giftkörner the following labelling and conditions of use are mandatory:

Classification and labelling

Relevant toxicity	Active substance: zink phosphide (content 0.8 %) 72-h E _r C ₅₀ of 0.00323 mg/L (<i>Desmodemus subspicatus</i>) Acute M-factor = 100 NOE _r C 0.00140 mg/L (<i>Desmodemus subspicatus</i>) Chronic M-factor:10
Classification and labelling according to Regulation (EC) No 1272/2008	
Hazard symbol	GHS09
Signal word	Warning
Hazard statement	H400, H410

Standard Phrases for special risks and safety precautions under Regulation (EU) No 547/2011 Annex II and III / conditions of use

- NW467 The product and its remains, empty containers and packaging and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.
- NS648 Application only if sample trappings or other suitable prognosis methods have proven that control measures are necessary.
- NT659 Do not put in exposed places.

For intended use group A 1:

- NW704 Due to the danger of run-off, there must be a buffer zone of at least 10 m between treated areas and surface waters - including periodically but excluding occasionally water-bearing surface waters - when applying the product.
- NT664 The bait must be placed deep down in the rodent burrows by using a commercially available bait dispenser to make it inaccessible for birds. There shall be no bait left on the surface.
- NT802 Not to be used in nature reserves and bird protection areas.
- NT803 Not to be used in resting areas of migratory birds on their migratory routes.
- NT820 Not to be used in areas inhabited by European hamster, hazel dormouse, northern birch mouse or Bavarian pine vole.

For intended use group A 2:

- NW704 Due to the danger of run-off, there must be a buffer zone of at least 10 m between treated areas and surface waters - including periodically but excluding occasionally water-bearing surface waters - when applying the product.
- NT680 Only bait stations may be used which are mechanically stable, weather-resistant and tamper-resistant. Both construction and installation have to ensure that bait stations are inaccessible to non-target organisms as possible. For control of common vole, field vole and bank vole the diameter of the opening may not exceed 6 cm. The bait stations have to be labelled legibly with the following safety phrase: „Caution rodenticide“, active substance(s), poison emergency number and note: „Keep away children and domestic animals“.
- NT802 Not to be used in nature reserves and bird protection areas.
- NT803 Not to be used in resting areas of migratory birds on their migratory routes.
- NT820 Not to be used in areas inhabited by European hamster, hazel dormouse, northern birch mouse or Bavarian pine vole.

Other labels

- NT671 The product is very toxic for birds and game.
- NW262 The product is toxic for algae.
- NW264 The product is toxic for fish and aquatic invertebrates.

3.1.7 Efficacy (Part B, Section 7, Point 8)

Zinc phosphide is exclusively uptaken via oral consumption by the target rodents. The mode of action of zinc phosphide is based on the formation of the toxic degradation product phosphine. Ingested zinc phosphide is degraded to phosphine by the influence of the acidic gastro-intestinal secretes.

Detia Mäuse Giftkörner, a bait ready for use, containing 25 g/kg zinc phosphide for use as a rodenticide for control of common voles (*Microtus arvalis*) in field crops, grassland, pasture and meadows, vegetables, fruit crops, grape vine, forest plants and ornamentals for professional use and amateur gardening, to be applied underground in the common voles' holes or in bait stations.

The applicant notes that no indications or test results are available to him, that the climatic, edaphic or agronomic conditions in the other EU zones have a negative effect on the efficacy of Detia Mäuse Giftkörner. When applied per label directions and use precautions, it will provide the expected control levels of the target species.

A total of four trials were conducted between 2009 and 2013 in order to assess the efficacy against common voles.

Detia Mäuse Giftkörner showed a good effectiveness against common voles. It is recommended to use the product up to three times per season resulting in a maximum amount of 6.0 kg/ha to obtain a steady efficacy. The application rate of 2.0 kg/ha per use can be divided into three single applications of 0.66 kg/ha resulting in nine applications per season. The maximum of 2.0 kg/ha per use must not be exceeded.

There is no risk of resistance development due to the mode of action of zinc phosphide.

3.2 Conclusions

With respect to physical, chemical and technical properties of the formulation an authorisation can be granted.

With respect to analytical methods (formulation and residues) an authorisation can be granted.

With respect to toxicology, residues and consumer protection an authorisation can be granted.

With respect to efficacy an authorisation can be granted.

Due to the manner in which authorisation governs application of the product, bees are not endangered.

Harmful effects on ground water consequent to the intended uses of the product Detia Mäuse Giftkörner have not to be apprehended. The environmental risk assessment shows that the intended field uses for professional users can be authorised under consideration of specific labelling and risk mitigation measures for the protection of non-target organisms, in particular wildlife birds and mammals. Unacceptable effects on wildlife vertebrates cannot be excluded for amateur gardening uses by non-professional users. An authorisation of the plant protection product Detia Mäuse Giftkörner for these uses can therefore not be granted.

An authorisation can be recommended for the uses 001, 002, 003, 005, 006, 008, 010, 011, 012, 013, 015, 016, 018 and 020.

3.3 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

No further information is required.

Appendix 1 – Copy of the product authorisation

- See below

Appendix 2 – Copy of the product label

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions drawn by the competent authority. The final version of the label is not available, because the layout is the sole responsibility of the applicant and will not be checked again.

Appendix 3 – Letter of Access

- Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.



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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.007851-00/00.77295
(bitte bei Antwort angeben)

DATUM 30. Juli 2018

ZV1 007851-00/00

Detia Mäuse Giftkörner

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit dem Wirkstoff: 25 g/kg Zinkphosphid

Zulassungsnummer: 007851-00

Versuchsbezeichnungen: DET-20905-R-3-RB

Antrag vom: 20. Dezember 2012

wird auf der Grundlage von Art. 29 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (ABl. L 309 vom 24.11.2009, S. 1), wie folgt zugelassen:

Zulassungsende

Die Zulassung endet am 30. April 2022.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

Es werden folgende Anwendungsgebiete bzw. Anwendungen festgesetzt (siehe Anlage 1):

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
007851-00/00-001, 007851-00/00-011	Feldmaus	Ackerbaukulturen	
007851-00/00-002, 007851-00/00-012	Feldmaus	Forstpflanzen	
007851-00/00-003, 007851-00/00-013	Feldmaus	Gemüsekulturen	
007851-00/00-006, 007851-00/00-016	Feldmaus	Obstkulturen	
007851-00/00-008, 007851-00/00-018	Feldmaus	Weinrebe	
007851-00/00-005, 007851-00/00-015	Feldmaus	Wiesen, Weiden	
007851-00/00-010, 007851-00/00-020	Feldmaus	Zierpflanzen	

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 4 Absatz 84 des Gesetzes vom 18. Juli 2016 (BGBl. I S. 1666), festgesetzt:

(NS648)

Anwendung nur, wenn die Notwendigkeit einer Bekämpfungsmaßnahme durch Probefänge oder ein anderes geeignetes Prognoseverfahren belegt ist.

Begründung:

Der im Pflanzenschutzmittel Detia Mäuse Giftkörner enthaltene Wirkstoff Zinkphosphid weist als Rodentizid ein hohes Gefährdungspotenzial für Wirbeltiere auf (Colinus virginianus LD50 = 12,9 mg/kg Körpergewicht, EU-abgestimmter Endpunkt für Säuger (Rattus) basierend auf geomean LD50 = 37 mg/kg Körpergewicht (s.EFSA Journal 2010; 8(7):1671)). Eine Portion Köder (4 Pellets) enthält nach Angaben der Antragstellerin 7,5 mg Zinkphosphid.

Der Fall, dass durch unvollständigen Verzehr eine komplette Portion Köder oder aber auch nur eine Teilportion für Nicht-Zielarten (granivore Vögel und Kleinsäuger) zugänglich wird, kann nicht mit ausreichender Sicherheit ausgeschlossen werden. Es besteht somit für Wirbeltiere ein Risiko für akute Vergiftung. Da, wie in der EU-Wirkstoffprüfung deutlich herausgestellt, das Potential für eine Primärvergiftung von Nicht-Zielarten nicht prinzipiell ausgeschlossen werden kann, muss das Risiko stattdessen durch entsprechende Risikominierungsmaßnahmen adressiert werden.

Da es sich bei dem Mittel Detia Mäuse Giftkörner um ein Mittel zur gezielten Tötung von Wirbeltieren handelt, bei dessen Anwendung die Schädigung und Tötung von Nicht-Ziel-Wirbeltieren nicht ausgeschlossen werden kann, sollte das Mittel gemäß den Prinzipien des integrierten Pflanzenschutzes stets nur nach Ausschluss der Möglichkeit von Alternativmethoden angewendet werden. Die Notwendigkeit der Bekämpfung mit Detia Mäuse Giftkörner ist daher zu dokumentieren.

Weitere Informationen sind den Bewertungsdokumenten (Registration Report, Part B, Sektion 6, Core Assessment und Nationales Addendum) zu entnehmen.

(NT659)

Nicht offen auslegen/ausbringen.

Begründung:

Der im Pflanzenschutzmittel Detia Mäuse Giftkörner enthaltene Wirkstoff Zinkphosphid weist als Rodentizid ein hohes Gefährdungspotenzial für Wirbeltiere auf (Colinus virginianus LD50 = 12,9 mg/kg Körpergewicht, EU-abgestimmter Endpunkt für Säuger (Rattus) basierend auf geomean LD50 = 37 mg/kg Körpergewicht (s.EFSA Journal 2010; 8(7):1671)). Eine Portion Köder (4 Pellets) enthält nach Angaben der Antragstellerin 7,5 mg Zinkphosphid.

Der Fall, dass durch unvollständigen Verzehr eine komplette Portion Köder oder aber auch nur eine Teilportion für Nicht-Zielarten (granivore Vögel und Kleinsäuger) zugänglich wird, kann nicht mit ausreichender Sicherheit ausgeschlossen werden. Es besteht somit für Wirbeltiere ein Risiko für akute Vergiftung. Da, wie in der EU-Wirkstoffprüfung deutlich herausgestellt, das Potential für eine Primärvergiftung von Nicht-Zielarten nicht prinzipiell ausgeschlossen werden kann, muss das Risiko stattdessen durch entsprechende Risikominierungsmaßnahmen adressiert werden.

Eine Ausbringung darf zur Minimierung der Risiken für Nicht-Zielorganismen nur verdeckt erfolgen. Bei Darreichung ohne Köderstation muss Detia Mäuse Giftkörner unter Verwendung einer handelsüblichen Legeflinte tief und unzugänglich für Vögel in die Nagetiergänge eingebracht werden. Es dürfen keine Köder an der Oberfläche zurückbleiben.

Zudem ist in Vorkommensgebieten des Feldhamsters sowie anderer gefährdeter Nagetierarten, in Vogel- und Naturschutzgebieten wie auch auf Rastplätzen von Zugvögeln während des Vogelzugs eine Anwendung des Mittels auszuschließen, da andernfalls eine Aufnahme der Köder durch Nichtziel-Organismen nicht ausgeschlossen werden kann.

Weitere Informationen sind den Bewertungsdokumenten (Registration Report, Part B, Sektion 6, Core Assessment und Nationales Addendum) zu entnehmen.

(NW467)

Mittel und dessen Reste, entleerte Behältnisse oder Packungen sowie Spülflüssigkeiten nicht in Gewässer gelangen lassen. Dies gilt auch für indirekte Einträge über die Kanalisation, Hof- und Straßenabläufe sowie Regen- und Abwasserkanäle.

Begründung:

Der im o.g. Pflanzenschutzmittel enthaltene Wirkstoff Zinkphosphid weist aufgrund seiner Toxizität ein hohes Gefährdungspotenzial für aquatische Organismen auf. Jeder Eintrag von Rückständen in Oberflächengewässer, der den Eintrag als Folge der bestimmungsgemäßen und sachgerechten Anwendung des Mittels entsprechend der guten fachlichen Praxis übersteigt, würde daher zu einer Gefährdung des Naturhaushaltes aufgrund von nicht akzeptablen Auswirkungen auf Gewässerorganismen führen. Da ein erheblicher Anteil der in Oberflächengewässern nachzuweisenden Pflanzenschutzmittelfrachten auf Einträge aus kommunalen Kläranlagen zurückzuführen ist, muss dieser Gefährdung durch die bußgeldbewehrte Anwendungsbestimmung durchsetzbar begegnet werden.

(SS1201-1)

Bei der Ausbringung/Handhabung des Mittels sind Schutzhandschuhe (Pflanzenschutz) zu tragen.

Begründung:

Im Ergebnis der Expositionsbewertung für den Anwender ist die Anwendungsbestimmung erforderlich, um den Referenzwert bei bestimmungsgemäßer Anwendung nicht zu überschreiten. Nur in Verbindung mit dieser Expositions-minderungsmaßnahme wird das Risiko als vertretbar beurteilt.

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

Verpackungen

Gemäß § 36 Abs. 1 S. 2 Nr. 1 PflSchG sind für das Pflanzenschutzmittel die nachfolgend näher beschriebenen Verpackungen für den beruflichen Anwender zugelassen:

Verpackungsart	Verpackungsmaterial	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Eimer	PP	1		5,00		kg
Sack	Kunststoff	1		25,00		kg

Die Verpackungen für den beruflichen Anwender sind wie folgt zu kennzeichnen:

Anwendung nur durch berufliche Anwender zulässig.

Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:

Kennzeichnungsaufgaben:

(NT660)

Die Anwendung des Mittels ist außerhalb von Forsten nur durch verdecktes Ausbringen

zulässig (§ 2 Abs. 1 Pflanzenschutz-Anwendungsverordnung). Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

(NT667)

Köder unzugänglich für Kinder und für Haus- und Wildtiere auslegen.

(NT668)

Falls während und nach Bekämpfungsmaßnahmen tote oder sterbende Ratten oder Mäuse gefunden werden, sind diese sofort wegzuräumen, um Sekundärvergiftungen vorzubeugen.

(NT671)

Das Mittel ist sehr giftig für Vögel und Wild.

(NW262)

Das Mittel ist giftig für Algen.

(NW264)

Das Mittel ist giftig für Fische und Fischnährtiere.

(SB001)

Jeden unnötigen Kontakt mit dem Mittel vermeiden. Missbrauch kann zu Gesundheitsschäden führen.

(SB005)

Ist ärztlicher Rat erforderlich, Verpackung oder Etikett des Produktes bereithalten.

(SB010)

Für Kinder unzugänglich aufbewahren.

(SB011)

Kinder fernhalten.

(SB111)

Für die Anforderungen an die persönliche Schutzausrüstung beim Umgang mit dem Pflanzenschutzmittel sind die Angaben im Sicherheitsdatenblatt und in der Gebrauchsanweisung des Pflanzenschutzmittels sowie die BVL-Richtlinie "Persönliche Schutzausrüstung beim Umgang mit Pflanzenschutzmitteln" des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit (www.bvl.bund.de) zu beachten.

(SB166)

Beim Umgang mit dem Produkt nicht essen, trinken oder rauchen.

(SS206)

Arbeitskleidung (wenn keine spezifische Schutzkleidung erforderlich ist) und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln.

Siehe anwendungsbezogene Kennzeichnungsaufgaben in Anlage 1, jeweils unter Nr. 2.

Vorbehalt

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

Angaben zur Einstufung und Kennzeichnung gemäß Verordnung (EG) Nr. 1272/2008

Signalwort:

(S1) Achtung

Gefahrenpiktogramme:

(GHS07) Ausrufezeichen

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(H302)

Gesundheitsschädlich bei Verschlucken.

(H400)

Sehr giftig für Wasserorganismen.

(H410)

Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

(EUH 032)

Entwickelt bei Berührung mit Säure sehr giftige Gase.

(EUH 401)

Zur Vermeidung von Risiken für Mensch und Umwelt die Gebrauchsanleitung einhalten.

Sicherheitshinweise (P-Sätze):

(P101)

Ist ärztlicher Rat erforderlich, Verpackung oder Kennzeichnungsetikett bereithalten.

(P102)

Darf nicht in die Hände von Kindern gelangen.

(P264)

Nach Gebrauch ... gründlich waschen.

(P270)

Bei Gebrauch nicht essen, trinken oder rauchen.

(P273)

Freisetzung in die Umwelt vermeiden.

(P280)

Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.

(P308+P313)

BEI Exposition oder falls betroffen: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

(P391)

Verschüttete Mengen aufnehmen.

(P404)

In einem geschlossenen Behälter aufbewahren.

(P405)

Unter Verschluss aufbewahren.

(P501)

Inhalt/Behälter ... zuführen.

Abgelehnte Anwendungsgebiete bzw. Anwendungen

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
007851-00/00-004, 007851-00/00-014	Feldmaus	Gemüsekulturen	
007851-00/00-007, 007851-00/00-017	Feldmaus	Obstkulturen	
007851-00/00-009, 007851-00/00-019	Feldmaus	Zierpflanzen	

Hinweise

Auf dem Etikett und in der Gebrauchsanleitung kann angegeben werden:

(NB663)

Aufgrund der durch die Zulassung festgelegten Anwendungen des Mittels werden Bienen nicht gefährdet (B3).

(NN001)

Aufgrund der durch die Zulassung festgelegten Anwendungen des Mittels werden Populationen der auf Pflanzen lebenden Nutzorganismen nicht gefährdet.

Weitere Hinweise und Bemerkungen

Zum Etikett:

Auf dem Etikett ist zusätzlich zum Wirkstoffgehalt anzugeben:

"Enthält ca. 15 g/kg Paraffinöl als Haftmittel".

Begründung:

Weißes Mineralöl (CAS 8042-47-5) wurde in der EU als Wirkstoff betrachtet. Eine Verwendung von Paraffinöl als Beistoff in Pflanzenschutzmitteln ist daher nach Auffassung des BVL deklarationspflichtig.

Vorsorglich weise ich darauf hin, dass bisher mitgeteilte Forderungen bestehen bleiben, soweit sie noch nicht erfüllt sind.

Unterbleibt eine Beanstandung der vorgelegten Gebrauchsanleitung, so ist daraus nicht zu schließen, dass sie als ordnungsgemäß angesehen wird. Die Verantwortung des Zulassungsinhabers für die Übereinstimmung mit dem Zulassungsbescheid bleibt bestehen.

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift einzulegen.

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Martin Streloke
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

Anlage

Anlage 1 zugelassene Anwendung: 007851-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Ackerbaukulturen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Ackerbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl

Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 5 Stück pro Loch

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F) Freiland: Ackerbaukulturen
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT664)

Der Köder muss unter Verwendung einer handelsüblichen Legeflinte tief und unzugänglich

für Vögel in die Nagetiergänge eingebracht werden. Es dürfen keine Köder an der Oberfläche zurückbleiben.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT802)

Keine Anwendung in Vogel- und Naturschutzgebieten.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT803)

Keine Anwendung auf Rastplätzen von Zugvögeln während des Vogelzuges.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT820)

Keine Anwendung in Vorkommensgebieten des Feldhamsters sowie der Haselmaus, Birkenmaus und Bayerischen Kleinwühlmaus.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NW704)

Aufgrund der Gefahr der Abschwemmung muss bei der Anwendung zwischen der behandelten Fläche und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - ein Sicherheitsabstand von mindestens 10 m eingehalten werden.

Begründung:

Das Mittel Detia Mäuse Giftkörner wird in die Mäuselöcher eingebracht und auch durch die Verwendung von Köderboxen ist nicht gänzlich ausgeschlossen, dass Pellets in Gänge der zu bekämpfenden Schadorganismen gelangen. Kommt der Köder dort mit Wasser (Bodenfeuchtigkeit, Regenwasser) in Kontakt wird aus Zinkphosphid Phosphorwasserstoff gebildet, der aufgrund der höheren Dichte gegenüber Luft in den Gängen und Bauen weiter nach unten absinken kann. Da Nagetiergänge bevorzugte Transportpfade für überschüssiges Regenwasser sind, besteht derart ein erhöhtes Risiko für aquatische Organismen infolge einer möglichen Exposition der Gewässer mit Phosphorwasserstoff nach Regenereignissen. Aufgrund der sehr hohen Toxizität des Wirkstoffes gegenüber aquatischen Organismen (*Desmodesmus subspicatus* NOErC50 = 1,4 µg a.i./L; *Daphnia magna* EC50 2 d semi. = 114 µg a.i./L; *Leuciscus idus* LC50 = 21,7 µg/L) ist derart eine Gefährdung aquatischer Biozöten möglich.

Die Einhaltung des Abstandes zu Oberflächengewässern ist zur Herstellung der Zulassungsvoraussetzungen durchsetzbar vorzuschreiben, da andernfalls unannehmbare Auswirkungen auf den Naturhaushalt nicht auszuschließen sind und somit der Schutz der Gewässer nicht gewährleistet ist.

Anlage 1 zugelassene Anwendung: 007851-00/00-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Forstpflanzen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Forst

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl

Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: verdeckt / von Giftgetreide / bis keine Annahme mehr erfolgt

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 5 Stück pro Loch

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(N) Freiland: Forstpflanzen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT664)

Der Köder muss unter Verwendung einer handelsüblichen Legeflinte tief und unzugänglich für Vögel in die Nagetiergänge eingebracht werden. Es dürfen keine Köder an der Oberfläche zurückbleiben.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT802)

Keine Anwendung in Vogel- und Naturschutzgebieten.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT803)

Keine Anwendung auf Rastplätzen von Zugvögeln während des Vogelzuges.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT820)

Keine Anwendung in Vorkommensgebieten des Feldhamsters sowie der Haselmaus, Birkenmaus und Bayerischen Kleinwühlmaus.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NW704)

Aufgrund der Gefahr der Abschwemmung muss bei der Anwendung zwischen der behandelten Fläche und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - ein Sicherheitsabstand von mindestens 10 m eingehalten werden.

Begründung:

Das Mittel Detia Mäuse Giftkörner wird in die Mäuselöcher eingebracht und auch durch die Verwendung von Köderboxen ist nicht gänzlich ausgeschlossen, dass Pellets in Gänge der zu bekämpfenden Schadorganismen gelangen. Kommt der Köder dort mit Wasser (Bodenfeuchtigkeit, Regenwasser) in Kontakt wird aus Zinkphosphid Phosphorwasserstoff gebildet, der aufgrund der höheren Dichte gegenüber Luft in den Gängen und Bauen weiter nach unten absinken kann. Da Nagetiergänge bevorzugte Transportpfade für überschüssiges Regenwasser sind, besteht derart ein erhöhtes Risiko für aquatische Organismen infolge einer möglichen Exposition der Gewässer mit Phosphorwasserstoff nach Regenereignissen. Aufgrund der sehr hohen Toxizität des Wirkstoffes gegenüber aquatischen Organismen (*Desmodesmus subspicatus* NOErC50 = 1,4 µg a.i./L; *Daphnia magna* EC50 2 d semi. = 114 µg a.i./L; *Leuciscus idus* LC50 = 21,7 µg/L) ist derart eine Gefährdung aquatischer Biozönosen möglich.

Die Einhaltung des Abstandes zu Oberflächengewässern ist zur Herstellung der Zulassungsvoraussetzungen durchsetzbar vorzuschreiben, da andernfalls unannehmbare Auswirkungen auf den Naturhaushalt nicht auszuschließen sind und somit der Schutz der Gewässer nicht gewährleistet ist.

Anlage 1 zugelassene Anwendung: 007851-00/00-003

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Gemüsekulturen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl

Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 5 Stück pro Loch

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F) Freiland: Gemüsekulturen
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT664)

Der Köder muss unter Verwendung einer handelsüblichen Legeflinte tief und unzugänglich

für Vögel in die Nagetiergänge eingebracht werden. Es dürfen keine Köder an der Oberfläche zurückbleiben.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT802)

Keine Anwendung in Vogel- und Naturschutzgebieten.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT803)

Keine Anwendung auf Rastplätzen von Zugvögeln während des Vogelzuges.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT820)

Keine Anwendung in Vorkommensgebieten des Feldhamsters sowie der Haselmaus, Birkenmaus und Bayerischen Kleinwühlmaus.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NW704)

Aufgrund der Gefahr der Abschwemmung muss bei der Anwendung zwischen der behandelten Fläche und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - ein Sicherheitsabstand von mindestens 10 m eingehalten werden.

Begründung:

Das Mittel Detia Mäuse Giftkörner wird in die Mäuselöcher eingebracht und auch durch die Verwendung von Köderboxen ist nicht gänzlich ausgeschlossen, dass Pellets in Gänge der zu bekämpfenden Schadorganismen gelangen. Kommt der Köder dort mit Wasser (Bodenfeuchtigkeit, Regenwasser) in Kontakt wird aus Zinkphosphid Phosphorwasserstoff gebildet, der aufgrund der höheren Dichte gegenüber Luft in den Gängen und Bauen weiter nach unten absinken kann. Da Nagetiergänge bevorzugte Transportpfade für überschüssiges Regenwasser sind, besteht derart ein erhöhtes Risiko für aquatische Organismen infolge einer möglichen Exposition der Gewässer mit Phosphorwasserstoff nach Regenereignissen. Aufgrund der sehr hohen Toxizität des Wirkstoffes gegenüber aquatischen Organismen (*Desmodesmus subspicatus* NOErC50 = 1,4 µg a.i./L; *Daphnia magna* EC50 2 d semi. = 114 µg a.i./L; *Leuciscus idus* LC50 = 21,7 µg/L) ist derart eine Gefährdung aquatischer Biozöten möglich.

Die Einhaltung des Abstandes zu Oberflächengewässern ist zur Herstellung der Zulassungsvoraussetzungen durchsetzbar vorzuschreiben, da andernfalls unannehmbare Auswirkungen auf den Naturhaushalt nicht auszuschließen sind und somit der Schutz der Gewässer nicht gewährleistet ist.

Anlage 1 zugelassene Anwendung: 007851-00/00-005

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Wiesen, Weiden

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Grünland

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl

Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 5 Stück pro Loch

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F) Freiland: Wiesen, Weiden
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT664)

Der Köder muss unter Verwendung einer handelsüblichen Legeflinte tief und unzugänglich

für Vögel in die Nagetiergänge eingebracht werden. Es dürfen keine Köder an der Oberfläche zurückbleiben.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT802)

Keine Anwendung in Vogel- und Naturschutzgebieten.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT803)

Keine Anwendung auf Rastplätzen von Zugvögeln während des Vogelzuges.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT820)

Keine Anwendung in Vorkommensgebieten des Feldhamsters sowie der Haselmaus, Birkenmaus und Bayerischen Kleinwühlmaus.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NW704)

Aufgrund der Gefahr der Abschwemmung muss bei der Anwendung zwischen der behandelten Fläche und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - ein Sicherheitsabstand von mindestens 10 m eingehalten werden.

Begründung:

Das Mittel Detia Mäuse Giftkörner wird in die Mäuselöcher eingebracht und auch durch die Verwendung von Köderboxen ist nicht gänzlich ausgeschlossen, dass Pellets in Gänge der zu bekämpfenden Schadorganismen gelangen. Kommt der Köder dort mit Wasser (Bodenfeuchtigkeit, Regenwasser) in Kontakt wird aus Zinkphosphid Phosphorwasserstoff gebildet, der aufgrund der höheren Dichte gegenüber Luft in den Gängen und Bauen weiter nach unten absinken kann. Da Nagetiergänge bevorzugte Transportpfade für überschüssiges Regenwasser sind, besteht derart ein erhöhtes Risiko für aquatische Organismen infolge einer möglichen Exposition der Gewässer mit Phosphorwasserstoff nach Regenereignissen. Aufgrund der sehr hohen Toxizität des Wirkstoffes gegenüber aquatischen Organismen (*Desmodesmus subspicatus* NOErC50 = 1,4 µg a.i./L; *Daphnia magna* EC50 2 d semi. = 114 µg a.i./L; *Leuciscus idus* LC50 = 21,7 µg/L) ist derart eine Gefährdung aquatischer Biozöten möglich.

Die Einhaltung des Abstandes zu Oberflächengewässern ist zur Herstellung der Zulassungsvoraussetzungen durchsetzbar vorzuschreiben, da andernfalls unannehmbare Auswirkungen auf den Naturhaushalt nicht auszuschließen sind und somit der Schutz der Gewässer nicht gewährleistet ist.

Anlage 1 zugelassene Anwendung: 007851-00/00-006

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Obstkulturen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Obstbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl

Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 5 Stück pro Loch

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F) Freiland: Obstkulturen
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT664)

Der Köder muss unter Verwendung einer handelsüblichen Legeflinte tief und unzugänglich

für Vögel in die Nagetiergänge eingebracht werden. Es dürfen keine Köder an der Oberfläche zurückbleiben.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT802)

Keine Anwendung in Vogel- und Naturschutzgebieten.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT803)

Keine Anwendung auf Rastplätzen von Zugvögeln während des Vogelzuges.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT820)

Keine Anwendung in Vorkommensgebieten des Feldhamsters sowie der Haselmaus, Birkenmaus und Bayerischen Kleinwühlmaus.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NW704)

Aufgrund der Gefahr der Abschwemmung muss bei der Anwendung zwischen der behandelten Fläche und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - ein Sicherheitsabstand von mindestens 10 m eingehalten werden.

Begründung:

Das Mittel Detia Mäuse Giftkörner wird in die Mäuselöcher eingebracht und auch durch die Verwendung von Köderboxen ist nicht gänzlich ausgeschlossen, dass Pellets in Gänge der zu bekämpfenden Schadorganismen gelangen. Kommt der Köder dort mit Wasser (Bodenfeuchtigkeit, Regenwasser) in Kontakt wird aus Zinkphosphid Phosphorwasserstoff gebildet, der aufgrund der höheren Dichte gegenüber Luft in den Gängen und Bauen weiter nach unten absinken kann. Da Nagetiergänge bevorzugte Transportpfade für überschüssiges Regenwasser sind, besteht derart ein erhöhtes Risiko für aquatische Organismen infolge einer möglichen Exposition der Gewässer mit Phosphorwasserstoff nach Regenereignissen. Aufgrund der sehr hohen Toxizität des Wirkstoffes gegenüber aquatischen Organismen (*Desmodesmus subspicatus* NOErC50 = 1,4 µg a.i./L; *Daphnia magna* EC50 2 d semi. = 114 µg a.i./L; *Leuciscus idus* LC50 = 21,7 µg/L) ist derart eine Gefährdung aquatischer Biozöten möglich.

Die Einhaltung des Abstandes zu Oberflächengewässern ist zur Herstellung der Zulassungsvoraussetzungen durchsetzbar vorzuschreiben, da andernfalls unannehmbare Auswirkungen auf den Naturhaushalt nicht auszuschließen sind und somit der Schutz der Gewässer nicht gewährleistet ist.

Anlage 1 zugelassene Anwendung: 007851-00/00-008

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Weinrebe

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Weinbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl

Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 5 Stück pro Loch

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F) Freiland: Weinrebe
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT664)

Der Köder muss unter Verwendung einer handelsüblichen Legeflinte tief und unzugänglich

für Vögel in die Nagetiergänge eingebracht werden. Es dürfen keine Köder an der Oberfläche zurückbleiben.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT802)

Keine Anwendung in Vogel- und Naturschutzgebieten.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT803)

Keine Anwendung auf Rastplätzen von Zugvögeln während des Vogelzuges.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT820)

Keine Anwendung in Vorkommensgebieten des Feldhamsters sowie der Haselmaus, Birkenmaus und Bayerischen Kleinwühlmaus.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NW704)

Aufgrund der Gefahr der Abschwemmung muss bei der Anwendung zwischen der behandelten Fläche und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - ein Sicherheitsabstand von mindestens 10 m eingehalten werden.

Begründung:

Das Mittel Detia Mäuse Giftkörner wird in die Mäuselöcher eingebracht und auch durch die Verwendung von Köderboxen ist nicht gänzlich ausgeschlossen, dass Pellets in Gänge der zu bekämpfenden Schadorganismen gelangen. Kommt der Köder dort mit Wasser (Bodenfeuchtigkeit, Regenwasser) in Kontakt wird aus Zinkphosphid Phosphorwasserstoff gebildet, der aufgrund der höheren Dichte gegenüber Luft in den Gängen und Bauen weiter nach unten absinken kann. Da Nagetiergänge bevorzugte Transportpfade für überschüssiges Regenwasser sind, besteht derart ein erhöhtes Risiko für aquatische Organismen infolge einer möglichen Exposition der Gewässer mit Phosphorwasserstoff nach Regenereignissen. Aufgrund der sehr hohen Toxizität des Wirkstoffes gegenüber aquatischen Organismen (*Desmodesmus subspicatus* NOErC50 = 1,4 µg a.i./L; *Daphnia magna* EC50 2 d semi. = 114 µg a.i./L; *Leuciscus idus* LC50 = 21,7 µg/L) ist derart eine Gefährdung aquatischer Biozöten möglich.

Die Einhaltung des Abstandes zu Oberflächengewässern ist zur Herstellung der Zulassungsvoraussetzungen durchsetzbar vorzuschreiben, da andernfalls unannehmbare Auswirkungen auf den Naturhaushalt nicht auszuschließen sind und somit der Schutz der Gewässer nicht gewährleistet ist.

Anlage 1 zugelassene Anwendung: 007851-00/00-010

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl

Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 5 Stück pro Loch

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(N) Freiland: Zierpflanzen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT664)

Der Köder muss unter Verwendung einer handelsüblichen Legeflinte tief und unzugänglich für Vögel in die Nagetiergänge eingebracht werden. Es dürfen keine Köder an der Oberfläche zurückbleiben.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT802)

Keine Anwendung in Vogel- und Naturschutzgebieten.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT803)

Keine Anwendung auf Rastplätzen von Zugvögeln während des Vogelzuges.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT820)

Keine Anwendung in Vorkommensgebieten des Feldhamsters sowie der Haselmaus, Birkenmaus und Bayerischen Kleinwühlmaus.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NW704)

Aufgrund der Gefahr der Abschwemmung muss bei der Anwendung zwischen der behandelten Fläche und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - ein Sicherheitsabstand von mindestens 10 m eingehalten werden.

Begründung:

Das Mittel Detia Mäuse Giftkörner wird in die Mäuselöcher eingebracht und auch durch die Verwendung von Köderboxen ist nicht gänzlich ausgeschlossen, dass Pellets in Gänge der zu bekämpfenden Schadorganismen gelangen. Kommt der Köder dort mit Wasser (Bodenfeuchtigkeit, Regenwasser) in Kontakt wird aus Zinkphosphid Phosphorwasserstoff gebildet, der aufgrund der höheren Dichte gegenüber Luft in den Gängen und Bauen weiter nach unten absinken kann. Da Nagetiergänge bevorzugte Transportpfade für überschüssiges Regenwasser sind, besteht derart ein erhöhtes Risiko für aquatische Organismen infolge einer möglichen Exposition der Gewässer mit Phosphorwasserstoff nach Regenereignissen. Aufgrund der sehr hohen Toxizität des Wirkstoffes gegenüber aquatischen Organismen (*Desmodesmus subspicatus* NOErC50 = 1,4 µg a.i./L; *Daphnia magna* EC50 2 d semi. = 114 µg a.i./L; *Leuciscus idus* LC50 = 21,7 µg/L) ist derart eine Gefährdung aquatischer Biozöten möglich.

Die Einhaltung des Abstandes zu Oberflächengewässern ist zur Herstellung der Zulassungsvoraussetzungen durchsetzbar vorzuschreiben, da andernfalls unannehmbare Auswirkungen auf den Naturhaushalt nicht auszuschließen sind und somit der Schutz der Gewässer nicht gewährleistet ist.

Anlage 1 zugelassene Anwendung: 007851-00/00-011

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Ackerbaukulturen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Ackerbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl

Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide / in geeigneten Köderstationen

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 50 g pro Köderstation

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F) Freiland: Ackerbaukulturen
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT680)

Es sind Köderstationen zu verwenden, die mechanisch stabil, witterungsresistent und mani-

pulationssicher sind. Sie müssen so in ihrer Form beschaffen sein und aufgestellt werden, dass sie möglichst unzugänglich für Nicht-Zieltiere sind. Die Durchlassgröße der Öffnung für die Bekämpfung von Feld-, Erd- und Rötelmaus darf maximal 6 cm im Durchmesser betragen. Die Köderstationen sind deutlich lesbar mit folgendem Warnhinweis zu beschriften: "Vorsicht Mäusegift", Wirkstoff(e), Giftnotruf und Hinweis "Kinder und Haustiere fernhalten".

Begründung:

Die Darreichung von Detia Mäuse Giftkörner in Köderstationen leistet einen Beitrag zur Risikominderung, da somit Attraktivität und Zugänglichkeit insbesondere für Vögel, aber auch für Nicht-Zielsäuger minimiert werden. Damit diese Risikominderungsmaßnahme möglichst wirksam ist, ist es wichtig, dass die Köderstation möglichst unzugänglich für Nicht-Zielarten aufgestellt wird. Im Falle der Zielart Feldmaus darf die Durchlassöffnung maximal 6 cm im Durchmesser betragen, damit der Zugang für Feldhamster verhindert wird. Die Köderstationen müssen mechanisch stabil, witterungsresistent und manipulationssicher sein, sodass ein Umkippen, Auskippen oder Verstreuen verhindert wird. Die Kennzeichnung der Köderstationen mit Warnhinweisen ist erforderlich, damit deutlich sichtbar ist, dass diese Rodentizide enthalten und nicht berührt werden dürfen.

Weitere Informationen sind den Bewertungsdokumenten (Registration Report, Part B, Sektion 6, Core Assessment und Nationales Addendum) zu entnehmen.

(NT802)

Keine Anwendung in Vogel- und Naturschutzgebieten.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT803)

Keine Anwendung auf Rastplätzen von Zugvögeln während des Vogelzuges.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT820)

Keine Anwendung in Vorkommensgebieten des Feldhamsters sowie der Haselmaus, Birkenmaus und Bayerischen Kleinwühlmaus.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NW704)

Aufgrund der Gefahr der Abschwemmung muss bei der Anwendung zwischen der behandelten Fläche und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - ein Sicherheitsabstand von mindestens 10 m eingehalten werden.

Begründung:

Das Mittel Detia Mäuse Giftkörner wird in die Mäuselöcher eingebracht und auch durch die Verwendung von Köderboxen ist nicht gänzlich ausgeschlossen, dass Pellets in Gänge der zu bekämpfenden Schadorganismen gelangen. Kommt der Köder dort mit Wasser (Bodenfeuchtigkeit, Regenwasser) in Kontakt wird aus Zinkphosphid Phosphorwasserstoff gebildet,

der aufgrund der höheren Dichte gegenüber Luft in den Gängen und Bauen weiter nach unten absinken kann. Da Nagetiergänge bevorzugte Transportpfade für überschüssiges Regenwasser sind, besteht derart ein erhöhtes Risiko für aquatische Organismen infolge einer möglichen Exposition der Gewässer mit Phosphorwasserstoff nach Regenereignissen. Aufgrund der sehr hohen Toxizität des Wirkstoffes gegenüber aquatischen Organismen (*Desmodesmus subspicatus* NOErC50 = 1,4 µg a.i./L; *Daphnia magna* EC50 2 d semi. = 114 µg a.i./L; *Leuciscus idus* LC50 = 21,7 µg/L) ist derart eine Gefährdung aquatischer Biozöten möglich.

Die Einhaltung des Abstandes zu Oberflächengewässern ist zur Herstellung der Zulassungsvoraussetzungen durchsetzbar vorzuschreiben, da andernfalls unannehmbare Auswirkungen auf den Naturhaushalt nicht auszuschließen sind und somit der Schutz der Gewässer nicht gewährleistet ist.

Anlage 1 zugelassene Anwendung: 007851-00/00-012

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Forstpflanzen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Forst

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl

Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: verdeckt / von Giftgetreide / bis keine Annahme mehr erfolgt / in geeigneten Köderstationen

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 50 g pro Köderstation

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(N) Freiland: Forstpflanzen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT680)

Es sind Köderstationen zu verwenden, die mechanisch stabil, witterungsresistent und manipulationssicher sind. Sie müssen so in ihrer Form beschaffen sein und aufgestellt werden, dass sie möglichst unzugänglich für Nicht-Zieltiere sind. Die Durchlassgröße der Öffnung für die Bekämpfung von Feld-, Erd- und Rötelmaus darf maximal 6 cm im Durchmesser betragen. Die Köderstationen sind deutlich lesbar mit folgendem Warnhinweis zu beschriften:

"Vorsicht Mäusegift", Wirkstoff(e), Giftnotruf und Hinweis "Kinder und Haustiere fernhalten".

Begründung:

Die Darreichung von Detia Mäuse Giftkörner in Köderstationen leistet einen Beitrag zur Risikominderung, da somit Attraktivität und Zugänglichkeit insbesondere für Vögel, aber auch für Nicht-Zielsäuger minimiert werden. Damit diese Risikominderungsmaßnahme möglichst wirksam ist, ist es wichtig, dass die Köderstation möglichst unzugänglich für Nicht-Zielarten aufgestellt wird. Im Falle der Zielart Feldmaus darf die Durchlassöffnung maximal 6 cm im Durchmesser betragen, damit der Zugang für Feldhamster verhindert wird. Die Köderstationen müssen mechanisch stabil, witterungsresistent und manipulationssicher sein, sodass ein Umkippen, Auskippen oder Verstreuen verhindert wird. Die Kennzeichnung der Köderstationen mit Warnhinweisen ist erforderlich, damit deutlich sichtbar ist, dass diese Rodentizide enthalten und nicht berührt werden dürfen.

Weitere Informationen sind den Bewertungsdokumenten (Registration Report, Part B, Sektion 6, Core Assessment und Nationales Addendum) zu entnehmen.

(NT802)

Keine Anwendung in Vogel- und Naturschutzgebieten.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT803)

Keine Anwendung auf Rastplätzen von Zugvögeln während des Vogelzuges.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT820)

Keine Anwendung in Vorkommensgebieten des Feldhamsters sowie der Haselmaus, Birkenmaus und Bayerischen Kleinwühlmaus.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NW704)

Aufgrund der Gefahr der Abschwemmung muss bei der Anwendung zwischen der behandelten Fläche und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - ein Sicherheitsabstand von mindestens 10 m eingehalten werden.

Begründung:

Das Mittel Detia Mäuse Giftkörner wird in die Mäuselöcher eingebracht und auch durch die Verwendung von Köderboxen ist nicht gänzlich ausgeschlossen, dass Pellets in Gänge der zu bekämpfenden Schadorganismen gelangen. Kommt der Köder dort mit Wasser (Bodenfeuchtigkeit, Regenwasser) in Kontakt wird aus Zinkphosphid Phosphorwasserstoff gebildet, der aufgrund der höheren Dichte gegenüber Luft in den Gängen und Bauen weiter nach unten absinken kann. Da Nagetiergänge bevorzugte Transportpfade für überschüssiges Regenwasser sind, besteht derart ein erhöhtes Risiko für aquatische Organismen infolge einer möglichen Exposition der Gewässer mit Phosphorwasserstoff nach Regenereignissen.

Aufgrund der sehr hohen Toxizität des Wirkstoffes gegenüber aquatischen Organismen (Desmodesmus subspicatus NOErC50 = 1,4 µg a.i./L; Daphnia magna EC50 2 d semi. = 114 µg a.i./L; Leuciscus idus LC50 = 21,7 µg/L) ist derart eine Gefährdung aquatischer Biozöten möglich.

Die Einhaltung des Abstandes zu Oberflächengewässern ist zur Herstellung der Zulassungsvoraussetzungen durchsetzbar vorzuschreiben, da andernfalls unannehmbare Auswirkungen auf den Naturhaushalt nicht auszuschließen sind und somit der Schutz der Gewässer nicht gewährleistet ist.

Anlage 1 zugelassene Anwendung: 007851-00/00-013

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Gemüsekulturen

Verwendungszweck:

2 Kennzeichnungsaufgaben

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl

Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide / in geeigneten Köderstationen

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 50 g pro Köderstation

2.2 Sonstige Kennzeichnungsaufgaben

- keine -

2.3 Wartezeiten

(F) Freiland: Gemüsekulturen
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT680)

Es sind Köderstationen zu verwenden, die mechanisch stabil, witterungsresistent und mani-

pulationssicher sind. Sie müssen so in ihrer Form beschaffen sein und aufgestellt werden, dass sie möglichst unzugänglich für Nicht-Zieltiere sind. Die Durchlassgröße der Öffnung für die Bekämpfung von Feld-, Erd- und Rötelmaus darf maximal 6 cm im Durchmesser betragen. Die Köderstationen sind deutlich lesbar mit folgendem Warnhinweis zu beschriften: "Vorsicht Mäusegift", Wirkstoff(e), Giftnotruf und Hinweis "Kinder und Haustiere fernhalten".

Begründung:

Die Darreichung von Detia Mäuse Giftkörner in Köderstationen leistet einen Beitrag zur Risikominderung, da somit Attraktivität und Zugänglichkeit insbesondere für Vögel, aber auch für Nicht-Zielsäuger minimiert werden. Damit diese Risikominderungsmaßnahme möglichst wirksam ist, ist es wichtig, dass die Köderstation möglichst unzugänglich für Nicht-Zielarten aufgestellt wird. Im Falle der Zielart Feldmaus darf die Durchlassöffnung maximal 6 cm im Durchmesser betragen, damit der Zugang für Feldhamster verhindert wird. Die Köderstationen müssen mechanisch stabil, witterungsresistent und manipulationssicher sein, sodass ein Umkippen, Auskippen oder Verstreuen verhindert wird. Die Kennzeichnung der Köderstationen mit Warnhinweisen ist erforderlich, damit deutlich sichtbar ist, dass diese Rodentizide enthalten und nicht berührt werden dürfen.

Weitere Informationen sind den Bewertungsdokumenten (Registration Report, Part B, Sektion 6, Core Assessment und Nationales Addendum) zu entnehmen.

(NT802)

Keine Anwendung in Vogel- und Naturschutzgebieten.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT803)

Keine Anwendung auf Rastplätzen von Zugvögeln während des Vogelzuges.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT820)

Keine Anwendung in Vorkommensgebieten des Feldhamsters sowie der Haselmaus, Birkenmaus und Bayerischen Kleinwühlmaus.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NW704)

Aufgrund der Gefahr der Abschwemmung muss bei der Anwendung zwischen der behandelten Fläche und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - ein Sicherheitsabstand von mindestens 10 m eingehalten werden.

Begründung:

Das Mittel Detia Mäuse Giftkörner wird in die Mäuselöcher eingebracht und auch durch die Verwendung von Köderboxen ist nicht gänzlich ausgeschlossen, dass Pellets in Gänge der zu bekämpfenden Schadorganismen gelangen. Kommt der Köder dort mit Wasser (Bodenfeuchtigkeit, Regenwasser) in Kontakt wird aus Zinkphosphid Phosphorwasserstoff gebildet,

der aufgrund der höheren Dichte gegenüber Luft in den Gängen und Bauen weiter nach unten absinken kann. Da Nagetiergänge bevorzugte Transportpfade für überschüssiges Regenwasser sind, besteht derart ein erhöhtes Risiko für aquatische Organismen infolge einer möglichen Exposition der Gewässer mit Phosphorwasserstoff nach Regenereignissen. Aufgrund der sehr hohen Toxizität des Wirkstoffes gegenüber aquatischen Organismen (*Desmodesmus subspicatus* NOErC50 = 1,4 µg a.i./L; *Daphnia magna* EC50 2 d semi. = 114 µg a.i./L; *Leuciscus idus* LC50 = 21,7 µg/L) ist derart eine Gefährdung aquatischer Biozöten möglich.

Die Einhaltung des Abstandes zu Oberflächengewässern ist zur Herstellung der Zulassungsvoraussetzungen durchsetzbar vorzuschreiben, da andernfalls unannehmbare Auswirkungen auf den Naturhaushalt nicht auszuschließen sind und somit der Schutz der Gewässer nicht gewährleistet ist.

Anlage 1 zugelassene Anwendung: 007851-00/00-015

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Wiesen, Weiden

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Grünland

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl

Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide / in geeigneten Köderstationen

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 50 g pro Köderstation

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F) Freiland: Wiesen, Weiden
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT680)

Es sind Köderstationen zu verwenden, die mechanisch stabil, witterungsresistent und mani-

pulationssicher sind. Sie müssen so in ihrer Form beschaffen sein und aufgestellt werden, dass sie möglichst unzugänglich für Nicht-Zieltiere sind. Die Durchlassgröße der Öffnung für die Bekämpfung von Feld-, Erd- und Rötelmaus darf maximal 6 cm im Durchmesser betragen. Die Köderstationen sind deutlich lesbar mit folgendem Warnhinweis zu beschriften: "Vorsicht Mäusegift", Wirkstoff(e), Giftnotruf und Hinweis "Kinder und Haustiere fernhalten".

Begründung:

Die Darreichung von Detia Mäuse Giftkörner in Köderstationen leistet einen Beitrag zur Risikominderung, da somit Attraktivität und Zugänglichkeit insbesondere für Vögel, aber auch für Nicht-Zielsäuger minimiert werden. Damit diese Risikominderungsmaßnahme möglichst wirksam ist, ist es wichtig, dass die Köderstation möglichst unzugänglich für Nicht-Zielarten aufgestellt wird. Im Falle der Zielart Feldmaus darf die Durchlassöffnung maximal 6 cm im Durchmesser betragen, damit der Zugang für Feldhamster verhindert wird. Die Köderstationen müssen mechanisch stabil, witterungsresistent und manipulationssicher sein, sodass ein Umkippen, Auskippen oder Verstreuen verhindert wird. Die Kennzeichnung der Köderstationen mit Warnhinweisen ist erforderlich, damit deutlich sichtbar ist, dass diese Rodentizide enthalten und nicht berührt werden dürfen.

Weitere Informationen sind den Bewertungsdokumenten (Registration Report, Part B, Sektion 6, Core Assessment und Nationales Addendum) zu entnehmen.

(NT802)

Keine Anwendung in Vogel- und Naturschutzgebieten.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT803)

Keine Anwendung auf Rastplätzen von Zugvögeln während des Vogelzuges.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT820)

Keine Anwendung in Vorkommensgebieten des Feldhamsters sowie der Haselmaus, Birkenmaus und Bayerischen Kleinwühlmaus.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NW704)

Aufgrund der Gefahr der Abschwemmung muss bei der Anwendung zwischen der behandelten Fläche und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - ein Sicherheitsabstand von mindestens 10 m eingehalten werden.

Begründung:

Das Mittel Detia Mäuse Giftkörner wird in die Mäuselöcher eingebracht und auch durch die Verwendung von Köderboxen ist nicht gänzlich ausgeschlossen, dass Pellets in Gänge der zu bekämpfenden Schadorganismen gelangen. Kommt der Köder dort mit Wasser (Bodenfeuchtigkeit, Regenwasser) in Kontakt wird aus Zinkphosphid Phosphorwasserstoff gebildet,

der aufgrund der höheren Dichte gegenüber Luft in den Gängen und Bauen weiter nach unten absinken kann. Da Nagetiergänge bevorzugte Transportpfade für überschüssiges Regenwasser sind, besteht derart ein erhöhtes Risiko für aquatische Organismen infolge einer möglichen Exposition der Gewässer mit Phosphorwasserstoff nach Regenereignissen. Aufgrund der sehr hohen Toxizität des Wirkstoffes gegenüber aquatischen Organismen (*Desmodesmus subspicatus* NOErC50 = 1,4 µg a.i./L; *Daphnia magna* EC50 2 d semi. = 114 µg a.i./L; *Leuciscus idus* LC50 = 21,7 µg/L) ist derart eine Gefährdung aquatischer Biozöten möglich.

Die Einhaltung des Abstandes zu Oberflächengewässern ist zur Herstellung der Zulassungsvoraussetzungen durchsetzbar vorzuschreiben, da andernfalls unannehmbare Auswirkungen auf den Naturhaushalt nicht auszuschließen sind und somit der Schutz der Gewässer nicht gewährleistet ist.

Anlage 1 zugelassene Anwendung: 007851-00/00-016

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Obstkulturen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Obstbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl

Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide / in geeigneten Köderstationen

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 50 g pro Köderstation

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F) Freiland: Obstkulturen
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT680)

Es sind Köderstationen zu verwenden, die mechanisch stabil, witterungsresistent und mani-

pulationssicher sind. Sie müssen so in ihrer Form beschaffen sein und aufgestellt werden, dass sie möglichst unzugänglich für Nicht-Zieltiere sind. Die Durchlassgröße der Öffnung für die Bekämpfung von Feld-, Erd- und Rötelmaus darf maximal 6 cm im Durchmesser betragen. Die Köderstationen sind deutlich lesbar mit folgendem Warnhinweis zu beschriften: "Vorsicht Mäusegift", Wirkstoff(e), Giftnotruf und Hinweis "Kinder und Haustiere fernhalten".

Begründung:

Die Darreichung von Detia Mäuse Giftkörner in Köderstationen leistet einen Beitrag zur Risikominderung, da somit Attraktivität und Zugänglichkeit insbesondere für Vögel, aber auch für Nicht-Zielsäuger minimiert werden. Damit diese Risikominderungsmaßnahme möglichst wirksam ist, ist es wichtig, dass die Köderstation möglichst unzugänglich für Nicht-Zielarten aufgestellt wird. Im Falle der Zielart Feldmaus darf die Durchlassöffnung maximal 6 cm im Durchmesser betragen, damit der Zugang für Feldhamster verhindert wird. Die Köderstationen müssen mechanisch stabil, witterungsresistent und manipulationssicher sein, sodass ein Umkippen, Auskippen oder Verstreuen verhindert wird. Die Kennzeichnung der Köderstationen mit Warnhinweisen ist erforderlich, damit deutlich sichtbar ist, dass diese Rodentizide enthalten und nicht berührt werden dürfen.

Weitere Informationen sind den Bewertungsdokumenten (Registration Report, Part B, Sektion 6, Core Assessment und Nationales Addendum) zu entnehmen.

(NT802)

Keine Anwendung in Vogel- und Naturschutzgebieten.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT803)

Keine Anwendung auf Rastplätzen von Zugvögeln während des Vogelzuges.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT820)

Keine Anwendung in Vorkommensgebieten des Feldhamsters sowie der Haselmaus, Birkenmaus und Bayerischen Kleinwühlmaus.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NW704)

Aufgrund der Gefahr der Abschwemmung muss bei der Anwendung zwischen der behandelten Fläche und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - ein Sicherheitsabstand von mindestens 10 m eingehalten werden.

Begründung:

Das Mittel Detia Mäuse Giftkörner wird in die Mäuselöcher eingebracht und auch durch die Verwendung von Köderboxen ist nicht gänzlich ausgeschlossen, dass Pellets in Gänge der zu bekämpfenden Schadorganismen gelangen. Kommt der Köder dort mit Wasser (Bodenfeuchtigkeit, Regenwasser) in Kontakt wird aus Zinkphosphid Phosphorwasserstoff gebildet,

der aufgrund der höheren Dichte gegenüber Luft in den Gängen und Bauen weiter nach unten absinken kann. Da Nagetiergänge bevorzugte Transportpfade für überschüssiges Regenwasser sind, besteht derart ein erhöhtes Risiko für aquatische Organismen infolge einer möglichen Exposition der Gewässer mit Phosphorwasserstoff nach Regenereignissen. Aufgrund der sehr hohen Toxizität des Wirkstoffes gegenüber aquatischen Organismen (*Desmodesmus subspicatus* NOErC50 = 1,4 µg a.i./L; *Daphnia magna* EC50 2 d semi. = 114 µg a.i./L; *Leuciscus idus* LC50 = 21,7 µg/L) ist derart eine Gefährdung aquatischer Biozöten möglich.

Die Einhaltung des Abstandes zu Oberflächengewässern ist zur Herstellung der Zulassungsvoraussetzungen durchsetzbar vorzuschreiben, da andernfalls unannehmbare Auswirkungen auf den Naturhaushalt nicht auszuschließen sind und somit der Schutz der Gewässer nicht gewährleistet ist.

Anlage 1 zugelassene Anwendung: 007851-00/00-018

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Weinrebe

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Weinbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl

Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide / in geeigneten Köderstationen

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 50 g pro Köderstation

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F) Freiland: Weinrebe
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT680)

Es sind Köderstationen zu verwenden, die mechanisch stabil, witterungsresistent und mani-

pulationssicher sind. Sie müssen so in ihrer Form beschaffen sein und aufgestellt werden, dass sie möglichst unzugänglich für Nicht-Zieltiere sind. Die Durchlassgröße der Öffnung für die Bekämpfung von Feld-, Erd- und Rötelmaus darf maximal 6 cm im Durchmesser betragen. Die Köderstationen sind deutlich lesbar mit folgendem Warnhinweis zu beschriften: "Vorsicht Mäusegift", Wirkstoff(e), Giftnotruf und Hinweis "Kinder und Haustiere fernhalten".

Begründung:

Die Darreichung von Detia Mäuse Giftkörner in Köderstationen leistet einen Beitrag zur Risikominderung, da somit Attraktivität und Zugänglichkeit insbesondere für Vögel, aber auch für Nicht-Zielsäuger minimiert werden. Damit diese Risikominderungsmaßnahme möglichst wirksam ist, ist es wichtig, dass die Köderstation möglichst unzugänglich für Nicht-Zielarten aufgestellt wird. Im Falle der Zielart Feldmaus darf die Durchlassöffnung maximal 6 cm im Durchmesser betragen, damit der Zugang für Feldhamster verhindert wird. Die Köderstationen müssen mechanisch stabil, witterungsresistent und manipulationssicher sein, sodass ein Umkippen, Auskippen oder Verstreuen verhindert wird. Die Kennzeichnung der Köderstationen mit Warnhinweisen ist erforderlich, damit deutlich sichtbar ist, dass diese Rodentizide enthalten und nicht berührt werden dürfen.

Weitere Informationen sind den Bewertungsdokumenten (Registration Report, Part B, Section 6, Core Assessment und Nationales Addendum) zu entnehmen.

(NT802)

Keine Anwendung in Vogel- und Naturschutzgebieten.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT803)

Keine Anwendung auf Rastplätzen von Zugvögeln während des Vogelzuges.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT820)

Keine Anwendung in Vorkommensgebieten des Feldhamsters sowie der Haselmaus, Birkenmaus und Bayerischen Kleinwühlmaus.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NW704)

Aufgrund der Gefahr der Abschwemmung muss bei der Anwendung zwischen der behandelten Fläche und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - ein Sicherheitsabstand von mindestens 10 m eingehalten werden.

Begründung:

Das Mittel Detia Mäuse Giftkörner wird in die Mäuselöcher eingebracht und auch durch die Verwendung von Köderboxen ist nicht gänzlich ausgeschlossen, dass Pellets in Gänge der zu bekämpfenden Schadorganismen gelangen. Kommt der Köder dort mit Wasser (Bodenfeuchtigkeit, Regenwasser) in Kontakt wird aus Zinkphosphid Phosphorwasserstoff gebildet,

der aufgrund der höheren Dichte gegenüber Luft in den Gängen und Bauen weiter nach unten absinken kann. Da Nagetiergänge bevorzugte Transportpfade für überschüssiges Regenwasser sind, besteht derart ein erhöhtes Risiko für aquatische Organismen infolge einer möglichen Exposition der Gewässer mit Phosphorwasserstoff nach Regenereignissen. Aufgrund der sehr hohen Toxizität des Wirkstoffes gegenüber aquatischen Organismen (*Desmodesmus subspicatus* NOErC50 = 1,4 µg a.i./L; *Daphnia magna* EC50 2 d semi. = 114 µg a.i./L; *Leuciscus idus* LC50 = 21,7 µg/L) ist derart eine Gefährdung aquatischer Biozöten möglich.

Die Einhaltung des Abstandes zu Oberflächengewässern ist zur Herstellung der Zulassungsvoraussetzungen durchsetzbar vorzuschreiben, da andernfalls unannehmbare Auswirkungen auf den Naturhaushalt nicht auszuschließen sind und somit der Schutz der Gewässer nicht gewährleistet ist.

Anlage 1 zugelassene Anwendung: 007851-00/00-020

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl

Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide / in geeigneten Köderstationen

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 50 g pro Köderstation

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(N) Freiland: Zierpflanzen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

(NT680)

Es sind Köderstationen zu verwenden, die mechanisch stabil, witterungsresistent und manipulationssicher sind. Sie müssen so in ihrer Form beschaffen sein und aufgestellt werden, dass sie möglichst unzugänglich für Nicht-Zieltiere sind. Die Durchlassgröße der Öffnung für die Bekämpfung von Feld-, Erd- und Rötelmaus darf maximal 6 cm im Durchmesser betragen. Die Köderstationen sind deutlich lesbar mit folgendem Warnhinweis zu beschriften:

"Vorsicht Mäusegift", Wirkstoff(e), Giftnotruf und Hinweis "Kinder und Haustiere fernhalten".

Begründung:

Die Darreichung von Detia Mäuse Giftkörner in Köderstationen leistet einen Beitrag zur Risikominderung, da somit Attraktivität und Zugänglichkeit insbesondere für Vögel, aber auch für Nicht-Zielsäuger minimiert werden. Damit diese Risikominderungsmaßnahme möglichst wirksam ist, ist es wichtig, dass die Köderstation möglichst unzugänglich für Nicht-Zielarten aufgestellt wird. Im Falle der Zielart Feldmaus darf die Durchlassöffnung maximal 6 cm im Durchmesser betragen, damit der Zugang für Feldhamster verhindert wird. Die Köderstationen müssen mechanisch stabil, witterungsresistent und manipulationssicher sein, sodass ein Umkippen, Auskippen oder Verstreuen verhindert wird. Die Kennzeichnung der Köderstationen mit Warnhinweisen ist erforderlich, damit deutlich sichtbar ist, dass diese Rodentizide enthalten und nicht berührt werden dürfen.

Weitere Informationen sind den Bewertungsdokumenten (Registration Report, Part B, Sektion 6, Core Assessment und Nationales Addendum) zu entnehmen.

(NT802)

Keine Anwendung in Vogel- und Naturschutzgebieten.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT803)

Keine Anwendung auf Rastplätzen von Zugvögeln während des Vogelzuges.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NT820)

Keine Anwendung in Vorkommensgebieten des Feldhamsters sowie der Haselmaus, Birkenmaus und Bayerischen Kleinwühlmaus.

Begründung:

Siehe Begründung zu den Anwendungsbestimmungen der Kodierung NS648 und NT659.

(NW704)

Aufgrund der Gefahr der Abschwemmung muss bei der Anwendung zwischen der behandelten Fläche und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - ein Sicherheitsabstand von mindestens 10 m eingehalten werden.

Begründung:

Das Mittel Detia Mäuse Giftkörner wird in die Mäuselöcher eingebracht und auch durch die Verwendung von Köderboxen ist nicht gänzlich ausgeschlossen, dass Pellets in Gänge der zu bekämpfenden Schadorganismen gelangen. Kommt der Köder dort mit Wasser (Bodenfeuchtigkeit, Regenwasser) in Kontakt wird aus Zinkphosphid Phosphorwasserstoff gebildet, der aufgrund der höheren Dichte gegenüber Luft in den Gängen und Bauen weiter nach unten absinken kann. Da Nagetiergänge bevorzugte Transportpfade für überschüssiges Regenwasser sind, besteht derart ein erhöhtes Risiko für aquatische Organismen infolge einer möglichen Exposition der Gewässer mit Phosphorwasserstoff nach Regenereignissen.

Aufgrund der sehr hohen Toxizität des Wirkstoffes gegenüber aquatischen Organismen (Desmodesmus subspicatus NOErC50 = 1,4 µg a.i./L; Daphnia magna EC50 2 d semi. = 114 µg a.i./L; Leuciscus idus LC50 = 21,7 µg/L) ist derart eine Gefährdung aquatischer Biozöten möglich.

Die Einhaltung des Abstandes zu Oberflächengewässern ist zur Herstellung der Zulassungsvoraussetzungen durchsetzbar vorzuschreiben, da andernfalls unannehmbare Auswirkungen auf den Naturhaushalt nicht auszuschließen sind und somit der Schutz der Gewässer nicht gewährleistet ist.

Anlage 2 nicht zugelassene Anwendung: 007851-00/00-004

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Gemüsekulturen

Verwendungszweck:

2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl
Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 5 Stück pro Loch

3 Begründung

Naturhaushalt

Die Prüfung der zum o.g. Antrag vorliegenden Untersuchungsergebnisse hat ergeben, dass für die beantragten Anwendungen 007851-00/00-004, -007, -009, -014, -017 und -019 die Zulassungsvoraussetzungen gemäß Artikel 29 Absatz 1 Buchstabe e i.V.m. Artikel 4 Absatz 3 Buchstabe e der Verordnung (EG) Nr. 1107/2009 für das Pflanzenschutzmittel Detia Mäuse Giftkörner nicht erfüllt sind. Es ist daher die Zulassung des o. g. Pflanzenschutzmittels für diese Indikationen zu versagen.

Der im Pflanzenschutzmittel Detia Mäuse Giftkörner enthaltene Wirkstoff Zinkphosphid weist als Rodentizid ein hohes Gefährdungspotenzial für Wirbeltiere auf (Colinus virginianus LD50 = 12,9 mg/kg Körpergewicht; EU-abgestimmter Endpunkt für Säuger (Rattus) basierend auf geomean LD50 = 37 mg/kg Körpergewicht (s. EFSA Journal 2010; 8 (7):1671)). Es besteht somit für Wirbeltiere ein Risiko der akuten Vergiftung.

Für die Anwendungen durch nichtberufliche Nutzer im Haus- und Kleingartenbereich kann die Zulassung vor diesem Hintergrund aus folgenden Gründen nicht unterstützt werden:

Gemäß § 2 PflSchG sind Pflanzenschutzmaßnahmen nach den Prinzipien der guten landwirtschaftlichen Praxis durchzuführen. Für die Zulassung von Mitteln für nichtberufliche Verwender ist zu beachten, dass eine vergleichbare Sachkunde wie bei beruflichen Verwendern nicht vorausgesetzt werden kann. Um das Risiko für Nicht-Zielarten auf ein annehmbares Risiko zu mindern ist für eine sichere und möglichst zielgerichtete chemische Nagetierbekämpfung jedoch ein hohes Maß an Sachkunde erforderlich. Dies umfasst die Fähigkeit sicher zwischen Zielarten und Nichtziel-Arten unterscheiden zu können, sicherzustellen, dass nur von der Zielart bewohnte Gänge behandelt werden, und dass die Köder mit Hilfe von geeigneter Technik (Legeflinte) tief und unzugänglich für Vögel in die Mäuselöcher eingebracht werden. Dies kann bei nichtberuflichen Verwendern nicht vorausgesetzt werden, so dass unannehmbare Auswirkungen in Folge der Anwendung durch nicht Sachkundige nicht ausgeschlossen werden können.

Die Notwendigkeit einer Bekämpfung mit einem chemischen Nagetierbekämpfungsmittel wie Detia Mäuse Giftkörner sollte bei Ausschöpfung der verfügbaren Alternativmethoden im Haus- und Kleingartenbereich zudem nicht auftreten (Informationen zu vorbeugenden und biozidfreien Alternativen sind u.a. unter www.biozid.info verfügbar).

Weitere Informationen zur Bewertung sind dem nationalen Addendum zum Part B des Registration Report zu entnehmen (Sektion 6, Kapitel 6.2 und 6.3).

Die Zulassung des Mittels Detia Mäuse Giftkörner setzt voraus, dass als Folge der Verwendung entsprechend der guten Pflanzenschutzpraxis und unter Voraussetzung realistischer Verwendungsbedingungen unannehmbare Auswirkungen auf den Naturhaushalt auszuschließen sind (Artikel 29 Absatz 1 Buchstabe e i.V.m. Artikel 4 Absatz 3 Buchstabe e der Verordnung (EG) Nr. 1107/2009). Nach dem Stand der wissenschaftlichen Erkenntnisse und der Technik erfüllt das Pflanzenschutzmittel Detia Mäuse Giftkörner bei den Anwendungen 00-004, -007, -009, -014, -017 und -019 diese Voraussetzung nicht, und es lassen sich auch keine Anwendungsbestimmungen und Auflagen gemäß § 36 Absatz 1, Absatz 3 PflSchG mit einem Mindestmaß an Praktikabilität und Kontrollierbarkeit (d.h. vom Anwender durchgängig einhaltbar und von den zuständigen Behörden kontrollierbar) festsetzen, die zu einer Herstellung dieser Voraussetzungen führen würden.

Anlage 2 nicht zugelassene Anwendung: 007851-00/00-007

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Obstkulturen

Verwendungszweck:

2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Obstbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl
Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 5 Stück pro Loch

3 Begründung

Naturhaushalt

Siehe Begründung zu Anwendung 007851-00/00-004.

Anlage 2 nicht zugelassene Anwendung: 007851-00/00-009

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen

Verwendungszweck:

2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl
Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 5 Stück pro Loch

3 Begründung

Naturhaushalt

Siehe Begründung zu Anwendung 007851-00/00-004.

Anlage 2 nicht zugelassene Anwendung: 007851-00/00-014

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Gemüsekulturen

Verwendungszweck:

2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl
Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide / in geeigneten Köderstationen

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 50 g pro Köderstation

3 Begründung

Naturhaushalt

Siehe Begründung zu Anwendung 007851-00/00-004.

Anlage 2 nicht zugelassene Anwendung: 007851-00/00-017

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Obstkulturen

Verwendungszweck:

2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Obstbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl
Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide / in geeigneten Köderstationen

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 50 g pro Köderstation

3 Begründung

Naturhaushalt

Siehe Begründung zu Anwendung 007851-00/00-004.

Anlage 2 nicht zugelassene Anwendung: 007851-00/00-019

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen

Verwendungszweck:

2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Bedarf

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Erläuterungen Anzahl
Behandlungen: eine Aufteilung der Behandlungen in jeweils drei einzelne Teilbehandlungen mit 0,66 kg/ha ist möglich

Anwendungstechnik: auslegen

- Erläuterungen: bis keine Annahme mehr erfolgt / verdeckt / von Giftgetreide / in geeigneten Köderstationen

Aufwand:

- 2 kg/ha

- Erläuterungen: Der Mittelaufwand entspricht 50 g pro Köderstation

3 Begründung

Naturhaushalt

Siehe Begründung zu Anwendung 007851-00/00-004.

REGISTRATION REPORT

Part B

Section 1: Identity, physical and chemical properties, other information

Detailed summary of the risk assessment

Product code: Detia Mäuse Giftkörner

Active Substance: Zinc phosphide 25 g/kg

Central Zone

Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Detia Freyberg GmbH

Submission Date: 22/12/2012

Date: February 2018

Table of Contents

III A 1	IDENTITY OF THE PLANT PROTECTION PRODUCT	7
III A 1.1	Applicant	7
III A 1.2	Manufacturer of the Preparation, Manufacturer and Purity of the Active Substance(s)	7
III A 1.2.1	Manufacturer(s) of the preparation	7
III A 1.2.2	Manufacturer(s) of the active substance(s)	7
III A 1.2.3	Statement of purity (and detailed information on impurities) of the active substance(s)	7
III A 1.3	Trade Names and Manufacturer’s Code Numbers for the Preparation	7
III A 1.4	Detailed Quantitative and Qualitative Information on the Composition of the Preparation	7
III A 1.4.1	Content of active substance and formulants	7
III A 1.4.2	Certified limits of each component	8
III A 1.4.3	Common names and code numbers for the active substance(s)	8
III A 1.4.4	Co-formulant details: identity, structure, codes, trade name, specification and function	8
III A 1.4.5	Formulation process	8
III A 1.4.5.1	Description of formulation process	8
III A 1.4.5.2	Discussion of the formation of impurities of toxicological concern	8
III A 1.5	Type of Preparation and Code	9
III A 1.6	Function	9
III A 1.7	Other/Special Studies	9
III A 2	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT	10
III A 2.16	Summary and Evaluation of Data Presented Under Points 2.1 to 2.15	20

IIIA 3	DATA ON APPLICATION OF THE PLANT PROTECTION PRODUCT	20
IIIA 3.1	Field of Use.....	20
IIIA 3.2	Nature of the Effects on Harmful Organisms.....	20
IIIA 3.3	Details of Intended Use	20
IIIA 3.3.1	Details of existing and intended uses	20
IIIA 3.3.2	Details of harmful organisms against which protection is afforded.....	20
IIIA 3.3.3	Effects achieved	20
IIIA 3.4	Proposed Application Rates (Active Substance and Preparation)	20
IIIA 3.5	Concentration of the Active Substance in the Material Used	20
IIIA 3.6	Method of Application, Type of Equipment Used and Volume of Diluent	21
IIIA 3.7	Number and Timings of Applications, Timing, Growth Stages (of Crop and Harmful Organism) and Duration of Protection	21
IIIA 3.7.1	Maximum number of applications and their timings	21
IIIA 3.7.2	Growth stages of crops or plants to be protected.....	21
IIIA 3.7.3	Development stages of the harmful organism concerned.....	21
IIIA 3.7.4	Duration of protection afforded by each application.....	21
IIIA 3.7.5	Duration of protection afforded by the maximum number of applications	21
IIIA 3.8	Necessary Waiting Periods or Other Precautions to Avoid Phytotoxic Effects on Succeeding Crops	21
IIIA 3.8.1	Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops.....	21
IIIA 3.8.2	Limitations on choice of succeeding crops.....	21
IIIA 3.8.3	Description of damage to rotational crops.....	21
IIIA 3.9	Proposed Instructions for Use as Printed on Labels.....	21
IIIA 3.10	Other/Special Studies.....	21

IIIA 4	FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT	22
IIIA 4.1	Packaging and Compatibility with the Preparation	22
IIIA 4.1.1	Description and specification of the packaging	22
IIIA 4.1.2	Suitability of the packaging and closures.....	23
IIIA 4.1.3	Resistance of the packaging material to its contents.....	23
IIIA 4.2	Procedures for Cleaning Application Equipment.....	24
IIIA 4.3	Re-entry Periods to Protect Man, Livestock and the Environment	24
IIIA 4.3.1	Pre-harvest interval (in days) for each relevant crop	24
IIIA 4.3.2	Re-entry period (in days) for livestock, to areas to be grazed.....	24
IIIA 4.3.3	Re-entry period (in hours or days) for man to crops, buildings or spaces treated.....	24
IIIA 4.3.4	Withholding period (in days) for animal feeding stuffs.....	24
IIIA 4.3.5	Waiting period (in days) between application and handling of treated products.....	24
IIIA 4.3.6	Waiting period (in days) between last application and sowing or planting succeeding crops.....	24
IIIA 4.3.7	Information on specific conditions under which the preparation may or may not be used	24
IIIA 4.4	Statement of the Risks Arising and the Recommended Methods and Precautions and Handling Procedures to Minimise Those Risks	24
IIIA 4.4.1	Warehouse storage	25
IIIA 4.4.2	User level storage.....	25
IIIA 4.4.3	Transport	25
IIIA 4.4.4	Fire.....	25
IIIA 4.4.5	Nature of protective clothing proposed.....	26
IIIA 4.4.6	Characteristics of protective clothing proposed.....	26
IIIA 4.4.7	Suitability and effectiveness of protective clothing and equipment	26
IIIA 4.4.8	Procedures to minimise the generation of waste	26

IIIA 4.4.9	Combustion products likely to be generated in the event of fire	26
IIIA 4.5	Detailed Procedures for Use in the Event of an Accident During Transport, Storage or Use	26
IIIA 4.5.1	Containment of spillages.....	26
IIIA 4.5.2	Decontamination of areas, vehicles and buildings.....	27
IIIA 4.5.3	Disposal of damaged packaging, adsorbents and other materials.....	27
IIIA 4.5.4	Protection of emergency workers and bystanders	27
IIIA 4.5.5	First aid measures	27
IIIA 4.6	Neutralisation Procedure for Use in the Event of Accidental Spillage.....	27
IIIA 4.7	Pyrolytic Behaviour of the Active Substance.....	28
IIIA 4.8	Disposal Procedures for the Plant Protection Product.....	28
IIIA 4.8.1	Detailed instructions for safe disposal of product and its packaging.....	28
IIIA 4.8.2	Methods other than controlled incineration for disposal.....	28
IIIA 4.9	Other/Special Studies.....	28
IIIA 11	FURTHER INFORMATION.....	28
IIIA 11.1	Information of Authorisations in Other Countries.....	28
IIIA 11.2	Information on Established Maximum Residue Limits (MRL) in Other Countries	28
IIIA 11.3	Justified Proposals for Classification and Labelling.....	28
IIIA 11.4	Proposals for Risk and Safety Phrases.....	29
IIIA 11.5	Proposed Label	29
IIIA 11.6	Specimens of Proposed Packaging.....	29
Appendix 1:	List of data used in support of the evaluation	30
Appendix 2:	Critical Uses – Justification and GAP tables	33

Introduction

This document summarises the information related to the identity, the physical and chemical properties, the data on application, further information and the classification for the product Detia Mäuse Giftkörner containing the active substance zinc phosphide which was approved according to Regulation (EC) No 1107/2009.

This product was not the representative formulation. The product has not been previously evaluated according to Uniform Principles.

The following table provides the EU endpoints to be used in the evaluation.

Agreed EU End-points

End-Point	Zinc phosphide Regulation (EU) No 540/2011
Purity of active substance	min 800 g/kg

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Information on the detailed composition of Detia Mäuse Giftkörner can be found in the confidential dossier of this submission (Registration Report - Part C).

III A 1 IDENTITY OF THE PLANT PROTECTION PRODUCT

III A 1.1 Applicant

Detia Freyberg GmbH
Dr.-Werner-Freyberg-Str. 11
69514 Laudenbach
Germany

Contact person:
Tel.No.:
Fax No:
e-mail:



III A 1.2 Manufacturer of the Preparation, Manufacturer and Purity of the Active Substance(s)

III A 1.2.1 Manufacturer(s) of the preparation

Confidential information - data provided separately (Part C).

III A 1.2.2 Manufacturer(s) of the active substance(s)

Confidential information - data provided separately (Part C).

III A 1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

Zinc phosphide: minimum 800 g/kg

Further information is provided in Part C.

III A 1.3 Trade Names and Manufacturer's Code Numbers for the Preparation

Trade name: Detia Mäuse Giftkörner

Company code number: None

III A 1.4 Detailed Quantitative and Qualitative Information on the Composition of the Preparation

III A 1.4.1 Content of active substance and formulants

The formulation was not the representative formulation.

Pure active substance:

Content of pure zinc phosphide:	25 g/kg
Limits zinc phosphide (according FAO/WHO manual 2010)	18.75 – 31.25 g/kg

Technical active substance:

Content of technical zinc phosphide at minimum purity (80.0 %):	31.25 g/kg	(3.125 % w/w)
Content of technical zinc phosphide at minimum purity (91.5 %):	27.3 g/kg	(2.73 % w/w)

Further information on the active substances and on the certified limits of formulants is considered confidential and is provided separately (Part C).

III A 1.4.2 Certified limits of each component

This is not an EC data requirement/ not required by regulation (EU) 2011/545.

III A 1.4.3 Common names and code numbers for the active substance(s)

Data Point	Type	Name/Code Number
1.4.3.1	ISO common name	Zinc phosphide
1.4.3.2	CAS No.	1314-84-7
1.4.3.2	EC No.	215-244-5
1.4.3.2	CIPAC No.	69
1.4.3.3	Salt, ester anion or cation present	Not relevant

III A 1.4.4 Co-formulant details: identity, structure, codes, trade name, specification and function.

CONFIDENTIAL information - data provided separately (Part C).

III A 1.4.5 Formulation process

III A 1.4.5.1 Description of formulation process

This is not an EC data requirement/ not required regulation (EU) 2011/545.

III A 1.4.5.2 Discussion of the formation of impurities of toxicological concern

Zinc phosphide does not contain any impurities of toxicological or ecotoxicological concern.

III A 1.5 Type of Preparation and Code

Type: Bait (ready for use)

Code: RB

III A 1.6 Function

The product will be used as rodenticide.

III A 1.7 Other/Special Studies

None.

IIIA 2 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

Table 1: Summary of the physical, chemical and technical properties of the plant protection product

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Colour, odour and physical state (IIIA 2.1)	Visual assessment and organoleptic determination	Batch.: 48077-1 2.49 % Zn ₃ P ₂	Mid-brown to black metallic shiny grain baits with a garlic-like odour.	Y	Wilfinger (2013) S13-03084	Acceptable
Explosive properties (IIIA 2.2.1)	EEC A14	Batch RS 12/21.19072012 2.49 % Zn ₃ P ₂	The decomposition energy (DSC) is > 500 J/g, but in the main test no thermal or mechanical sensitivity was observed. Formulation has no explosive properties.	Y	Krack, M. (2013) 20120321.04	Acceptable..
Oxidizing properties (IIIA 2.2.2)	EEC A17	Batch RS 12/21.19072012 2.49 % Zn ₃ P ₂	No test was performed because the oxidising properties of the formulation can be excluded by the evaluation of the chemical structure of the components.	Y	Krack, M. (2013) 20120321.06	Acceptable.
Flash point (IIIA 2.3.1)	-	-	Not required for solid formulations	-	-	Acceptable.
Flammability (IIIA 2.3.2)	EEC A10	Batch RS 12/21.19072012 2.49 % Zn ₃ P ₂	No reaction when an ignition source was applied. Test item is not a highly flammable solid.	Y	Krack, M. (2013) 20120321.03	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Auto-flammability (IIIA 2.3.3)	EEC A16	Batch RS 12/21.19072012 2.49 % Zn ₃ P ₂	Exothermic effect at 220 °C; The observed relative self-ignition temperature was 395 °C.	Y	Krack, M. (2013) 20120321.05	Acceptable.
Acidity or alkalinity and pH (IIIA 2.4.1)	-	-	Not required for RB formulations	-	-	Acceptable.
pH of a 1% aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	-	-	Not required for RB formulations	-	-	Acceptable
Kinematic viscosity (IIIA 2.5.1)	-	-	Not required for RB formulations	-	-	Acceptable
Dynamic viscosity (IIIA 2.5.2)	-	-	Not required for RB formulations	-	-	Acceptable
Surface tension (IIIA 2.5.3)	-	-	Not required for RB formulations	-	-	Acceptable
Relative density (IIIA 2.6.1)	-	-	Not required for solid formulations	-	-	Acceptable
Bulk or tap density (IIIA 2.6.2)	CIPAC MT 159	Batch.: RS 12/21, 19072012, purity: 2.54%	pour: 0.820 g/mL tapped: 0.832 g/mL	Y	Krack, M., 2012, 20120321.02	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Storage Stability after 14 days at 54° C (IIIA 2.7.1)	CIPAC MT 46.3	Batch 37 05	Storage material: commercial container (plastic bottles) Average mass decrease: 6.3 % Content of zinc phosphide: before storage: 2.85 % (*) after storage: 2.80 %	Y	Schreiner, G., Michael, H., Spieß, W., Biber, B. (2002) KBL/2002/1372 ASTH	Acceptable (*)The initial value was calculated from a threefold determination of a sample, the individual values were 2.57 – 3.06 %.
		Batch.: 48077-1 2.49 % Zn ₃ P ₂	Storage material: original container (5 kg bucket) The changes of the physical and chemical properties appearance, dry sieve analysis, dustiness and friability are negligible. A weight decrease of 0.38 % was observed, the package was not damaged.	Y	Wilfinger, W. (2013) S13-03081	Acceptable
		Batch.: 48077-1 2.49 % Zn ₃ P ₂	Storage material: original container (25 kg bags) The changes of the physical and chemical properties appearance, dry sieve analysis, dustiness and friability are negligible. A weight decrease of 4 % was observed, the package was not damaged.	Y	Wilfinger, W. (2013) S13-03084	Acceptable

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
		Batch.: 48077-1 2.49 % Zn ₃ P ₂	Storage material: original container (180 g cans) The changes of the physical and chemical properties appearance, dry sieve analysis, dustiness and friability are negligible. A weight decrease of 0.19 % was observed, the package was not damaged.	Y	Wilfinger, W. (2013) S13-03087	Acceptable
	Analytical method Detia SOP-025 Version 2	Batch 48077-1	Storage in 180 g cans Initial: 2.54 % After 14 d at 54 °C: 2.50 %	Y	Morlock, G. (2013) 13D06144-01-ASFO	Acceptable
	Analytical method Detia SOP-025 Version 2	Batch 48077-1	Storage in 5 kg buckets Initial: 2.39 % After 14 d at 54 °C: 2.30 %	Y	Morlock, G. (2013) 13D06144-02-ASFO	Acceptable
	Analytical method Detia SOP-025 Version 2	Batch 48077-1	Storage in 25 kg sacs Initial: 2.46 % After 14 d at 54 °C: 2.39 %	Y	Morlock, G. (2013) 13D06144-03-ASFO	Acceptable
Stability after storage for other periods and/or temperatures (IIIA 2.7.2)	-	-	Not required, please refer to 2.7.1	-		Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Minimum content after heat stability testing (IIIA 2.7.3)	-	-	Not necessary, since the decrease of the active substance did not exceed 5 %.	-	-	Acceptable.
Effect of low temperatures on stability (IIIA 2.7.4)	-	-	Not required for solid formulations	-	-	Acceptable.
Ambient temperature shelf life (IIIA 2.7.5)	Analytical method: see <i>W.E. White & A.H. Bushey (J. Am. Chem. Soc. 1944, 66, 1966-1972)</i>	Charge: 46076.1 and 47004.2	Storage for 21 months: Storage material: not stated Average temperature: 15 – 25 °C. Content of zinc phosphide 46076.1: before storage: 2.9 % after 21 month: 2.8 % Content of zinc phosphide 47004.2: before storage: 3.2 % after 21 month: 3.2 %	N	Lorenzen, V., Köhler, C., 2012, Z0037a	Acceptable. No information with respect to change in appearance or other technical parameters.
Shelf life in months (if less than 2 years) (IIIA 2.7.6)	-	-	Please refer to 2.7.5	-	-	Acceptable.
Wettability (IIIA 2.8.1)	-	-	Not required for RB formulations	-	-	Acceptable

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Persistence of foaming (IIIA 2.8.2)	-	-	Not required for RB formulations	-	-	Acceptable
Suspensibility (IIIA 2.8.3.1)	-	-	Not required for RB formulations	-	-	Acceptable
Spontaneity of dispersion (IIIA 2.8.3.2)	-	-	Not required for RB formulations	-	-	Acceptable
Dilution stability (IIIA 2.8.4)	-	-	Not required for RB formulations	-	-	Acceptable
Dry sieve test (IIIA 2.8.5.1)	CIPAC MT 170	Batch.: 48077-1 2.49 % Zn ₃ P ₂	Initial: 62.81 % on 3350 µm sieve 36.59 % on 2000 µm sieve After 14 d at 54 °C: 64.34 % on 3350 µm sieve 34.98 % on 2000 µm sieve	Y	Wilfinger (2013) S13-03081	Acceptable
	CIPAC MT 170	Batch.: 48077-1 2.49 % Zn ₃ P ₂	Initial: 62.39 % on 3350 µm sieve 37.08 % on 2000 µm sieve After 14 d at 54 °C: 58.88 % on 3350 µm sieve 40.40 % on 2000 µm sieve	Y	Wilfinger, W. (2013) S13-03084	Acceptable
	CIPAC MT 170	Batch.: 48077-1 2.49 % Zn ₃ P ₂	Initial: 62.25 % on 3350 µm sieve 36.95 % on 2000 µm sieve After 14 d at 54 °C:	Y	Wilfinger, W. (2013) S13-03087	Acceptable

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Wet sieve test (IIIA 2.8.5.2)			61.08 % on 3350 µm sieve 38.03 % on 2000 µm sieve			
	-	-	Not required for RB formulations	-	-	Acceptable
Particle size distribution (IIIA 2.8.6.1)	CIPAC MT 59.1	Batch.: RS 12/21, 19072012, purity: 2.54%	0.41 % residue on 4000 µm sieve 38.04 % residue on 3350 µm sieve 29.89 % residue on 3150 µm sieve 22.64 % residue on 2800 µm sieve 8.9 % residue on 2000 µm sieve 0.13 % residue 0 - 2000 µm D(v, 0.1) ≈ 2800 µm D(v, 0.5) ≈ 3200 µm D(v, 0.9) ≈ 3800 µm Please also refer to 2.8.5.1	Y	Krack, M (2012) 20120321.01	Acceptable
Nominal size range of granules (IIIA 2.8.6.2)	-	-	Please refer to 2.8.5.1	-	-	acceptable
Dust content (IIIA 2.8.6.3)	CIPAC MT 171	Batch.: 48077-1 2.49 % Zn ₃ P ₂	Initial: after 14 d at 54 °C: Nearly dust-free	Y	Wilfinger (2013) S13-03081	Acceptable
	CIPAC MT 171	Batch.: 48077-1 2.49 % Zn ₃ P ₂	Initial: after 14 d at 54 °C: 0.1 mg 0.1 mg	Y	Wilfinger, W. (2013) S13-03084	Acceptable

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			Nearly dust-free			
	CIPAC MT 171	Batch.: 48077-1 2.49 % Zn ₃ P ₂	Initial: after 14 d at 54 °C: Nearly dust-free	Y	Wilfinger, W. (2013) S13-03087	Acceptable
Particle size of dust (IIIA 2.8.6.4)	-	-	Not required by regulation (EU) 2011/545.	-	-	Acceptable
Friability and attrition (IIIA 2.8.6.5)	CIPAC MT 178	Batch.: 48077-1 2.49 % Zn ₃ P ₂	Initial: after 14 d at 54 °C:	Y	Wilfinger (2013) S13-03081	Acceptable
	CIPAC MT 178	Batch.: 48077-1 2.49 % Zn ₃ P ₂	Initial: after 14 d at 54 °C:	Y	Wilfinger, W. (2013) S13-03084	Acceptable
	CIPAC MT 178	Batch.: 48077-1 2.49 % Zn ₃ P ₂	Initial: after 14 d at 54 °C:	Y	Wilfinger, W. (2013) S13-03087	Acceptable
Emulsifiability (IIIA 2.8.7.1)	-	-	Not required for RB formulations	-	-	Acceptable
Dispersibility (IIIA 2.8.7.1)	-	-	Not required for RB formulations	-	-	Acceptable
Flowability (IIIA 2.8.8.1)	CIPAC MT 172	Batch.: 48077-1 2.49 % Zn ₃ P ₂	100 % of the sample passed the sieve spontaneously.	Y	Wilfinger, W (2013) S13-03083	Acceptable

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Pourability (including rinsed residue) (IIIA 2.8.8.2)	-	-	Not required for RB formulations	-	-	Acceptable
Dustability following accelerated storage (IIIA 2.8.8.3)	-	-	Not required for RB formulations	-	-	Acceptable
Physical compatibility of tank mixes (IIIA 2.9.1)	-	-	No mixtures are recommended	-	-	Acceptable.
Chemical compatibility of tank mixes (IIIA 2.9.2)	-	-	No mixtures are recommended	-	-	Acceptable.
Distribution to seed (IIIA 2.10.1)	-	-	Not intended for seed treatment	-	-	Acceptable
Adhesion to seeds (IIIA 2.10.2)	-	-	Not intended for seed treatment	-	-	Acceptable
Miscibility (IIIA 2.11)	-	-	Not required by regulation (EU) 2011/545.	-	-	Acceptable.
Dielectric breakdown (IIIA 2.12)	-	-	Not required by regulation (EU) 2011/545.	-	-	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Corrosion characteristics (IIIA 2.13)	-	-	Not required by regulation (EU) 2011/545.	-	-	Acceptable.
Container material (IIIA 2.14)	-	-	Not required by regulation (EU) 2011/545.	-	-	Acceptable.
Other/special studies (IIIA 2.15)	-	-	Not required by regulation (EU) 2011/545.	-	-	Acceptable.

IIIA 2.16 Summary and Evaluation of Data Presented Under Points 2.1 to 2.15

The product is a mid-brown to black metallic shiny grain bait with a garlic-like odour. It is not explosive, has no oxidising properties, is not highly flammable and shows no self ignition. The stability data indicate a shelf life of at least 2 years at ambient temperature.

The technical characteristics are acceptable for a ready-for-use bait.

Experimental testing of the product's physico-chemical and technical characteristics:

No sample was requested from the applicant for experimental testing.

Implications for labelling: none

IIIA 3 DATA ON APPLICATION OF THE PLANT PROTECTION PRODUCT

IIIA 3.1 Field of Use

Pest controlled: common vole.

Crop or situation: Outdoor control of rodent species (surface control and underground control) in fields and meadows, orchards, forests, agricultural crops, ornamental crops, vegetable crops, viticulture and for amateur gardening.

IIIA 3.2 Nature of the Effects on Harmful Organisms

After ingestion by the target organism, zinc phosphide is degraded to phosphine by the influence of the acidic gastro-intestinal secretions. Phosphine acts as an inhibitor of important enzymes in tissue cells, and in high concentrations it causes alterations to blood haemoglobin by formation of methaemoglobin. It is highly toxic to target species (voles).

IIIA 3.3 Details of Intended Use

IIIA 3.3.1 Details of existing and intended uses

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.3.2 Details of harmful organisms against which protection is afforded

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.3.3 Effects achieved

Please refer to Part B Section 7.

IIIA 3.4 Proposed Application Rates (Active Substance and Preparation)

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.5 Concentration of the Active Substance in the Material Used

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.6 Method of Application, Type of Equipment Used and Volume of Diluent

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7 Number and Timings of Applications, Timing, Growth Stages (of Crop and Harmful Organism) and Duration of Protection

IIIA 3.7.1 Maximum number of applications and their timings

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.2 Growth stages of crops or plants to be protected

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.3 Development stages of the harmful organism concerned

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.4 Duration of protection afforded by each application

Please refer to Part B Section 7.

IIIA 3.7.5 Duration of protection afforded by the maximum number of applications

Please refer to Part B Section 7.

IIIA 3.8 Necessary Waiting Periods or Other Precautions to Avoid Phytotoxic Effects on Succeeding Crops

IIIA 3.8.1 Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops

Please refer to Part B Section 7.

IIIA 3.8.2 Limitations on choice of succeeding crops

Please refer to Part B Section 7.

IIIA 3.8.3 Description of damage to rotational crops

Please refer to Part B Section 7.

IIIA 3.9 Proposed Instructions for Use as Printed on Labels

Please refer to Registration Report – Part A, Appendix 2 for the relevant country.

IIIA 3.10 Other/Special Studies

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA 4 FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT

IIIA 4.1 Packaging and Compatibility with the Preparation

Packaging Summary

Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

IIIA 4.1.1 Description and specification of the packaging

Detia Mäuse Giftkörner is to be marketed in in cans or buckets made of PE or PP, protected by lids or caps made of the same material..

Non professional users:

180 g can:	material:	HDPE
	shape/size:	cylindrical / approx. 62.5 mm diameter x 131.3 mm
	opening:	42 mm inner diameter
	closure:	SK50/25 two piece screw cap, with EPE liner
	seal:	HF-seal

1 kg bucket:	material:	PP
	shape/size:	cylindrical / approx. 168.5 - 142.5 mm diameter x 128 mm
	closure:	water tight PP lid
	seal:	none

To be noted:

In DE the packaging for non-professional users could not be approved based on concerns in the ecotox section.

Professionell users:

5 kg bucket: material: PP

 shape/size: cylindrical / approx. 293 – 242 mm diameter x 245 mm

 closure: PP lid

 seal: none

25 kg sack: material: PP (50 – 80 µm) or
 PE (0.11 mm, 80 g/m²)

IIIA 4.1.2 Suitability of the packaging and closures

Report:	Prinz, S. 2006
Title:	Technische Daten Eimer 1,8 L und Konformitätserklärung Eimer Ausgabe 2011/3
Document No:	ERE 0180 P S68
Guidelines:	ADR/RID
GLP	No
Report:	Anonymous, 2012
Title:	Technisches Datenblatt 11 L Eimer Rund aus Kunststoff - Modell Supra mit Metall- oder Kunststoffbügel und Konformitätserklärung
Guidelines:	ADR/RID
GLP	No
Report:	Anonymous, 2012
Title:	Datenblatt für Polyäthylenfoliensäcke
Guidelines:	EG and LMBG
GLP	No
Report:	Anonymous, 2010
Title:	Datenblatt für Polypropylen- Bändchengewebe
Guidelines:	EG and LMBG
GLP	No

IIIA 4.1.3 Resistance of the packaging material to its contents

Justification of non- submission:

The packaging in which Detia Giftkörner baits are contained are considered to be resistant against zinc phosphide, since this is not a corrosive substance. Furthermore, no complaints that the packaging was

damaged during storage of the bait have become known. Since the content of zinc phosphide in the product is low and the formulation base is of food/ feedsstuff nature, it is concluded that the packaging materials are suitable for packagings and transport of Detia Mäuse Giftkörnern.

IIIA 4.2 Procedures for Cleaning Application Equipment

Justification of non- submission:

The submission if information on procedures for cleaning application equipment and protective clothing for the product Detia Mäuse Giftkörner is not considered to be required, since Detia Mäuse Giftkörner is laid out with an application tool e.g. application lance.

IIIA 4.3 Re-entry Periods to Protect Man, Livestock and the Environment

IIIA 4.3.1 Pre-harvest interval (in days) for each relevant crop

See section 4.

IIIA 4.3.2 Re-entry period (in days) for livestock, to areas to be grazed

See section 4.

IIIA 4.3.3 Re-entry period (in hours or days) for man to crops, buildings or spaces treated

See section 4.

IIIA 4.3.4 Withholding period (in days) for animal feeding stuffs

See section 4.

IIIA 4.3.5 Waiting period (in days) between application and handling of treated products

See section 4.

IIIA 4.3.6 Waiting period (in days) between last application and sowing or planting succeeding crops

See section 4.

IIIA 4.3.7 Information on specific conditions under which the preparation may or may not be used

See section 4.

IIIA 4.4 Statement of the Risks Arising and the Recommended Methods and Precautions and Handling Procedures to Minimise Those Risks

The safety data sheet complies with actual EEC regulations and is based on the present state of knowledge.

Hazard identification:

Harmfull if swallowed.

Toxic to aquatic life with long lasting effects.

Contact with water liberates toxic gas.

Contact with acids liberates very toxic gas.

IIIA 4.4.1 Warehouse storage

Keep away from food, drink and animal feeding stuffs.

Keep away from water.

Keep locked up and out of reach of children.

Protect against moisture.

Storage in unopened original containers in a cool and dry place.

Storage stability: > 24 months.

Protect from temperatures above: +30 °C

Changes in the properties of the product may occur if substance/ product is stored above indicated temperature for extended periods of time.

IIIA 4.4.2 User level storage

Keep away from food, drink and animal feeding stuffs.

Keep away from water.

Keep locked up and out of reach of children.

Protect against moisture.

Storage in unopened original containers in a cool and dry place.

Storage stability: > 24 months.

Protect from temperatures above: +30 °C

Changes in the properties of the product may occur if substance/ product is stored above indicated temperature for extended periods of time.

IIIA 4.4.3 Transport

Transportation by road or railway, inland- navigation, vessels, aeroplane:

Not classified as dangerous in the meaning of transport regulations (ADR, RID, ADNR, IMDG/GGVSea, ICAO/IATA).

IIIA 4.4.4 Fire

Suitable extinguishing media:

Extinguishing powder and CO₂ dry sand or powder and then CO₂.

Extinguishing media that must be not used for safety reasons:

Water and foam water, extinguishers containing water.

Special hazards from the substance itself, its combustion products or from its vapours:

In case of fire may be realised:

phosphorous oxides (e.g. phosphorous pentoxide), phosphine corrosive phosphoric acid aerosols (phosphorous pentoxide).

Special protective equipment for fire fighting:

Wear self- contained breathing apparatus and chemical- protective clothing. Full mask with filters B23-P2 or self- contained breathing apparatus.

Further instructions:

In case of fire and/ or explosion do not breathe fumes. Collect contaminated extinguishing water separately, do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulation.

IIIA 4.4.5 Nature of protective clothing proposed

General:

Take into account the usual safety measures in chemical handling. Keep away from food and feed stuff. When using, do not eat, drink or smoke. Misuse can cause adverse effects on health.

Hand protection:

Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact. (Recommended: Protective index 6, corresponding >480 minutes of permeation time according to EN 374): E.G. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), polyvinylchloride (0.7 mm) and other.

Eye protection:

Safety glasses with side- shield (EN 166).

Body protection:

Overall work clothes.

IIIA 4.4.6 Characteristics of protective clothing proposed

No study or specific information on the effectiveness of PPE is available. However, in view of the preparatin and in consideration of the toxicological properties of the active substance, no particular requirements in excess of standard expectations are considered to be given.

IIIA 4.4.7 Suitability and effectiveness of protective clothing and equipment

No information available.

IIIA 4.4.8 Procedures to minimise the generation of waste

Deplete contaminated containers completely, then disposal via house garbage after cleaning possible. Only purchase and store quantities of product required in the short term.

IIIA 4.4.9 Combustion products likely to be generated in the event of fire

In the event of fire and/ or explosion, phosphorous oxides and phosphine may be formed.

IIIA 4.5 Detailed Procedures for Use in the Event of an Accident During Transport, Storage or Use

IIIA 4.5.1 Containment of spillages

Justification of non- submission: not applicable.

IIIA 4.5.2 Decontamination of areas, vehicles and buildings

Justification of non- submission: not applicable.

IIIA 4.5.3 Disposal of damaged packaging, adsorbents and other materials

Justification of non- submission: not applicable.

IIIA 4.5.4 Protection of emergency workers and bystanders

Justification of non- submission: not applicable.

IIIA 4.5.5 First aid measures

General:

Remove contaminated clothes.

Inhalation:

Repose, remove to fresh air, consult a physician. In case of headache, dizziness, feeling of constriction, difficult breathing and nausea immediately leave the danger zone and seek fresh air; consult a physician; inhale products for acute treatment following exposition of smoke gas (e.g. beclometasone (Ventolair) spray).

Eye contact:

Irrigate immediately over 15 min with running water, with spread eyelids. Consult an oculist. Remove rests of preparation with fluff-free cloth; rinse with plenty of water and apply eye drops only after no more powdery residues are visible.

Skin contact:

Immediately wash off with soap and water, consult a physician. Remove any rests by brushing; only then use water for cleansing.

Ingestion:

Consult immediately a physician. Immediately get medical attention.

Medical advice:

Show physician product label and instruction for use and/ or safety data sheet. Information to the physician: If unconscious, call emergency physician. Special aids required for First Aid measures: have methyl prednisolon (application by physician) and products for acute treatment following exposition of smoke gas (e.g. beclometasone (Ventolair) spray) available.

IIIA 4.6 Neutralisation Procedure for Use in the Event of Accidental Spillage

Small quantities pick up with suitable appliance and dispose of.

The submission of data or the performance of test on possibility of neutralisation/ neutralisation procedures for use in the event of accidental spillages for the product Detia Mäuse Giftkörner is not considered to be required, since the product is neither liquid nor soluble in water.

Large quantities pick up in dry foam. Dispose of absorbed material in accordance with regulations. Collect waste in suitable containers, which can be labelled and sealed. Incinerate or take to a special waste disposal site in accordance with local authority regulations.

III A 4.7 Pyrolytic Behaviour of the Active Substance

Controlled incineration:

The submission of data on the pyrolytic behaviour of the product Detia Mäuse Giftkörner is not considered to be required, since zinc phosphide is not a halogenated molecule, and all other major product constituents are of food/ feed status.

III A 4.8 Disposal Procedures for the Plant Protection Product

III A 4.8.1 Detailed instructions for safe disposal of product and its packaging

Deliver residues according to regional regulations to a special treatment e.g. appropriate waste incineration plant. Empty contaminated packaging completely. After cleaning, treat as domestic waste (recycling if applicable).

Detailed instructions for safe disposal of the plant protection product and its packaging:

See above.

III A 4.8.2 Methods other than controlled incineration for disposal

Disposal considerations:

Apart from disposal via controlled incineration, the product Detia Mäuse Giftkörner should be disposed of accordance with regional legislation e.g. in licenced landfill sites.

III A 4.9 Other/Special Studies

No additional studies were performed.

III A 11 FURTHER INFORMATION

III A 11.1 Information of Authorisations in Other Countries

see EU pesticide data base (http://ec.europa.eu/sanco_pesticides/public/)

III A 11.2 Information on Established Maximum Residue Limits (MRL) in Other Countries

MRLs are set at European level, see Regulation (EC) No. 396/2005.

III A 11.3 Justified Proposals for Classification and Labelling

Proposals for classification and labelling of BAS 512 16 F in accordance with the EC Directive on dangerous preparations 1999/45/EC and Directive 2001/59/EC (as amended) are presented below:

Physico-chemical properties

Table 11.3-1 Physico-chemical properties

Study Type	Findings (triggered risk phrase)	Reference
Explosivity	Not explosive.	Krack, M. (2013) 20120321.04
Oxidizing properties	Not oxidizing.	Krack, M. (2013) 20120321.06
Flammability	Not self igniting.	Krack, M. (2013) 20120321.03

Toxicology

see section 3.

Ecotoxicology/Environment

see section 6.

IIIA 11.4 Proposals for Risk and Safety Phrases

Please refer to Registration Report – Part A.

IIIA 11.5 Proposed Label

Please refer to Registration Report – Part A.

IIIA 11.6 Specimens of Proposed Packaging

Specimens of the packaging were not provided as there was no request.

Appendix 1: List of data used in support of the evaluation

Annex point/ reference No. OECD	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant)	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA1 2.1 2.7.1/04 2.8.5.1/03 2.8.6.3/02 2.8.6.5/02	Wilfinger, W	2013	Physico-Chemical properties of the formulation DETIA MÄUSE GIFTKÖRNER before and after accelerated storage at 54 °C for 2 weeks (in 25 kg bags) S13-03084, GLP: Y, unpublished	Y	DET = Detia Freyberg GmbH	1
KIIIA1 2.2.1			See part C			1
KIIIA1 2.2.2						1
KIIIA1 2.3.2						1
KIIIA1 2.3.3						1
KIIIA1 2.6.2	Krack, M.	2012	Detia Mäuse Giftkörner – Batch.: RS 12/21. 19072012 – Tap Density CIPAC MT 159, 20120321.02, GLP: Y, unpublished	Y	DET	1
KIIIA1 2.7.1/01	Schreiner, G., Michael, H., Spieß, W., Biber, B.	2002	Evaluation of Storage Stability of Detia Mäuse Giftkörner by the Accelerated Storage Procedure by means of the Determination of the Concentration of Active Ingredient in the Test Item, KBL/2002/1372 ASTH, GLP: Y, published: N	Y	DET	1
KIIIA1 2.7.1/02 2.8.5.1/02 2.8.6.3/01 2.8.6.5/01	Wilfinger, W.	2013	Physico-Chemical properties of the formulation DETIA MÄUSE GIFTKÖRNER before and after accelerated storage at 54 °C for 2 weeks (in 5 kg buckets) S13-03081 , GLP: Y, unpublished	Y	DET	1
KIIIA1 2.7.1/03	Morlock, G.	2013	Content analysis of the formulation Detia Mäuse Giftkörner / 5 kg bucket before and after accelerated storage at 54 °C for 2 weeks 13D06144-02-ASFO GLP: Y, unpublished	Y	DET	1

Annex point/ reference No. OECD	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant)	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA1 2.7.1/05	Morlock, G.	2013	Content analysis of the formulation Detia Mäuse Giftkörner / 25 kg sacs before and after accelerated storage at 54 °C for 2 weeks 13D06144-03-ASFO GLP: Y, unpublished	Y	DET	1
KIIIA1 2.7.1/06 2.8.5.1/04 2.8.6.3/03 2.8.6.5/03	Wilfinger, W.	2013	Physico-Chemical properties of the formulation DETIA MÄUSE GIFTKÖRNER before and after accelerated storage at 54 °C for 2 weeks (in 180 g cans) S13-03087 , GLP: Y, unpublished	Y	DET	1
KIIIA1 2.7.1/07	Morlock, G.	2013	Content analysis of the formulation Detia Mäuse Giftkörner / 180 g cans before and after accelerated storage at 54 °C for 2 weeks 13D06144-01-ASFO GLP: Y, unpublished	Y	DET	1
KIIIA1 2.7.5	Lorenzen, V., Köhler, C.	2012	Storage Stability of Detia Mäuse Giftkörner, Z0037a, GLP: N, unpublished	Y	DEL	1
KIIIA1 2.8.6.1	Krack, M.	2012	Detia Mäuse Giftkörner – Batch.: RS 12/21. 19072012 – Particle Size Distribution (CIPAC MT 59.1), 20120321.01, GLP: Y, published: N	Y	DET	1
KIIIA1 2.8.8.1	Wilfinger, W	2013	Flowability of the formulation DETIA MÄUSE GIFTKÖRNER S13-03083 GLP: Y, unpublished	Y	DET	1
KIIIA1 4.1.1	Thiels, J.	2012	Produktinformation Agro Pack Dual 250 ml HDPE UN GLP: N, published: Y 2453157 /	N	DET	1

Annex point/ reference No. OECD	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant)	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA1 4.1.2	Prinz, S.	2006	Technische Daten Eimer 1,8 L und Konformitätserklärung Eimer Ausgabe 2011/3, GLP: N, published: Y	N	DET	1
KIIIA1 4.1.2	Anonymou s	2012	Technisches Datenblatt 11 L Eimer Rund aus Kunststoff - Modell Supra mit Metall- oder Kunststoffbügel und Konformitätserklärung, GLP: N, published: Y	N	DET	1
KIIIA1 4.1.2	Anonymou s	2012	Datenblatt für Polyäthylenfoliensäcke, GLP: N, published: Y	N	DET	1
KIIIA1 4.1.2	Anonymou s	2010	Datenblatt für Polypropylen- Bändchengewebe, GLP: N, published: Y	N	DET	1

- * 1 accepted (study valid and considered for evaluation)
 2 not accepted (study not valid and not considered for evaluation)
 3 not considered (study not relevant for evaluation)
 4 not submitted but necessary (study not submitted by applicant but necessary for evaluation)
 5 supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 2: Critical Uses – Justification and GAP tables

GAP rev. (No), date: 2013-08-15

GAP-Table of intended uses for Germany

PPP (product name/code) **Detia Mäuse Giftkörner**
active substance 1 **zinc phosphide**

Formulation type: **bait (ready for use)**
Conc. of as 1: **25 g/kg**

Applicant: **Detia Fryberg GmbH**
Zone(s): **central**

professional use **x**
non professional use **x**

Verified by MS: yes

Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	4	5	6	7		8	10	11		12	13	14	Remarks:
							Method / Kind	Timing / Growth stage of crop & season			Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season				
001	DE	Field crops (NNNAC)	F		Common vole (MICRAR)	lay out poisoned cereal grams	if required		a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha				5 piece(s) per hole (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.	
002	DE	Forest plants (NNNW/W)	F		Common vole (MICRAR)	lay out poisoned cereal grams	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha					5 piece(s) per hole (hide) The application rate of 2 kg/ha per application can be	

003	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	5 piece(s) per hole (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.
004	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	5 piece(s) per hole (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. Amateur gardening
005	DE	Grassland, Pasture, Meadow (NNNFW)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	5 piece(s) per hole (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.
006	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	5 piece(s) per hole (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.
007	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	5 piece(s) per hole (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. Amateur gardening
008	DE	Grape vine (VITVI)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	5 piece(s) per hole (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.

009	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	applications of 0.66 kg/ha.
010	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	5 piece(s) per hole (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. Amateur gardening
011	DE	Field crops (NNNAC)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.

012	DE	Forest plants (NNNW)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.
013	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.
014	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. Amateur gardening
015	DE	Grassland, Pasture, Meadow (NNNFW)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.
016	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.
017	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. Amateur gardening

018	DE	Grape vine (VITVI)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.
019	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha. Amateur gardening
020	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	50 g per bait station (hide) The application rate of 2 kg/ha per application can be divided into 3 single applications of 0.66 kg/ha.

Remarks:

- (1) Numeration of uses in accordance with the application/as verified by MS
- (2) Member State(s) or zone for which use is applied for
- (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (5) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds, developmental stages
- (6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row; individual plant, between the plants - type of equipment used must be indicated
- (7) Growth stage of treatment(s) (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

- (8) The maximum number of applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
- (8) Min. interval between applications (days) were relevant
- (10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
- (11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
- (12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
- (13) PHI - minimum pre-harvest interval
- (14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

GAP-Table of intended uses for all cMS (without Germany), not verified by zRMS

PPP (product name/code) Detia Mäuse Giftkörner **Formulation type:** bait (ready for use)
active substance 1 zinc phosphide **Conc. of as 1:** 25 g/kg

Applicant: Detia Fryberg GmbH **professional use** x
Zone(s): central **non professional use** x

Verified by MS: no

1	2	3	4	5	6	7		8	10	11		12	13	14
						Method / Kind	Application			kg, L, product / ha	Application rate			
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/season	a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Min / max	PHI (days)	Remarks:			
1	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Agricultural crops	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.		
2	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Agricultural crops	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded.		

3	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vegetable crops	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
4	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vegetable crops	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
5	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Fruit crops	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
6	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Fruit crops	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season

7	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vinicultural crops	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	(resulting in 6.00 kg/ha) must not be exceeded. Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
8	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vinicultural crops	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
9	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Grassland, lawns and meadows	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
10	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Grassland, lawns and meadows	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.

11	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Ornamental crops	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
12	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Ornamental crops	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
13	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Coniferous and deciduous trees	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
14	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Coniferous and deciduous trees	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
15	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland,	Vegetable crops (home and garden	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.

	Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)								b) 6.00 kg/ha									use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
16	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9		20-50 g /bait station a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required							Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
17	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9		5 grains / hole a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required							Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
18	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9		20-50 g /bait station a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required							Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
19	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania,	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9		5 grains / hole a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required							Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66kg/ha.

	Slovakia, Slovenia, United Kingdom)																The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
20	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Ornamental crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00 kg/ha b) 6.00 kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required						Type/formulation: RB The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha. The maximum of 2.00 kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.

Remarks:

- (1) Numeration of uses in accordance with the application/as verified by MS
- (2) Member State(s) or zone for which use is applied for
- (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
- (6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (7) Growth stage of treatment(s) (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (8) The maximum number of applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
- (8) Min. interval between applications (days) were relevant
- (10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
- (11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
- (12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
- (13) PHI - minimum pre-harvest interval
- (14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

**REGISTRATION REPORT
Part B**

**Section 2: Analytical Methods
Detailed summary of the risk assessment**

Product code: Detia Mäuse Giftkörner
Active Substance: Zinc phosphide 25 g/kg

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Detia Freyberg GmbH
Submission Date: 22/12/2012
Date: October 2017

Table of Contents

III A 5	METHODS OF ANALYSIS.....	3
III A 5.1	Analytical Standards and Samples	3
III A 5.1.1	Samples of the preparation.....	3
III A 5.1.2	Analytical standards for the pure active substance	3
III A 5.1.3	Samples of the active substance as manufactured.....	3
III A 5.1.4	Analytical standards for relevant metabolites and all other components included in the residue definition	3
III A 5.1.5	Samples of reference substances for relevant impurities	3
III A 5.2	Methods for the Analysis of the Plant Protection Product.....	3
III A 5.2.1	Description of the analytical methods for the determination of the active substance in the plant protection product.....	4
III A 5.2.2	For preparations containing more than one active substance, description of method for determining each in the presence of the other	5
III A 5.2.3	Applicability of existing CIPAC methods	5
III A 5.2.4	Description of analytical methods for the determination of relevant impurities.....	5
III A 5.2.5	Description of analytical methods for the determination of formulants	5
III A 5.3	Description of Analytical Methods for the Determination of Residues.....	5
Appendix 1	– List of data submitted in support of the evaluation	9

IIIA 5 METHODS OF ANALYSIS

This document summarises the information related to the analytical methods for the product Detia Mäuse Giftkörner containing the active substance zinc phosphide which was approved according to Regulation (EC) No 1107/2009.

This product was not the representative formulation. The product has not been previously evaluated according to Uniform Principles.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Information on the detailed composition of Detia Mäuse Giftkörner can be found in the confidential dossier of this submission (Registration Report - Part C).

IIIA 5.1 Analytical Standards and Samples

IIIA 5.1.1 Samples of the preparation

A sample of the preparation was provided by the applicant but no analysis of the contents of the active substances or the impurities was performed.

IIIA 5.1.2 Analytical standards for the pure active substance

Analytical standards of zinc phosphide were not provided because there was no request.

IIIA 5.1.3 Samples of the active substance as manufactured

No samples were provided because there was no request.

IIIA 5.1.4 Analytical standards for relevant metabolites and all other components included in the residue definition

No samples were provided because there was no request.

IIIA 5.1.5 Samples of reference substances for relevant impurities

No samples were provided because there was no request.

Zinc phosphide does not contain any impurity of toxicological or ecotoxicological concern.

IIIA 5.2 Methods for the Analysis of the Plant Protection Product

Analytical methods for the determination of zinc phosphide and their impurities and relevance of CIPAC methods were evaluated as part in the EU review. The respective data are considered adequate and are not included in this submission. Additional studies to support the registration of Detia Mäuse Giftkörner not previously assessed are given below. All relevant data are provided and are considered adequate.

IIIA 5.2.1 Description of the analytical methods for the determination of the active substance in the plant protection product

The following analytical method for the determination of the active substances in the plant protection product performed on Detia Mäuse Giftkörner has not previously been reviewed.

Report:	Schott, C., 2012
Title:	Validation of an analytical method for the determination of Zinc phosphide in Detia Mäuse Giftkörner
Document No:	12D05134-01-VMFO
Guidelines:	SANCO/3030/99 rev. 4
GLP	Yes

Method description

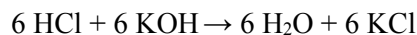
The content of zinc phosphide in Detia Mäuse Giftkörner was determined after hydrolysis of the test item with sulphuric acid.



The released phosphine reacted with mercury(II)chloride to generate hydrogen chloride.



The amount of hydrogen chloride was determined by titration with potassium hydroxide solution (0.1 N).



The analytic procedure is based on **Detia SOP-025 Version 02** dated 05 June 2012.

Method validation

The validation data of method Detia SOP-025/2 were determined for the formulation Detia Mäuse Giftkörner.

Table containing the methods and validation of the methods (formulation Detia Mäuse Giftkörner)

Analyte	Linearity n = 5	Accuracy Mean [%]	Repeatability n = 5 [%RSD]	Specificity/Interferences
Zinc phosphide	10.7 – 102.1 mg of reference item (2.08 – 19.81 mg of active P) r = 0.99995	Not determined	2.01 RSDr = 2.33 %	No information

Summary

The phosphine of Detia Mäuse Giftkörner can be quantified using the titration method Detia SOP-025/2.

With respect to repeatability and linearity the method is suitable for the determination of zinc phosphide in the RB-formulation. Further information on accuracy and specificity are missing.

IIIA 5.2.2 For preparations containing more than one active substance, description of method for determining each in the presence of the other

Please refer to chapter 5.2.1 as Detia Mäuse Giftkörner contains only one active substance.

IIIA 5.2.3 Applicability of existing CIPAC methods

There is no CIPAC method available for the determination of zinc phosphide in RB formulations like Detia Mäuse Giftkörner.

A routine analysis of zinc phosphide content was laid down in CIPAC 69, which however was not of accepted specificity. It is noted that CIPAC does not longer support this method (see DAR+AR for Zinc phosphide, point B.1.1)

IIIA 5.2.4 Description of analytical methods for the determination of relevant impurities

Zinc phosphide does not contain any impurity of toxicological or ecotoxicological concern.

IIIA 5.2.5 Description of analytical methods for the determination of formulants

No formulants with toxicological or ecotoxicological relevant compounds are present in the formulation. Therefore, no analytical methods for the determination of formulants are necessary.

IIIA 5.3 Description of Analytical Methods for the Determination of Residues

IIIA 5.3.1 Evaluation of zinc phosphide

The conclusions regarding the peer review of the analytical methods for residues of zinc phosphide are summarized in EFSA Journal 2010, 8(7): 1671 ([ASB2012-3394](#))

Table 5.3-1: Information on the active substance zinc phosphide

Name of component of residue definition substance code IUPAC name formula	Structural formula
Zinc phosphide	Zn ₃ P ₂

IIIA 5.3.1.1 Overview of residue definitions and levels for which compliance is required

The residue definition proposed in the Draft Assessment Report (incl. its addenda) is different from the current legal residue definition.

The residue definition for phosphines and phosphides in Regulation (EC) No 149/2008, annex III part A is “sum of aluminium phosphide, aluminium phosphine, magnesium phosphide, magnesium phosphine,

zinc phosphide and zinc phosphine”, which is incorrect from a chemical point of view (aluminium phosphine, magnesium phosphine and zinc phosphine do not exist).

The peer review of the pesticide risk assessment of the active substance zinc phosphide however concluded that a residue definition for food of plant and animal origin is not needed. The decisions made in this Registration Report are based on this conclusion, because the intended use (granular bait in special boxes) is not expected to result in residues in food.

Table 5.3-2: Relevant residue definitions

Matrix	Relevant residue	Reference Remarks
plant material	not relevant	EFSA Journal 2010, 8(7): 1671 (ASB2012-3394)
foodstuff of animal origin	not relevant	
soil	zinc phosphide and phosphine which are determined as phosphine	
surface water	not relevant	
drinking/ground water	zinc phosphide and phosphine which are determined as phosphine	
air	not relevant	
body fluids/tissue	not relevant	

Table 5.3-3: Levels for which compliance is required

Matrix	MRL	Reference for MRL/level Remarks
soil	0.05 mg/kg	common limit
drinking water	0.1 µg/L	general limit for drinking water

IIIA 5.3.1.2 Description of Analytical Methods for the Determination of Residues of zinc phosphide in Plant Matrices (OECD KIII A 5.3.1)

Analytical methods for analysis of residues of zinc phosphide in plant matrices are not required.

IIIA 5.3.1.3 Description of Analytical Methods for the Determination of Residues of zinc phosphide in Animal Matrices (OECD KIII A 5.3.1)

Analytical methods for analysis of residues of zinc phosphide in animal matrices are not required.

IIIA 5.3.1.4 Description of Methods for the Analysis of zinc phosphide in Soil (OECD KIII A 5.4)

An overview of the acceptable methods and possible data gaps for analysis of zinc phosphide in soil is given in the following tables. The study is evaluated in the Additional Report, RMS Germany, October 2009 (ASB2010-10164). New studies were not provided.

Table 5.3-4: Overview of suitable primary and confirmatory methods for soil

Component(s) of residue definition	Primary method	Confirmatory method
zinc phosphide and phosphine which are determined as phosphine	Witte, 2009	Witte, 2009

Table 5.3-5: Methods for soil

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in section B.5.3.1 of the Additional Report, October 2009
Witte, 2009	0.0007 mg/kg phosphine or 0.0025 mg/kg Zn ₃ P ₂	headspace GC/NPD with ZB-1 column and ZB-35 column	confirmation of results with second GC column	BVL no 1859406 <u>ASB2009-7434</u>

IIIA 5.3.1.5 Description of Methods for the Analysis of zinc phosphide in Water (OECD KIII A 5.6)

An overview of the acceptable methods and possible data gaps for analysis of zinc phosphide in surface and drinking water is given in the following table. These studies are evaluated in the Draft Assessment Report, RMS Germany, October 2009 (ASB2010-10165). The one study (Shrimali, 2001) was not submitted by the applicant, but Detia Freyberg GmbH is one of the notifiers for the active substance zinc phosphide. New studies were not provided.

Table 5.3-6: Overview of suitable primary and confirmatory methods for water

Component(s) of residue definition	Matrix	Primary method	Confirmatory method
zinc phosphide and phosphine which are determined as phosphine	drinking water/ surface water	Werle, 1999	Shrimali, 2001

Table 5.3-7: Methods for drinking water and surface water

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in section B.5.3.2 of the DAR, October 2009
Werle, 1999	0.1 µg/L	headspace GC/NPD with Poraplot U capillary column		Report no. 995040303 <u>MET2000-49</u>
Shrimali, 2001	0.1 µg/L	headspace GC/FPD using a 2 m column filled with 3 % OV	FPD accepted as confirmatory detector	JRF study no. 3569 <u>MET2002-40</u>

IIIA 5.3.1.6 Description of Methods for the Analysis of zinc phosphide in Air (OECD KIII A 5.7)

No method required, since exposure of operators, workers and bystanders can be excluded. Nevertheless, the Draft Assessment Report, RMS Germany, October 2009 (ASB2010-10165) has evaluated a method for air. The LOQ of this method is lower than the limit according to Council Directive 98/24/EC.

IIIA 5.3.1.7 Description of Methods for the Analysis of zinc phosphide in Body Fluids and Tissues (OECD KIII A 5.8)

Zinc phosphide is classified as highly toxic. A sensitive analytical method for the determination of residues of phosphine in human blood could not be validated because phosphine reacted with components of the blood matrix. Phosphine is very quickly transformed in blood. Consequently, the transport into the tissues via blood is limited. Therefore, it seems to be not necessary to develop analytical methods for determination of phosphine in body fluids and tissues even if the active substance zinc phosphide is classified as highly toxic. See Draft Assessment Report, RMS Germany, October 2009 (ASB2010-10165).

IIIA 5.3.1.8 Other Studies/ Information

Not required.

IIIA 5.4 Conclusion on the availability of analytical methods for the determination of residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions. Data gaps were not noticed.

Appendix 1 – List of data submitted in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA1 5.2.1	Schott, C.	2012	Validation of an analytical method for the determination of zinc phosphide in Detia Mäuse Giftkörner 12D05134-01-VMFO GLP: Y, unpublished	Y	DET	1

- * 1 accepted (study valid and considered for evaluation)
2 not accepted (study not valid and not considered for evaluation)
3 not considered (study not relevant for evaluation)
4 not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5 supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
	EFSA	2010	European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance zinc phosphide EFSA Journal 2010; 8(7):1671, 1-48 ASB2012-3394		Add
	Germany	2007	Zinc phosphide: Draft Assessment Report Vol. 1-3 ASB2010-10165		Add
	Germany	2009	Zinc phosphide: (Additional Report) Vol. 3 BVL-0003, AR, ASB2010-10164		Add
	Shrimali, A.	2001	Determination of Phosphine concentration in water treated with Aluminium Phosphide bag 3569 BVL-1963693, MET2002-40	Zinc Phosphide Pool (BAS, DET, DDZ und ZPP)	Add
KIIA 4.3	Corley, J.; Kahl, J.; Burkhart, D.; Diaz, E; Möller, G.	1998	Rapid Zinc Phosphide trace analysis in agricultural commodities by phosphine generation, toluene trapping, and gas chromatography GLP: Open Published: Open BVL-2448082, MET2002-58	LIT	N
KIIA 4.3	Godall, M.J.; Volz, S.A.; Johnston, J.J.; Hurlbut, D.B.; Mauldin, R.E.; Griffin, D.L.; Petty. E.E.	1998	Determination of Zinc phosphide residues in corn (Zea mays) grain, fodder, and forage GLP: Open Published: Open BVL-2448081, MET2002-57	LIT	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 4.3	Mauldin, R. E.; Goodall, M. J.; Griffin, D. L.; Petty, E. J.; Johnston J. J.	1997	Zinc phosphide residue determination in alfalfa (Medicago sativa) GLP: Open Published: Open BVL-2448083, MET2002-59	LIT	N
KIIA 4.3	Witte, A.	2001	Residue analysis of Zinc phosphide in animal tissues method validation - Method validation 2001426/01-RVAT GLP: Open Published: Open BVL-2448084, MET2002-60	ZPP	N
KIIA 4.4	Witte, A.	2001	Residue analysis of Zinc phosphide in soil method validation - Method validation 2001426/01-RVS GLP: Open Published: Open BVL-2448085, MET2002-56	ZPP	N
KIIA 4.4	Witte, A.	2009	Development and validation of an analytical method for the determination of residues of zinc phosphide in soil (including confirmatory method). Addendum to "Residue analysis of zinc phosphide in soil - method validation. 08W01020-01-VMS; 20001426/01-RVS GLP: Yes Published: No BVL-2442729, ASB2009-7434	ZPP	Y
KIIA 4.5	Walter, D.	2001	Water solubility of Zinc phosphide 20001426/01-PCSB GLP: Open Published: Open BVL-2448143, CHE2002-209	ZPP	N
KIIA 4.5	Werle, H.	1999	Method validation for the determination of residues of Phosphine in surface water and potable water 995040303 GLP: Open Published: Open BVL-2448086, MET2000-49	ZPP	Y
KIIA 4.7	Kettrup, A.; Angerer, J.	1993	Air analysis - Engl. transl. of the German document: Luftanalysen #1031 GLP: Open Published: Open BVL-2448087, MET2006-164	LIT	N
KIIA 4.8	Heenan, M. P.; Thomas, M. D.; Dickson, S. J.; Loris, H.	2003	Analysis of zinc phosphide in baits, water, soil, and biological specimens GLP: Open Published: Open BVL-2448089, MET2006-165	LIT	N
KIIA 4.8	Heintze, A.	2001	Residue analysis of Zink phosphide in human blood method validation 20001426/01-PVAT GLP: Open Published: Open BVL-2448088, MET2002-62	ZPP	N
KIIA 4.8	Mauldin, R. E.; Goldade, D. A.; Engeman, R. M. et al.	1996	Determination of Zinc phosphide residues in the california ground squirrel (spermophilus beecheryi) by gas chromatography - flame photometric detection J. Agric. Food Chem. 1996, 44, pp. 189 - 194 GLP: Open Published: Open BVL-2448090, MET2002-63	LIT	N
KIIA 6.3	Noack, S. et al.	1983	Relationship of phosphine residues after fumigation to concentration, time of exposure and length of storage #1017 ! #36 ! 177,87-93 GLP: No Published: Yes BVL-2442800, RIP2002-313	LIT	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
MIIIA1 Sec 2	Anon.	2012	Zinkphosphid / Detia Mäuse Giftkörner: Analytical methods - Tier 2, IIIA-5 MIII / Sec. 2 GLP: Open Published: No BVL-2447303, ASB2013-11652	DET	N

- * Y: Yes, relied on
N: No, not relied on
Add: Relied on, study not submitted by applicant but necessary for evaluation

REGISTRATION REPORT
Part B

Section 3: Mammalian Toxicology
Detailed summary of the risk assessment

Product code: Detia Mäuse Giftkörner
Active Substance: Zinc phosphide 25 g/kg

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Detia Freyberg GmbH
Date: March 2014

Table of Contents

3	Mammalian Toxicology (IIIA 7)	3
3.1	Summary	3
3.2	Toxicological Information on Active Substance(s)	5
3.3	Toxicological Evaluation of Plant Protection Product.....	6
3.4	Dermal Absorption (IIIA 7.6).....	7
3.5	Exposure Assessment of Plant Protection Product	7
3.5.1	Selection of critical use(s) and justification.....	8
3.5.2	Operator exposure (IIIA 7.3)	8
3.5.2.1	Estimation of operator exposure	8
3.5.2.2	Measurement of operator exposure.....	9
3.5.3	Worker exposure (IIIA 7.5)	9
3.5.3.1	Estimation of worker exposure	9
3.5.3.2	Measurement of worker exposure.....	9
3.5.4	Bystander and resident exposure (IIIA 7.4)	9
3.5.4.1	Estimation of bystander and resident exposure	9
3.5.4.2	Measurement of bystander and/or resident exposure.....	9
3.5.5	Statement on combined exposure	9
Appendix 1	Reference list	11
Appendix 2	Detailed evaluation of the studies relied upon.....	12
A 2.1	Statement on bridging possibilities.....	12
A 2.2	Acute oral toxicity (IIIA1 7.1.1).....	12
A 2.3	Acute percutaneous (dermal) toxicity (IIIA1 7.1.2)	12
A 2.4	Acute inhalation toxicity (IIIA1 7.1.3).....	13
A 2.5	Skin irritation (IIIA1 7.1.4).....	13
A 2.6	Eye irritation (IIIA1 7.1.5).....	14
A 2.7	Skin sensitisation (IIIA1 7.1.6).....	14
A 2.8	Supplementary studies for combinations of plant protection products (IIIA1 7.1.7)	15
A 2.9	Data on co-formulants (III1 7.9).....	15
A 2.9.1	Material safety data sheet for each co-formulant.....	15
A 2.9.2	Available toxicological data for each co-formulant.....	15
A 2.10	Studies on dermal absorption (IIIA 7.6)	15
A 2.11	Other/Special Studies.....	15

3 Mammalian Toxicology (IIIA 7)

3.1 Summary

Table 3.1-1: Information on Detia Mäuse Giftkörner *

Product name and code	Detia Mäuse Giftkörner (DET-20905-R-3-RB)
Formulation type	Bait (ready for use; RB)
Active substance(s) (incl. content)	Zinc phosphide; 25 g/kg
Function	Rodenticide
Product already evaluated as the 'representative formulation' during the Annex I inclusion	No
Product previously evaluated in an other MS according to Uniform Principles	No

* Information on the detailed composition of Detia Mäuse Giftkörner can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

In accordance with the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 3.1-2: Justified proposals for classification and labelling

C&L according to Regulation (EC) No 1272/2008	
Hazard class(es), categories:	Acute Tox. 4
Signal word:	302
Hazard statement(s):	Warning
Precautionary statement(s):	101-102-264-270-280-308+313-404-405-501
Additional labelling phrases:	'To avoid risks to man and the environment, comply with the instructions for use.' [EUH401]
	'Contact with acids liberates very toxic gas.' [EUH032]

Table 3.1-3: Summary of risk assessment for operators, workers, bystanders and residents for Detia Mäuse Giftkörner

	Result	PPE / Risk mitigation measures
Operators	Acceptable	<ul style="list-style-type: none"> - Avoid any unnecessary contact with the product. Misuse can lead to health damage. - The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed. - Wear standard protective gloves (plant protection) when handling the product. (professional use) - Wear protective gloves when handling the product. (amateur use) - The product is poisonous for pets. - Place bait out of reach for children, domestic animals and animals living in the wild. - Application of the product outside the forest is only permissible by subsurface placing (§ 2 Abs. 1 Pflanzenschutz-Anwendungsverordnung). Violations may be punished by fines of up to 50.000 Euro. <p>Particular regulations for packages in the home and allotment garden area:</p> <ul style="list-style-type: none"> - The packaging/container must carry a tactile warning of danger for home and garden use. <p>Maximal allowed quantity: Approval for the home and allotment garden area applies only for positive evaluated containers up 180 g.</p>
Workers	Acceptable	None
Bystanders	Acceptable	None
Residents	Acceptable	None

No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in Table 3.1-3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents is presented in Table 3.1-4.

Table 3.1-4 Critical uses and overall conclusion of exposure assessment

1 Crops ¹⁾ and situation (e.g. growth stage of crop)	2 F/G or I ²⁾	3 Application		5 Application rate		7 Remarks: (e.g. surfactant (L /ha)) critical gap for operator, worker, bystander or resident exposure based on [<i>Exposure model</i>]	8 Acceptability of exposure assessment			
		Method / Kind (incl. application technique)	Max. number (min. interval between applications) a) per use b) per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		Operator	Worker	Bystander	Residents
Field crops, vegetables, orchards, vineyards, ornamentals, grassland, pasture, meadow, forest plants	F	Placing baits in vole holes or bait stations	a) 3 b) 3	a) 0.05 b) 0.15		Professional use				
Vegetables, fruit crops, ornamentals	F	Placing baits in vole holes or bait stations	a) 3 b) 3	a) 0.05 b) 0.15		Amateur use				

	Exposure acceptable without PPE / risk mitigation measures
	Further refinement and/or risk mitigation measures required
	Exposure not acceptable/ Evaluation not possible

¹⁾ Pooled critical GAPS with the same max. application rate per application and using the same application technique

²⁾ F: field or outdoor application, G: greenhouse application, I: indoor application³⁾

3.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 3.2-1.

Table 3.2-1: Information on active substance(s)

	Zinc phosphide
Common Name	Trizinc diphosphide
CAS-No.	1314-84-7
Classification and proposed labelling Trizinc diphosphide	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008)	Table 3.1 of Annex VI to CLP 00 / ATP 01 Water-react. cat. 1 Acute toxicity, cat. 2 H260 - In contact with water releases flammable gases which may ignite spontaneously H300 - Fatal if swallowed EUH029- Contact with water liberates toxic gas EUH032- Contact with acids liberates very toxic gas Proposal Germany*: Acute toxicity, cat. 2 H300 - Fatal if swallowed H311 - Toxic in contact with skin EUH032- Contact with acids liberates very toxic

	gas
* The substance is practically insoluble in water (solubility: < 1.4 µg/L), therefore, H260 and EUH029 are not supported.	
Classification and proposed labelling Phosphine	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008)	Table 3.1 of Annex VI to CLP 00 Acute toxicity, cat. 2 Skin corrosion, cat. 1B H330 - Fatal if inhaled H314 - Causes severe skin burns
Agreed EU endpoints	
Trizinc diphosphide AOEL systemic	0.042 mg/kg bw/d (based on a maximum liberation of gas of 0.26 g PH ₃ /g zinc phosphide in acidic medium)
Phosphine AOEL systemic	0.03 ppm ≈ 0.042 µg/L air ≈ 0.011 mg/kg bw
Reference	EFSA Journal 2010; 8(7):1671
Conditions to take into account/critical areas of concern with regard to toxicology	
Review Report for active substance	None

3.3 Toxicological Evaluation of Plant Protection Product

With respect to the low content of zinc phosphide in Detia Mäuse Giftkörner, the non-toxic product matrix containing mostly of foodstuff and the physical properties of the formulated product (ready-to-use bait pellets) no further tests on the product were considered necessary; instead the evaluation of product toxicity is based on data for the active substance zinc phosphide. The justifications for waiving the studies are given in Appendix 2. MSDS on Detia Mäuse Giftkörner can be found in the confidential dRR Part C.

Table 3.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for Detia Mäuse Giftkörner

Type of test, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Dir. 67/548/EEC)	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral	Not submitted, not necessary.				
LD ₅₀ dermal	Not submitted, not necessary.				
LC ₅₀ inhalation	Not submitted, not necessary (vapour pressure of zinc phosphide: 6.5 x 10 ⁻⁹ Pa at 20°C). Phosphine release in acidic medium only.				

Skin irritation	Not submitted, not necessary.				
Eye irritation	Not submitted, not necessary.				
Skin sensitisation	Not submitted, not necessary.				
Supplementary studies for combinations of plant protection products	No data – not required.				

Table 3.3-2: Additional toxicological information relevant for classification/labelling of Detia Mäuse Giftkörner

	Substance (Concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Zinc phosphide (2.5 % (w/w))	H300; H302 (principle of additivity) EUH029 ¹⁾ EUH032	Reg. (EC) No 1272/2008	H302 EUH032
Toxicological properties of non-active substance(s) (relevant for classification of product)	None			
Further toxicological information	No data – not required			

¹⁾ not considered since active substance is practically insoluble in water

3.4 Dermal Absorption (IIIA 7.6)

No data on dermal absorption for zinc phosphide in Detia Mäuse Giftkörner are available. The default value for dermal absorption used for risk assessment here is presented in Table 3.4-1.

Table 3.4-1: Dermal absorption endpoints for active substances in Detia Mäuse Giftkörner

	Zinc phosphide	
	Value	Reference
Zinc phosphide, phosphine	10%	EFSA conclusion (EFSA Journal 2010; 8(7):1671), based on expert judgment

3.5 Exposure Assessment of Plant Protection Product

Table 3.5-1: Product information and toxicological reference values used for exposure assessment

Product name and code	Detia Mäuse Giftkörner (DET-20905-R-3-RB)
Formulation type	Bait (ready for use; RB)

Category	Rodenticide
Container size(s), short description	180 g can, 1 kg and 5 kg bucket, 25 kg sack
Active substance(s) (incl. content)	Zinc phosphide 25 g/kg
AOEL systemic	0.042 mg/kg bw/d ¹⁾
Inhalative absorption	100 %
Oral absorption	100 %
Dermal absorption	Default value of 10 % for zinc phosphide and phosphine

¹⁾ based on a maximum liberation of gas of 0.26 g PH₃/g zinc phosphide in acidic medium

3.5.1 Selection of critical use(s) and justification

The critical GAPS used for the exposure assessment of the plant protection product are shown in Table 3.1-4.

3.5.2 Operator exposure (IIIA 7.3)

3.5.2.1 *Estimation of operator exposure*

No exposure data were submitted by the applicant. Therefore, operator exposure during application of rodenticides was estimated with an approach that is used for biocidal products (see Annex 4: Human Exposure to Rodenticides (Product type 14), TNsG on Human Exposure to Biocidal Products, 2007). According to that approach dermal exposure to bait pellets results from contact during the application phase (handling the bait pellets, placing the baits in the vole holes or bait stations) and the disposal phase (collecting and discarding excessive amounts of pellets, handling of carcasses). The total amount to which the skin is exposed during the application of pellets can be calculated by the following equation:

$$A_{\text{der}} = Q_{\text{prod}} \times F_{\text{Cprod}} / V_{\text{prod}} / D \times \text{TH}_{\text{der}} \times \text{Area}_{\text{der}}$$

A_{der}	amount of active substance (mg) on the skin
D	dilution factor = 1
Q_{prod}	amount of undiluted product (mg) used = 2000000 mg
F_{Cprod}	weight fraction of active substance in the product = 2.5 %
V_{prod}	volume of undiluted product (cm ³) = 2000 g / 0.5 g/cm ³ = 4000 cm ³
TH_{der}	thickness of layer of product (cm) in contact with skin = 0.01 cm
Area_{der}	surface area (cm ²) of exposed skin = 820 cm ² (hands adult; 25 th percentile, US EPA)

Assuming that 2 kg product (area: 1 ha) with a density of 0.5 g/cm³ are applied per day by a professional operator and that the hands of the operator get into contact with the product then:

$$A_{\text{der}} = 2000000 \text{ mg} \times 2.5 \% / 4000 \text{ cm}^3 / 1 \times 0.01 \text{ cm} \times 820 \text{ cm}^2 = 102.5 \text{ mg a.s.}$$

The dermal exposure during the disposal phase accounts for about 10-20 % of the exposure during the application phase based on the experience that 10-20 % of the bait pellets are left after application. Using the maximum value of 20 %, the total dermal exposure is:

$$A_{\text{der}} = A_{\text{der}} (\text{appl.}) + A_{\text{der}} (\text{disp.}) = 102.5 \text{ mg a.s.} + 102.5 \text{ mg a.s.} \times 20 \% = 123 \text{ mg a.s.}$$

The exposure via inhalation is considered negligible. Zinc phosphide is not volatile (vapour pressure at 20°C: 6.5 x 10⁻⁹ Pa) and the liberation of phosphine is unlikely. Moreover, the product contains only 0.13 % of particles in the range of 0 – 2 mm (statement of applicant). Therefore, the overall exposure is only based on dermal contact and was calculated as follows:

$$\% \text{ AOEL-S} = A_{\text{der}} \times \text{Abs}_{\text{der}} / \text{BW} / \text{AOEL-S} \times 100$$

AOEL-S systemic AOEL (mg/kg bw/d) = 0.042 mg/kg bw/d
Abs_{der} dermal absorption (%) = 10 %
BW body weight (kg) = 70 kg

$$\% \text{ AOEL-S} = 123 \text{ mg a.s.} \times 10 \% / 70 \text{ kg} / 0.042 \text{ mg/kg bw/d} \times 100 = 418.4 \%$$

The estimated worst case exposure for a professional operator exceeds the systemic AOEL. Hence, gloves should be taken into account. Assuming a protection factor of 99 % for wearing protective gloves the operator exposure will be below the AOEL-S with 4.2 %. Non-professional operators would be exposed to a lower extent as they would handle smaller amounts. Based on a treated area of 0.05 ha per day the amount of product handled would be 0.1 kg. Thus, the exposure of non-professional operators would amount to 20.9 % of the AOEL-S without PPE. Nevertheless, with respect to the classification of the product non-professional operators should use gloves as well.

3.5.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses, a study to provide measurements of operator exposure was not necessary and was therefore not performed.

3.5.3 Worker exposure (IIIA 7.5)

3.5.3.1 Estimation of worker exposure

Detia Mäuse Giftkörner is a ready-to-use rodenticide bait, which is laid out directly into vole holes or in bait stations. Hence, worker exposure during re-entry activities is not considered to occur. The estimation of worker exposure during re-entry tasks is therefore not considered to be required for this product type.

3.5.3.2 Measurement of worker exposure

For reasons given above (see 3.5.3.1), no particular risk for workers is expected following the intended GAP uses of Detia Mäuse Giftkörner. Thus, measurements of worker exposure are not required.

3.5.4 Bystander and resident exposure (IIIA 7.4)

3.5.4.1 Estimation of bystander and resident exposure

In view of the low zinc phosphide content of the preparation and the application method, any quantitatively relevant exposure of bystanders or residents to the active ingredient or the co-formulants is unlikely. Detia Mäuse Giftkörner is a formulated product of a grain bait type. The potential for dust exposure is considered negligible, which was confirmed by a dry sieve analysis (0.13 % of particles in the range of 0 – 2 mm; statement of applicant). In addition, the product is applied directly into vole holes or in bait stations. Therefore, inhalation exposure and dermal exposure to bystanders and residents can be excluded during application. Ingestion of bait pellets by children can be excluded provided that the bait is securely deposited.

3.5.4.2 Measurement of bystander and/or resident exposure

For reasons given above (see 3.5.4.1), no particular risk for bystanders and residents is expected following the intended GAP uses of Detia Mäuse Giftkörner. Thus, measurements of bystander and/or resident exposure are not required.

3.5.5 Statement on combined exposure

The product contains only one active substance.

Appendix 1 Reference list

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No.	Owner	How considered in dRR *
	EFSA	2010	Conclusion on the peer review of the pesticide risk assessment of the active substance zinc phosphide EFSA Journal 2010; 8(7):1671, 1-48 ASB-2012-3394		Add

*Y, Yes/relied on; N, No/not relied on; Add, Additional, Relied on/study not submitted by applicant but necessary for evaluation

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Studies on acute toxicity, irritation and sensitisation were waived with respect to the low content of zinc phosphide, the toxicological profile of the co-formulants consisting mostly of foodstuff and the physical properties of the formulated product.

Comments of zRMS:	Acceptable.
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A 2.2 Acute oral toxicity (IIIA1 7.1.1)

Comments of zRMS:	Waiving of the study acceptable.
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zRMS

The applicant gave no justification for non-submission but referred to Annex B.6 of the DAR on zinc phosphide. The representative formulation during the EU peer review on zinc phosphide was ARREX E Köder, a ready-to-use grain bait formulation, containing 30 g/kg active substance. For this formulation an LD₅₀ of 500 mg/kg bw could be derived from an acute oral toxicity study.

The acute oral toxicity LD₅₀ for zinc phosphide is 12 mg/kg bw in rats. Therefore, classification as ‘very toxic if swallowed’ (T+; R28) is required for zinc phosphide. According to the concentration limits set in Dir. 1999/45/EEC Detia Mäuse Giftkörner containing 2.5 % zinc phosphide (1 % ≤ conc. < 7 %) should be classified with T; R25. However, with respect to the calculation method giving an acute oral toxicity estimate of 480 mg/kg bw in rats the classification of Detia Mäuse Giftkörner with R22 according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations and with H302 according to Regulation (EC) No. 1272/2008 is considered sufficient which is in line with study results for similar zinc phosphide formulations.

Conclusion

The estimated acute oral toxicity of Detia Mäuse Giftkörner is 480 mg/kg bw in rats. Thus, classification with Xn; R22 / H302 is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.3 Acute percutaneous (dermal) toxicity (IIIA1 7.1.2)

Comments of zRMS:	Justification for waiving of the study acceptable.
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Justification for non-submission as given by the applicant

The submission of data or the performance of a test on the acute percutaneous toxicity of the product Detia Mäuse Giftkörner is not considered to be required, for the following reasons:

Zinc phosphide is practically water insoluble (< 1.4 µg/L, pH 6.49 - 6.88, 20 °C) and also insoluble in organic solvents (< 0.5 g/L in all tested solvents e.g. octanol). Given that conventional thinking assumes that a substance needs to dissolve prior to any absorption taking place, then intrinsically the potential for dermal absorption would therefore be extremely limited.

It is also noted (IIA 5.1.1/03: Andreev, 1959) that even 24 hours after a subcutaneous administration of radiolabelled zinc phosphide, the radioactivity was detectable only at the site of injection, indicating that neither decomposition nor the formation of mobile toxic compounds would occur under these circumstances, nor would the substance be mobile even if it had penetrated through skin.

In the recently published EU Risk Assessment on zinc and zinc compounds (ECB 2004: European Risk Assessment Report, Zinc oxide, CAS 1314-13-2, Rapporteur NL, European Commission, Joint Research Centre, 2004), the in-vitro investigation (performed according to OECD guidelines and under GLP) of dermal absorption of zinc oxide (as an example of a poorly soluble zinc compound) and zinc sulphate (as

an example for a compound of high water solubility) through porcine skin is described. The rapporteur at the time concluded that 2 % would constitute a conservative default value for dermal absorption of zinc compounds in general. However, whereas the solubility of zinc oxide in water is low (approx. 1 mg/L), the solubility of zinc phosphide is in fact negligible (at least a factor 1000 below that of zinc oxide), and read-across from the other zinc compounds to zinc phosphide intrinsically constitutes an overestimation. The plant protection product represents a ready-to-use rodenticide bait, in which zinc phosphide in a low concentration and an adhesive agent are combined to foodstuff material. Due to the application method, no contact of the user or other persons with the active substance itself is to be expected. The potential for any dermal exposure is practically zero.

zRMS

The acute dermal toxicity of Detia Mäuse Giftkörner was estimated according to Regulation (EC) No 1272/2008. As none of the co-formulants is classified for acute dermal toxicity the calculation is only based on the acute dermal LD₅₀ of approx. 1000 mg/kg bw (rat) for zinc phosphide:

Acute dermal toxicity estimate for Detia Mäuse Giftkörner = 1000 mg/kg bw / 2.5 % = 40,000 mg/kg bw

Conclusion

The estimated acute dermal toxicity of Detia Mäuse Giftkörner is 40000 mg/kg bw in rats. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.4 Acute inhalation toxicity (IIIA1 7.1.3)

Comments of zRMS:	Justification for waiving of the study acceptable.
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Justification for non-submission as given by the applicant

The submission of data or the performance of a test on the acute inhalation toxicity of the product Detia Mäuse Giftkörner is not considered to be required, for the following reasons:

No potential for any inhalation exposure is expected, due to the extremely low vapour pressure of the active substance zinc phosphide (6.5×10^{-9} hPa at 20 °C, IIA 2.3.1/01).

The GAP use of zinc phosphide does not involve either spraying or any dust exposure, as the formulated product Detia Mäuse Giftkörner is of “grain bait” type, so that the potential for dust exposure is considered negligible. This was confirmed experimentally under GLP by a dry sieve analysis, which yielded 0.13 % of particles are in the range of 0 – 2 mm (for further information see DAR of zinc phosphide, Annex B6 Toxicology and metabolism). Thus, the granular bait material that forms the basis of the formulated product Detia Mäuse Giftkörner does not contain any measurable content of particles of an inhalable particle size.

Therefore, release of the active substance or the metabolite phosphine is not to be expected to any relevant extent during normal handling and use of the product, and the potential for any inhalation exposure is practically zero.

Conclusion

As phosphine will be released from zinc phosphide only in acidic medium and none of the co-formulants is classified for acute inhalation toxicity, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.5 Skin irritation (IIIA1 7.1.4)

Comments of zRMS:	Justification for waiving of the study acceptable.
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Justification for non-submission as given by the applicant

The submission of data or the performance of a test on the skin irritation of the product Detia Mäuse

Giftkörner is not considered to be required, for the following reasons:

The plant protection product represents a ready-to-use rodenticide bait, in which zinc phosphide in a low concentration and a red dye are combined to foodstuff materials.

Due to the GAP use, no relevant extent of dermal contact of the user or other persons with the active substance itself is to be expected.

Further, it is noted that in a test for acute skin irritation of zinc phosphide in the rabbit (report IIA 5.2.4/01), no skin irritation was observed. Considering the composition of the formulated product, which consists largely of food-grade materials, Detia Mäuse Giftkörner does not require classification for skin irritation according to the requirements specified by Directive 1999/45/EC.

Conclusion

None of the substances in Detia Mäuse Giftkörner is classified as skin irritant. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.6 Eye irritation (IIIA1 7.1.5)

Comments of zRMS:	Justification for waiving of the study acceptable.
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Justification for non-submission as given by the applicant

The submission of data or the performance of a test on the eye irritation of the product Detia Mäuse Giftkörner is not considered to be required, for the following reasons:

The plant protection product represents a ready-to-use rodenticide bait, in which zinc phosphide in a low concentration and an adhesive agent are combined to foodstuff material.

Due to the GAP use, no exposure of the eyes or mucous membranes with the active substance or the product is expected.

Further, it is noted that in a test for acute eye irritation of zinc phosphide in the rabbit (report IIA 5.2.5/01), no eye irritation was observed. Considering the composition of the formulated product, which consists largely of food-grade materials, Detia Mäuse Giftkörner does not require classification for eye irritation according to the requirements specified by Directive 1999/45/EC.

Conclusion

None of the substances in Detia Mäuse Giftkörner is classified as eye irritant. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.7 Skin sensitisation (IIIA1 7.1.6)

Comments of zRMS:	Waiving of the study acceptable.
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zRMS

The applicant gave no justification for non-submission but presented a skin sensitisation study on zinc phosphide that was already evaluated during the EU peer review process (Brunt, P.; 2001).

Regarding the information on zinc phosphide and the co-formulants in Detia Mäuse Giftkörner no sensitising potential of the formulation is expected.

Conclusion

Neither zinc phosphide nor any of the co-formulants is classified as skin sensitiser. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.8 **Supplementary studies for combinations of plant protection products (IIIA1 7.1.7)**

Not necessary as combinations with other plant protecting products are not envisaged or required.

A 2.9 **Data on co-formulants (III1 7.9)**

A 2.9.1 **Material safety data sheet for each co-formulant**

Material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 **Available toxicological data for each co-formulant**

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 **Studies on dermal absorption (IIIA 7.6)**

No studies on dermal absorption were provided.

A 2.11 **Other/Special Studies**

No other studies on the product were submitted.

REGISTRATION REPORT
Part B

Section 4: Metabolism and Residues
Detailed summary of the risk assessment

Product code: Detia Mäuse Giftkörner
Active Substance: zinc phosphide, 25 g/kg

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Detia Freyberg GmbH
Date: December 2013

Table of Contents

8	METABOLISM AND RESIDUES DATA	3
8.1	Evaluation of the active substances	3
8.1.1	Zinc phosphide	3
8.1.1.1	Storage stability	3
8.1.1.2	Metabolism in plants and plant residue definition(s).....	3
8.1.1.3	Metabolism in livestock and animal residue definition(s).....	3
8.1.1.4	Residues in rotational crops.....	4
8.1.1.5	Residues in livestock	4
8.2	Evaluation of the intended use(s)	5
8.2.1	Selection of critical use and justification.....	5
8.2.2	All crops	8
8.2.2.1	Residues in primary crops	8
8.2.2.2	Distribution of the residue in peel/pulp	8
8.2.2.3	Residues in processed commodities	8
8.2.2.4	Proposed pre-harvest intervals, withholding periods.....	8
8.3	Consumer intake and risk assessment.....	8
8.3.1	Zinc phosphide	8
8.4	Proposed maximum residue levels (MRLs)	9
8.5	Conclusion	9
Appendix 1	Reference list	10
Appendix 2	Detailed evaluation of the additional studies relied upon.....	10
A 2.1	Storage stability	10
A 2.2	Residues in primary crops	10
A 2.3	Residues in processed commodities	10
A 2.4	Residues in rotational crops.....	10
A 2.5	Residues in livestock	10
A 2.6	Other studies/information	10
Appendix 3	Pesticide Residue Intake Model (PRIMo).....	11

8 METABOLISM AND RESIDUES DATA

8.1 Evaluation of the active substances

8.1.1 Zinc phosphide

Table 8.1-1: Identity of the active substance

Structural formula	Zn ₃ P ₂
Common Name	Zinc phosphide
CAS number	1314-84-7

8.1.1.1 Storage stability

The issue has been discussed at EU level and the outcome is described in the DAR (Germany 2009, [ASB2010-10165](#)) and in the conclusion of the peer review (EFSA 2010, [ASB2012-3394](#)).

Table 8.1-2: Stability of residues (Annex IIA, point 6.1)

Stability of zinc phosphide	Instable, no further guideline compliant data required.
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8.1.1.2 Metabolism in plants and plant residue definition(s)

The issue has been discussed at EU level and the outcome is described in the DAR (Germany 2009, [ASB2010-10165](#)) and in the conclusion of the peer review (EFSA 2010, [ASB2012-3394](#)).

Table 8.1-3: Metabolism in plants (Annex IIA, point 6.2.1; 6.5.1, 6.5.2, 6.6.2 and 6.7.1)

Plant groups covered	no guideline compliant data available and none required
Rotational crops	no data available and none required
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	not applicable
Distribution of the residue in peel/ pulp	not applicable
Processed commodities (nature of residue)	no data available and none required
Residue pattern in raw and processed commodities similar? (yes/no)	not applicable
Plant residue definition for monitoring	not relevant (EFSA, 2010, ASB2012-3394) Currently set in Reg. 396/2005: Phosphines and phosphides: sum of aluminium phosphide, aluminium phosphine, magnesium phosphide, magnesium phosphine, zinc phosphide and zinc phosphine
Plant residue definition for risk assessment	not relevant (EFSA, 2010, ASB2012-3394)
Conversion factor(s) (monitoring to risk assessment)	none

8.1.1.3 Metabolism in livestock and animal residue definition(s)

The issue has been discussed at EU level and the outcome is described in the DAR (Germany 2009, [ASB2010-10165](#)) and in the conclusion of the peer review (EFSA 2010, [ASB2012-3394](#)).

Table 8.1-4: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)

Animals covered	no data available and none required
Time needed to reach a plateau concentration in milk and eggs	not applicable
Animal residue definition for monitoring	not relevant (EFSA, 2010, ASB2012-3394) Currently set in Reg. 396/2005: Phosphines and phosphides: sum of aluminium phosphide, aluminium phosphine, magnesium phosphide, magnesium phosphine, zinc phosphide and zinc phosphine
Animal residue definition for risk assessment	not required
Conversion factor(s) (monitoring to risk assessment)	not applicable
Metabolism in rat and ruminant similar (yes/no)	not applicable
Fat soluble residue: (yes/no)	not applicable

8.1.1.4 Residues in rotational crops

The issue has been discussed at EU level and the outcome is described in the DAR (Germany 2009, [ASB2010-10165](#)) and in the conclusion of the peer review (EFSA 2010, [ASB2012-3394](#)).

Table 8.1-5: Residues in rotational crops (Annex IIA, point 6.6.3)

Field studies	no data available and none required
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8.1.1.5 Residues in livestock

Even though in some post harvest treatments involving phosphine, magnesium phosphide and aluminium phosphide residues >0.1 mg/kg were detected in potential feed items, these results were seen immediately after treatment, i.e. after a withholding period of 0 days. Due to the volatility of the active substance and its fast oxidation to toxicologically irrelevant compounds, phosphine residues > 0.1 mg/kg are extremely unlikely to reach livestock animals via their feed and the more, to form quantifiable residues in commodities of animal origin destined for human consumption. Therefore no calculation of dietary exposure of livestock was made.

Table 8.1-6: Conditions of requirement of livestock feeding studies on zinc phosphide

	Ruminant:	Poultry:	Pig:
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	no	no	no
Potential for accumulation (yes/no):	no	no	no
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	not required	not required	not required

With a view to the residue levels expected in feedstuffs no livestock feeding studies are deemed necessary (RMS Germany 2009, [ASB2010-10165](#) and EFSA 2010, [ASB2012-3394](#)).

Table 8.1-7: Results of livestock feeding studies (Annex IIA, point 6.4)

	Ruminant:	Poultry:	Pig:
Feeding levels (mg/kg feed dry matter) in feeding studies	no	no	no
Relevant dosing levels in feeding study:	n/a	n/a	n/a

	Expected residue levels in animal matrices (mg/kg):		
Muscle	–	–	–
Liver	–	–	–
Kidney	–	–	–
Fat	–	–	–
Milk	–	–	–
Eggs	–	–	–

8.2 **Evaluation of the intended use(s)**

8.2.1 **Selection of critical use and justification**

The GAPs reported for the zone are presented in Table 8.2-1. It has been used for consumer intake and risk assessment.

Table 8.2-1: GAPs used for consumer intake and risk assessment

1	2	3	4	5	6	7	8	9	10	11	12	13
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop) (a)	F G or I (b)	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) (c)	Application		Timing / Growth stage of crop & season (g)	Max. number (min. interval between applications) a) per use b) per crop/ season (h)	Application rate		PHI (days) (i)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures (j)
					Method / Kind (d-f)	Application Method / Kind (d-f)			kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season		
001, 004, 006, 008	DE	field crops, vegetables, fruit crops, table and wine grapes	F	common vole	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 b) 6	a) 50 b) 150		F	5 baits per vole hole (hide)
002, 005, 009	DE	forest plants, grassland, pasture, meadow, ornamentals	F	common vole	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 b) 6	a) 50 b) 150		N	5 baits per vole hole (hide)
003, 007	DE	vegetables, fruit crops (house and allotment)	F	common vole	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 b) 6	a) 50 b) 150		F	5 baits per vole hole (hide)
010	DE	ornamentals (house and allotment)	F	common vole	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 b) 6	a) 50 b) 150		N	5 baits per vole hole (hide)
013, 017	DE	vegetables, fruit crops (house and allotment)	F	common vole	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 b) 6	a) 50 b) 150		F	50 g per bait station (hide)
011, 014, 016, 018	DE	field crops, vegetables, fruit crops, table and wine grapes	F	common vole	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 b) 6	a) 50 b) 150		F	50 g per bait station (hide)
012, 015, 019	DE	forest plants, grassland, pasture, meadow, ornamentals	F	common vole	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 b) 6	a) 50 b) 150		N	50 g per bait station (hide)
020	DE	ornamentals (house and allotment)	F	common vole	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 b) 6	a) 50 b) 150		N	50 g per bait station (hide)

- Remarks:
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
 - (d) All abbreviations used must be explained
 - (e) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (f) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

- (g) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (h) The minimum and maximum number of application possible under practical conditions of use must be provided
- (i) PHI - minimum pre-harvest interval
- (j) Remarks may include: Extent of use/economic importance/restrictions

8.2.2 All crops

8.2.2.1 Residues in primary crops

The intended uses are not relevant in terms of consumer health protection. The submission of supervised residue trials is not necessary.

8.2.2.2 Distribution of the residue in peel/pulp

Not relevant.

8.2.2.3 Residues in processed commodities

Not relevant.

8.2.2.4 Proposed pre-harvest intervals, withholding periods

Not required

8.3 Consumer intake and risk assessment

8.3.1 Zinc phosphide

Consequent to the intended uses no residues of zinc phosphide or phosphine are expected in food or feed commodities. Hence, the envisaged uses are not relevant in terms of consumer health protection. Risk assessment is made for long term exposure only, based on the diets contained in revision 2 of the EFSA PRIMo and German NVS II, and the ADI of phosphine (0.011 mg/kg bw/d).

The MRLs as laid down in EU residue legislation for “phosphines and phosphides” (Reg. (EC) No 149/2008) represent up to ca. 23% (WHO cluster diet) of the EU PRIMo diets and 22% (2-4 year old children) of German consumer group diets.

Table 8.3-1: Residue input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
all commodities	variable	MRL	-	not applicable

Table 8.3-2: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.042 mg/kg bw/d (zinc phosphide) 0.011 mg phosphine/kg bw/d
TMDI (% ADI) according to EFSA PRIMo	23 % (WHO cluster diet B)
NTMDI (% ADI) according to NVS II	22 % (2-4 years old DE children)
IEDI (EFSA PRIMo) (% ADI)	not required
NEDI (NVS II) (% ADI)	not required
Factors included in IEDI and NEDI	not applicable
ARfD	0.073 mg/kg bw (zinc phosphide) 0.019 mg phosphine/kg bw
IESTI (EFSA PRIMo) (% ARfD)	not required
NESTI (NVS II) (% ARfD)	not required
Factors included in IESTI and NESTI	not applicable

8.4 **Proposed maximum residue levels (MRLs)**

No new MRLs are required.

8.5 **Conclusion**

As the intended uses of zinc phosphide are not residue relevant, an exceedance of the current MRLs as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intake of zinc phosphide residues is unlikely to present a public health concern.

As far as consumer health protection is concerned, BfR/Germany agrees with the authorization of the intended uses.

Appendix 1 Reference list

Table A 1: Reference list

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
	EFSA	2010	European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance zinc phosphide EFSA Journal 2010; 8(7):1671, 1-48 ASB2012-3394		Add
	Germany (RMS)	2007	Zinc phosphide: Draft Assessment Report Vol. 1-3 GLP: Open Published: Yes ASB2010-10165		Add
KIIA 6.3	Noack, S. et al.	1983	Relationship of phosphine residues after fumigation to concentration, time of exposure and length of storage #1017 ! #36 ! 177,87-93 GLP: Open Published: Open BVL-2442800, RIP2002-313	LIT	N
KIIA 6.3	Noack, S.; Reichmuth, C.; Wohlgemuth, R.	1984	Rückstandsverhalten von Phosphin in begasten Lebensmitteln in Abhängigkeit von der Lagertemperatur und der Belüftung - Decomposition of Phosphine in treated foods as related to storage temperature and aeration (pages 31-37) #1016 ! #94 ! 178, 31-37 GLP: Open Published: Open BVL-2442799, RIP2002-312	LIT	N
KIIA 6.3	Sato, K.; Suwanai, M.	1974	Adsorption of Hydrogen Phosphide to cereal products (received 08.10.1973) GLP: Open Published: Open BVL-2442801, RIP2002-314	LIT	N

- * 1 accepted (study valid and considered for evaluation)
 2 not accepted (study not valid and not considered for evaluation)
 3 not considered (study not relevant for evaluation)
 4 not submitted but necessary (study not submitted by applicant but necessary for evaluation)
 5 supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Storage stability

No further study on storage stability needed.

A 2.2 Residues in primary crops

No further study on primary crops needed.

A 2.3 Residues in processed commodities

No further study on processed commodities needed.

A 2.4 Residues in rotational crops

No new study on residues in rotational crops has been submitted.

A 2.5 Residues in livestock

No new study on residues in livestock has been submitted.

A 2.6 Other studies/information

None

Appendix 3 Pesticide Residue Intake Model (PRIMO)

phosphide, aluminium phosphine, magnesium phosphide, magnesium phosphine, zinc phosphide	
Status of the active substance:	Code no. proposed LOQ:
LOQ (mg/kg bw):	Toxicological end points
AD1 (mg/kg bw/day):	AR1D (mg/kg bw):
Source of AD1:	Source of AR1D:
Year of evaluation:	Year of evaluation:

Explain choice of toxicological reference values.
 The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
 The pTMRLs have been submitted to EFSA in September 2006.

		Chronic risk assessment						
		TMDI (range) in % of ADI minimum - maximum						
		No of diets exceeding ADI: 3 ----- 23						
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
22.7	WHO Cluster diet B	10.8	CEREALS	3.3	FRUIT (FRESH OR FROZEN)	2.6	Fruiting vegetables	
20.4	DE child	6.5	FRUIT (FRESH OR FROZEN)	5.1	CEREALS	2.1	PRODUCTS OF ANIMAL ORIGIN	
18.3	NL child	6.8	FRUIT (FRESH OR FROZEN)	5.1	CEREALS	3.0	Tropical root and tuber vegetables	
17.2	IE adult	6.0	CEREALS	4.9	FRUIT (FRESH OR FROZEN)	1.6	CEREALS	
16.4	FR toddler	5.3	FRUIT (FRESH OR FROZEN)	3.9	PRODUCTS OF ANIMAL ORIGIN	2.7	Other root and tuber vegetables	
16.2	DK child	6.5	FRUIT (FRESH OR FROZEN)	2.3	FRUIT (FRESH OR FROZEN)	2.0	PRODUCTS OF ANIMAL ORIGIN	
13.6	FR infant	9.9	FRUIT (FRESH OR FROZEN)	2.5	PRODUCTS OF ANIMAL ORIGIN	1.4	FRUIT (FRESH OR FROZEN)	
13.4	UK infant	4.1	CEREALS	3.8	PRODUCTS OF ANIMAL ORIGIN	2.5	FRUIT (FRESH OR FROZEN)	
13.2	UK toddler	4.2	CEREALS	2.9	FRUIT (FRESH OR FROZEN)	2.1	PRODUCTS OF ANIMAL ORIGIN	
13.1	WHO cluster diet D	7.6	CEREALS	1.3	FRUIT (FRESH OR FROZEN)	1.2	Fruiting vegetables	
13.0	WHO cluster diet E	5.5	CEREALS	2.6	FRUIT (FRESH OR FROZEN)	0.6	PRODUCTS OF ANIMAL ORIGIN	
11.9	SE general population 90th percentile	4.5	CEREALS	2.6	FRUIT (FRESH OR FROZEN)	1.6	PRODUCTS OF ANIMAL ORIGIN	
11.4	ES child	4.7	CEREALS	2.6	FRUIT (FRESH OR FROZEN)	1.6	PRODUCTS OF ANIMAL ORIGIN	
11.4	PT General population	4.9	CEREALS	2.9	FRUIT (FRESH OR FROZEN)	1.2	Brassica vegetables	
11.0	IT kidstoddler	7.6	CEREALS	1.6	FRUIT (FRESH OR FROZEN)	0.9	Fruiting vegetables	
10.4	WHO Cluster diet F	5.0	CEREALS	1.7	FRUIT (FRESH OR FROZEN)	1.0	PRODUCTS OF ANIMAL ORIGIN	
9.1	WHO regional European diet	3.4	CEREALS	1.6	FRUIT (FRESH OR FROZEN)	1.0	Fruiting vegetables	
8.1	FR all population	3.1	CEREALS	2.8	FRUIT (FRESH OR FROZEN)	0.4	Fruiting vegetables	
7.6	IT adult	4.6	CEREALS	1.3	FRUIT (FRESH OR FROZEN)	0.8	Fruiting vegetables	
7.4	ES adult	2.9	CEREALS	1.9	FRUIT (FRESH OR FROZEN)	0.7	PRODUCTS OF ANIMAL ORIGIN	
7.3	NL general	2.5	CEREALS	2.2	FRUIT (FRESH OR FROZEN)	0.7	PRODUCTS OF ANIMAL ORIGIN	
6.0	UK vegetarian	2.3	CEREALS	1.5	FRUIT (FRESH OR FROZEN)	0.5	Fruiting vegetables	
5.9	DK adult	2.6	CEREALS	1.5	FRUIT (FRESH OR FROZEN)	0.7	PRODUCTS OF ANIMAL ORIGIN	
5.3	LT adult	2.5	CEREALS	1.1	FRUIT (FRESH OR FROZEN)	0.5	PRODUCTS OF ANIMAL ORIGIN	
5.1	UK Adult	1.9	CEREALS	1.3	FRUIT (FRESH OR FROZEN)	0.4	PRODUCTS OF ANIMAL ORIGIN	
4.4	FI adult	1.7	CEREALS	1.1	FRUIT (FRESH OR FROZEN)	0.6	PRODUCTS OF ANIMAL ORIGIN	
3.2	PL general population	1.5	FRUIT (FRESH OR FROZEN)	0.5	Fruiting vegetables	0.3	Potatoes	

Conclusion:
 The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
 A long-term intake of residues of Phosphines and phosphides: sum of aluminium phosphide, aluminium phosphine, magnesium phosphide, magnesium phosphine, zinc phosphide and zinc phosphine is unlikely to present a public health concern.

REGISTRATION REPORT

Part B

Section 5 Environmental Fate

Detailed summary of the risk assessment

Product code: Detia Mäuse Giftkörner

Active Substance(s): Zinc phosphide 25 g/kg

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Detia Freyberg GmbH

**Date: January 2014, updated April
2018**

Table of Contents

TABLE OF CONTENTS	2
SEC 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)	3
5.1 GENERAL INFORMATION ON THE FORMULATION	3
5.2 PROPOSED USE PATTERN	3
5.3 INFORMATION ON THE ACTIVE SUBSTANCES.....	4
5.3.1 Zinc phosphide	4
5.4 SUMMARY ON INPUT PARAMETER FOR ENVIRONMENTAL EXPOSURE ASSESSMENT	6
5.4.1 Rate of degradation in soil.....	6
5.4.2 Adsorption/desorption	7
5.4.3 Rate of degradation in water and sediment	7
5.5 ESTIMATION OF CONCENTRATIONS IN SOIL (PEC _{SOIL}) (KIIIA1 9.4).....	7
5.6 ESTIMATION OF CONCENTRATIONS IN SURFACE WATER AND SEDIMENT (PEC _{SW} /PEC _{SED}) (KIIIA1 9.7)	8
5.7 RISK ASSESSMENT GROUND WATER (KIIIA1 9.6).....	9
5.7.1 Predicted environmental concentration in groundwater (PEC _{GW}) calculation for active substance and its metabolites (Tier 1 and 2).....	9
5.7.2 Higher tier leaching assessment (Tier 3).....	9
5.7.3 Summary of risk assessment for ground water.....	9
5.8 POTENTIAL OF ACTIVE SUBSTANCE FOR AERIAL TRANSPORT	9
APPENDIX 1 LIST OF DATA SUBMITTED IN SUPPORT OF THE EVALUATION	10
APPENDIX 2 DETAILED EVALUATION OF STUDIES RELIED UPON	11
APPENDIX 3 TABLE OF INTENDED USES JUSTIFICATION AND GAP TABLES	13

Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for the plant protection product Detia Mäuse Giftkörner containing the active substance zinc phosphid in its intended uses in agriculture, orchard, vegetables, ornamentals, grassland, grape vine and forestry, according to Appendix 3 /Part B.

National Addenda are included containing country specific assessments for some annex points.

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation Detia Mäuse Giftkörner

Code	007851-00/00		
plant protection product	Detia Mäuse Giftkörner		
applicant	Detia Freyberg GmbH		
date of application	2013		
Formulation type (WP, EC, SC, ...; density)	Ready for use-bait		
active substance	Zinc phosphide		
Concentration of as	25 g/kg		

5.2 Proposed use pattern

The critical GAP used for exposure assessment is presented in Table 5.2-1. It has been selected from the individual GAPs in the zone for Detia Mäuse Giftkörner. A list of all intended uses within the zone is given in Appendix 3 /Part B.

Table 5.2-1: Critical use pattern of Detia Mäuse Giftkörner

Group*	Crop/growth stage	Application method / Drift scenario	Number of applications, Minimum application interval, interception, application time (season)	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
A	agriculture Orchard* Vegetables* Ornamentals* Grassland Forestry grape vine / all stages	placing of baits in vole hole or placing of baits in bait stations	3 x 3 Appl. per season	Zinc phosphide Max. 3 x 50	Zinc phosphide Max. 150

* Group A covers all intended uses in all use areas in the central zone. All applications rates are also intended for use see appendix 3.

5.3 Information on the active substances

5.3.1 Zinc phosphide

5.3.1.1 Identity, further information of zinc phosphide

Table 5.3-1: Identity, further information on zinc phosphide

Active substance (ISO common name)	Zinc phosphide
IUPAC	Trizinc diphosphide
Function (e.g. fungicide)	rodenticide
Status under Reg. (EC) No 1107/2009	approval
Date of approval	01.05.2011
Conditions of approval	PART A Only uses as rodenticide in the form of ready-to-use baits placed in bait stations or target locations may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on zinc phosphide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010, shall be taken into account. In this overall assessment Member States should pay particular attention to: — the protection of non-target organisms. Risk mitigation measures should be applied as appropriate in particular to avoid the spread of baits where only part of the content has been consumed.
Confirmatory data	-
RMS	DE
Minimum purity of the active substance as manufactured (g/kg)	800 g/kg
Molecular formula	Zn ₃ P ₂
Molecular mass	258.1 g/mol
Structural formula	Zn ₃ P ₂

5.3.1.2 Physical and chemical properties of Zinc phosphide

Physical and chemical properties of zinc phosphid as agreed at EU level (see SANCO/12548/ 2010 – final, 28 October 2010) and considered relevant for the exposure assessment are listed in Table 5.3-2.

Table 5.3-2: EU agreed physical chemical properties of zinc phosphide relevant for exposure assessment

	Value	Reference
Vapour pressure (at 20 °C) (Pa)	6.5 x 10 ⁻⁹ Pa at 20 °C (purity: 82%)	EFSA_LOEP_April_2010
Henry's law constant (Pa × m³ × mol⁻¹)	Not applicable	See above
Solubility in water (at 25 °C in mg/L)	< 1.4 µg/L (20 °C) (purity: 82%)	See above
Partition co-efficient (at 25 °), log Pow	Not applicable	See above
Dissociation constant, pKa	Not applicable	See above

Hydrolytic degradation	Hydrolytically stable at pH 5 to 9 and 20 °C pH 4 and 20 °C: DT ₅₀ = 38 d metabolite PH ₃ (gas): Not required for the representative use	See above
Photolytic degradation	Not relevant	See above
Quantum yield of direct phototransformation in water > 290 nm	Not relevant	See above
Photochemical oxidative degradation in air (calculation according to Atkinson)	Not applicable PH ₃ (gas, vapour pressure 34600 hPa, 20 °C): DT ₅₀ of 24 hours. OH (24 h) concentration assumed = 5 x 10 ⁵ OH/cm ³ (rate constant 1.6 x 10 ⁻¹¹ cm ³ /mol sec)	See above

5.3.1.3 *Metabolites of zinc phosphide*

Environmental occurring metabolites of zinc phosphide requiring further assessment according to the results of the assessment of zinc phosphide for EU approval are summarized in Table 5.3-3.

No new study on the fate and behaviour of zinc phosphide or Detia Mäuse Giftkörner has been performed. Hence no potentially new metabolites need to be considered.

The risk assessment for these metabolites has already been performed for EU approval (see SANCO/12548/2010 – final, 28 October 2010). Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.

Potential ground water contamination by the soil metabolites phosphide was evaluated for EU approval of zinc phosphide. PEC_{gw} modelled with FOCUS PELMO (version 3.3.2) was less than 0,1 µg/L for the metabolites in all of 9 scenarios based on an application of 60 g as/ha.

However, in the indented uses of Detia Mäuse Giftkörner in all crops the application rate of zinc phosphid is higher, so that the leaching potential of the soil metabolites phosphide doesn't needs to be assessed.

Table 5.3-3: Metabolites of zinc phosphide potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolite	Structural formula/Molecular formula	occurrence in compartments	Status of Relevance (SANCO/12548/ 2010 – final, 28 October 2010) and LOEP April 2010 (EFSA-Conclusion)

Phosphine	PH ₃	* Recent, "state-of-the-art" investigations according to current guidelines for the elucidation of the degradation pathway of zinc phosphide in soil do not exist. Zinc phosphide is an inorganic molecule, and therefore evolution of carbon dioxide is not possible, but ultimate transformation to inorganic salts occurs. Hydrolysis leading to the evolution of phosphine and residual salts will prevail when soil matrix is present to mediate the reaction. The former is expected to either partition to the atmosphere due to its volatility, or become re-adsorbed onto soil. In both cases, oxidative processes are effective in finally transforming phosphine to phosphate anions.	Soil: relevant Water: not relevant Sediment: not relevant Groundwater: not relevant (Step 2/Step 3-4) ¹⁾
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¹⁾ According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

5.4 Summary on input parameter for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Zinc phosphide

No new studies have been submitted regarding route and rate of degradation in soil of zinc phosphide. The environmental exposure assessment is based on the EU agreed DT₅₀ values from the laboratory as summarized in Table 5.4-1 (see Assessment Report, Part B 8, Okt. 2009).

Table 5.4-1: Summary of aerobic degradation rates for zinc phosphide - laboratory studies

Compound	Parameter	Endpoint	Kinetic	Used for the evaluation of
Zinc phosphide	DT _{50lab} [days] (extrapolated to 20 °C*)	14.1 maximum (n = 3)	SFO	PECsoil
Phosphine	DT _{50lab} [days] (at 20 °C)	13.6 maximum (n = 3)	SFO	PECsoil

* extrapolated using the Arrhenius equation and considering a Q₁₀ of 2.2

5.4.1.2 *Field studies*

Zinc phosphide

No field soil dissipation studies are triggered for parent zinc phosphide and the major metabolite phosphine ($DT_{50lab} < 60$ days).

5.4.2 **Adsorption/desorption**

Zinc phosphide

No new studies have been submitted regarding adsorption/desorption in soil of zinc phosphide.

The following is stated in the EFSA Journal (2010) 8(7):1671, zinc phosphide, on soil adsorption/desorption:

“The performance of ”state-of-the-art” adsorption/desorption experiments with zinc phosphide is not considered to be required for the following reasons: The preparation of a solution in water for the subsequent adsorption/desorption experiments is not possible. As a result, this renders the performance of such studies as technically and scientifically unfeasible.”

However, in order to establish K_{OC} values for zinc phosphide and the metabolite phosphine as input figures for the prediction of environmental concentrations in groundwater (PEC_{gw}) the following empirical estimation methods were applied for zinc phosphide (1) and phosphine (2) based on its water solubility:

$$(1) \quad \text{Log } K_{oc} = -0.55 \log S + 3.64 \quad [\text{mg/L}] \quad [\text{Kenaga, E.E. \& Goring, C.A.I. (1978)}]$$

$$(2) \quad \text{Log } K_{oc} = -0.557 \log S + 4.277 \quad [\mu\text{mol/L}] \quad [\text{Chiou, C.T.; et al. (1979)}]$$

The choice of these regression equations yielded K_{OC} values of 162.043 mL/g for the parent compound (1) and 103 mL/g for the metabolite (2), which were the lowest estimable K_{OC} values in a range of other estimation methods.

5.4.3 **Rate of degradation in water and sediment**

Zinc phosphide

Justification for non-submission: No data on the behaviour of zinc phosphide in water/sediment systems are considered to be required due to its inaccessibility to surface waters in view of the specific conditions of use of the rodenticide baits.

5.5 **Estimation of concentrations in soil (PEC_{soil}) (KIIIA1 9.4)**

PEC_{soil} of zinc phosphide and phosphine have been calculated according to the risk envelope approach, considering a worst case application pattern of all proposed GAP uses as presented in **Fehler!**

Verweisquelle konnte nicht gefunden werden. and covering all other intended uses. The maximum rate of application is 2 kg product/ha and treatment, i.e. 50 g zinc phosphide/ha and treatment. The respective product is laid out directly into the passages of the voles (worst-case) or in bait stations.

Based on a hypothetical assumption of a total and immediate transfer of the entire zinc phosphide content of the ready-to-use bait to the soil surface layer and a homogeneous distribution of the compound in the upper 5 cm soil layer, calculations were conducted for a single application and the highest rate of application, for which authorisation is sought, considered to represent a very conservative worst-case

exposure scenario. PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters as presented below.

Table 5.5-1: Input parameters related to application for PEC_{soil} calculations

Plant protection product	Detia Mäuse Giftkörner
Use No.:	00-01 to 00-020
Crop:	All crops
Application rate:	150 g ai/ha (3 per crop = 50g/ha and 3 per season)
Number of application/interval:	1
Crop interception:	Not relevant

Table 5.5-2: Input parameter for active substance for PEC_{soil} calculation

Active substance	DT ₅₀	value in accordance to EU endpoint
Zinc phosphide	14 d (SFO, Maximum, laboratory study, see Table 5.5-3)	Yes
Phosphine	13.6 d	

Beside PEC_{act} values also PEC_{twa} , 21 d values are required for risk assessment. $PEC_{twa,21 d}$ values are also presented in Table 5.5-4

Table 5.5-4: Results of PEC_{soil} calculation for application of Detia Mäuse Giftkörner in all crops (soil bulk density 1.5 g/cm³, soil depth 5 cm)

active substance/ preparation	soil relevant application rate (g/ha)	PEC_{act} (mg/kg)	$PEC_{twa 21 d}$ (mg/kg)	tillage depth (cm)	PEC_{bkgd} (mg/kg)	$PEC_{accu} =$ $PEC_{act} +$ PEC_{bkgd} (mg/kg)
Zinc phosphide	150	0.2	0.1244	5	-	-
		1.0	0.62	1	-	-
Detia Mäuse Giftkörner	6000	8.00	4.975	5	-	-
		40	24.9	1	-	-

5.6 Estimation of concentrations in surface water and sediment (PEC_{sw}/PEC_{sed}) (KIIIA1 9.7)

Justification for non-submission

The calculation of predicted environmental concentrations in surface waters (PEC_{sw}) and consequently in sediments for zinc phosphide and the metabolite phosphine following the GAP uses of Detia Mäuse Giftkörner is not considered to be required, since the uses of the rodenticide bait merely involve laying out of ready-to-use zinc phosphide-dressed voles' holes or voles' passages or onto soil surfaces in bait stations. Thus, any contamination of the compartment surface water by routes of exposure, such as run-off

and drainage is not to be expected. Spray drift and overspray are not applicable routes of exposure and outflow is only relevant for paddy rice cultivation. In addition, atmospheric deposition is not relevant with regard to the low vapour pressure of zinc phosphide.

5.7 Risk assessment ground water (KIIIA1 9.6)

5.7.1 Predicted environmental concentration in groundwater (PEC_{GW}) calculation for active substance and its metabolites (Tier 1 and 2)

Justification for non-submission: According to the EFSA Journal (2010) 8(7):1671, zinc phosphide, the calculation of predicted environmental concentrations of zinc phosphide in groundwater is not considered to be required. The risk of contamination of groundwater to any relevant degree is negligible for the following reasons:

(i) PEC calculations for zinc phosphide in soil (chapter 5.5 above) following the GAP uses of Detia Mäuse Giftkörner have shown that only quantitatively insignificant amounts of the active substance will reach the soil, even on a hypothetical worst-case basis as described for the intended GAP uses as bait sticks with foil enclosure in voles' holes or bait stations (i.e., $PEC_{initial}(5\text{ cm}) = 0.2\text{ mg/kg soil}$).

(ii) Zinc phosphide is of extremely low water solubility ($< 1.4\text{ }\mu\text{g/L}$ at $20\text{ }^{\circ}\text{C}$) and correspondingly will be of poor mobility in soil.

(iii) Zinc phosphide is degraded rapidly in moist soils, leading to the formation of zinc and phosphine as an intermediate, which in turn is either volatilised, or following re-absorption, is subsequently rapidly degraded to phosphate ions.

Furthermore, it can reasonably be assumed that under practical conditions of use approx. 90 % of the bait should be consumed by the target pests within a short period after application.

Thus, the potential for groundwater exposure of zinc phosphide from the GAP uses of Detia Mäuse Giftköder envisaged is considered negligible (due to its formulation as a bait), and its transformation products do not have parametric drinking water limits set in the relevant EU legislation.

Overall, it can be concluded that the GAP uses of Detia Mäuse Giftkörner do not pose an unacceptable risk to groundwater.

5.7.2 Higher tier leaching assessment (Tier 3)

Not required.

5.7.3 Summary of risk assessment for ground water

It can be concluded that the GAP uses of Detia Mäuse Giftkörner do not pose an unacceptable risk to groundwater.

5.8 Potential of active substance for aerial transport

The vapour pressure at $20\text{ }^{\circ}\text{C}$ of the active substance zinc phosphide is $\ll 10^{-5}\text{ Pa}$. Hence the active substance zinc phosphide is regarded as non-volatile.

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed	Owner	How considered in dRR Study-Status/Usage*
none						

*

- 1) accepted (study valid and considered for evaluation)
- 2) not accepted (study not valid and not considered for evaluation)
- 3) not considered (study not relevant for evaluation)
- 4) not submitted but necessary (study not submitted by applicant but necessary for evaluation)
- 5) supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 2 Detailed evaluation of studies relied upon

None studies are evaluated.

Appendix 3 Table of Intended Uses justification and GAP tables

The table below includes all individual GAP uses envisaged for the registration of Detia Mäuse Giftkörner in the Central Zone.

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application		Max. number (min. interval between applications) a) per use b) per crop/ season	Application rate		PHI (days)	Remarks:	
					Method / Kind	Timing / Growth stage of crop & season		kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season			Water L/ha min / max
1	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Agricultural crops	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
2	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Agricultural crops	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g / bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
3	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vegetable crops	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.

1 Use- No.	2 Member state(s)	3 Crop and/ or situation (crop destination / purpose of crop)	4 F G or I	5 Pests or Group of pests controlled	6 Method / Kind	7 Application		8 Max. number (min. interval between applications) a) per use b) per crop/ season	10 kg. L product / ha a) max. rate per appl. b) max. total rate per crop/season	11 Application rate		12 Water L/ha min / max	13 PHI (days)	14 Remarks:
						Timing / Growth stage of crop & season	Max. interval between applications)			g. kg.as/ha a) max. rate per appl. b) max. total rate per crop/season	g. kg.as/ha a) max. rate per appl. b) max. total rate per crop/season			
4	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vegetable crops	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded. Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.		
5	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Fruit crops	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.		
6	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Fruit crops	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.		

1 Use- No.	2 Member state(s)	3 Crop and/ or situation (crop destination / purpose of crop)	4 F G or I	5 Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	6 Method / Kind	7 Application		8 Max. number (min. interval between applications) a) per use b) per crop/ season	10 kg. L product / ha a) max. rate per appl. b) max. total rate per crop/season	11 Application rate		12 Water L/ha min / max	13 PHI (days)	14 Remarks:
						Timing / Growth stage of crop & season	kg. L product / ha a) max. rate per appl. b) max. total rate per crop/season			g. kg.as/ha a) max. rate per appl. b) max. total rate per crop/season				
7	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vinicultural crops	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded. Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.		
8	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vinicultural crops	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.		
9	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Grassland, lawns and meadows	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.		

1	2	3	4	5	6	7		8	10	11		12	13	14
						Application				Application rate				
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg. L product / ha a) max. rate per appl. b) max. total rate per crop/season	g. kg.as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max				
10	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Grassland, lawns and meadows	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded. Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.		
11	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Ornamental crops	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.		
12	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Ornamental crops	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.		

1	2	3	4	5	6	7		8	10	11		12	13	14
						Application				Application rate				
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled	Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg. L product / ha a) max. rate per appl. b) max. total rate per crop/season	g. kg.as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	PHI (days)	Remarks:		
13	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Coniferous and deciduous trees	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.		
14	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Coniferous and deciduous trees	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.		
15	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vegetable crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.		

1	2	3	4	5	6	7		8	10	11		12	13	14
						Application	Application rate			PHI (days)	Remarks:			
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg. L product / ha a) max. rate per appl. b) max. total rate per crop/season	g. kg.as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	PHI (days)	Remarks:		
16	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vegetable crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.		
17	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Fruit crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.		
18	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Fruit crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.		

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Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application		Max. number (min. interval between applications) a) per use b) per crop/ season	kg. L product / ha a) max. rate per appl. b) max. total rate per crop/season	Application rate		PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season			g. kg.as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
19	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Ornamental crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
20	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Ornamental crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.

**REGISTRATION REPORT
Part B**

**Section 5 Environmental Fate
Detailed summary of the risk assessment**

**Product code: Detia Mäuse Giftkörner
Active Substance(s): Zinc phosphide 25 g/kg**

**Central Zone
Zonal Rapporteur Member State: Germany**

NATIONAL ADDENDUM – Germany

**Applicant: Detia Freyberg GmbH
Date: January 2014, updated April
2018**

Table of Contents

TABLE OF CONTENTS	2
SEC 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)	3
5.1 GENERAL INFORMATION ON THE FORMULATION	3
5.2 PROPOSED USE PATTERN	3
5.3 INFORMATION ON THE ACTIVE SUBSTANCES.....	4
5.3.1 Zinc phosphide	4
5.4 SUMMARY ON INPUT PARAMETERS FOR ENVIRONMENTAL EXPOSURE ASSESSMENT	4
5.4.1 Rate of degradation in soil.....	4
5.4.2 Adsorption/desorption	4
5.4.3 Rate of degradation in water/sediment	4
5.5 ESTIMATION OF CONCENTRATIONS IN SOIL (KIIIA1 9.4).....	4
5.6 ESTIMATION OF CONCENTRATIONS IN SURFACE WATER AND SEDIMENT (KIIIA1 9.7).....	5
5.7 RISK ASSESSMENT FOR GROUNDWATER (KIIIA1 9.6).....	5
APPENDIX 1 LIST OF DATA SUBMITTED IN SUPPORT OF THE EVALUATION	7
APPENDIX 2 DETAILED EVALUATION OF STUDIES RELIED UPON	8
APPENDIX 3 TABLE OF INTENDED USES IN GERMANY (ACCORDING TO BVL 15.08.2013)	9

Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

The exposure assessment of the plant protection product Detia Mäuse Giftkörner in its intended uses in agriculture, orchard, vegetables, ornamentals, grassland, forestry and vineyards is documented in detail in the core assessment of the plant protection product Detia Mäuse Giftkörner dated from January 2014 performed by zRMS Germany.

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for authorization of the plant protection product Detia Mäuse Giftkörner in Germany according to uses listed in Appendix 3.

A risk assessment for PEC_{gw} and PEC_{sw} is not considered to be required. Justification for non-submission see core assessment, Part B, section 5, chapter 5.6 and 5.7.

PEC_{soil} is used for risk assessment to derive specific risk mitigation measures if necessary (see core assessment and National Addendum, part B, section 6 and part A).

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation Detia Mäuse Giftkörner

Code	007851-00/00		
plant protection product	Detia Mäuse Giftkörner		
applicant	Detia Freyberg GmbH		
date of application	2013		
Formulation type (WP, EC, SC, ...; density)	Ready for use-bait		
active substances (as)	Zinc phosphide		
Concentration of as	25 g/kg		
Data pool/task force			
letter of access/cross reference			
existing authorisations in DE	yes		

5.2 Proposed use pattern

The intended uses in Germany classified according the soil effective application rate (cumulative, disregarding degradation in soil) is presented in Table 5.2-1. Full details of the proposed uses that will be assessed is included in Appendix 3.

Table 5.2-1: Classification of intended uses in Germany for Detia Mäuse Giftkörner

Group/ use No*	Crop/growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
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A/ 00-001 to 00-024	agriculture Orchard VegetablesOrna mentals Grassland Forestry grape vine / all stages	placing of baits in vole hole or placing of baits in bait stations	3 x 3 Appl. per season	Zinc phosphide Max. 3 x 50	Zinc phosphide Max. 150
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* For administrative purposes, each intended use of a plant protection product in Germany is assigned with an individual use number from the German Federal Office of Consumer Protection and Food Safety (BVL). A complete list of the individual GAPs in Germany together with their assigned use numbers is given in Appendix 3 of this Addendum.

5.3 Information on the active substances

5.3.1 Zinc phosphide

Please refer to the core assessment (January 2014), part B, section 5, point 5.3.1.

5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

Zinc phosphide

Please refer to the core assessment (January 2014), part B, section 5, point 5.4.1.

5.4.2 Adsorption/desorption

Zinc phosphide

Please refer to the core assessment (January 2014), part B, section 5, point 5.4.2.

5.4.3 Rate of degradation in water/sediment

Zinc phosphide

Please refer to the core assessment (January 2014), part B, section 5, point 5.4.3.

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Results of PECsoil calculation for Detia Mäuse Giftkörner according to EU assessment considering 5 cm soil depth are given in the core assessment January 2014, part B, section 5, chapter 5.5.

5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

Justification for non-submission of PEC_{sw} calculation of zinc phosphide for the intended for uses of Detia Mäuse Giftkörner in all crops using are given in the core assessment (January 2014), part B, section 5, chapter 5.6.

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Justification for non-submission of PEC_{gw} calculation of zinc phosphide for the intended uses of Detia Mäuse Giftkörner in all crops are given in the core assessment (January 2014), part B, section 5, chapter 5.7.

Consequences for authorization:

None

Appendix 1 List of data submitted in support of the evaluation

No additional data for national assessment submitted.

Appendix 2 Detailed evaluation of studies relied upon

No additional data for national assessment submitted.

Appendix 3 Table of Intended Uses in Germany (according to BVL 15.08.2013)

PPP (product name/code) active substance 1 Detia Mäuse Giftkörner Zinkphosphid
Formulation type: BB
Conc. of as 1: 25 g/kg

Applicant: frumol delicia GmbH professional use x
Zone(s): central non professional use x

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method/ Kind	Application		Application rate		PHI (days)	Remarks:	
						Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg. L product / ha a) max. rate per appl. b) max. total rate per crop/season	g. kg as/ha a) max. rate per appl. b) max. total rate per crop/season			Water L/ha min / max
001	DE	Field crops (NNNAC)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha		5 piece(s) per hole (hide)	
002	DE	Forest plants (NINWW)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha		5 piece(s) per hole (hide)	

003	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha		5 piece(s) per hole (hide)
004	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha		5 piece(s) per hole (hide) Amateur gardening
005	DE	Grassland, Pasture, Meadow (NNNFW)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha		5 piece(s) per hole (hide)
006	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha		5 piece(s) per hole (hide)
007	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha		5 piece(s) per hole (hide) Amateur gardening
008	DE	Grape vine (VITVI)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha		5 piece(s) per hole (hide)
009	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha		5 piece(s) per hole (hide) Amateur gardening
010	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha		5 piece(s) per hole (hide)
011	DE	Field crops (NNNAC)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha		50 g per bait station (hide)

012	DE	Forest plants (NNNWW)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	50 g per bait station (hide)
013	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	50 g per bait station (hide)
014	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	50 g per bait station (hide) Amateur gardening
015	DE	Grassland, Pasture, Meadow (NNNFW)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	50 g per bait station (hide)
016	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	50 g per bait station (hide)
017	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	50 g per bait station (hide) Amateur gardening
018	DE	Grape vine (VITVI)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	50 g per bait station (hide)
019	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	50 g per bait station (hide) Amateur gardening
020	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha	50 g per bait station (hide)

General remarks/explanations:

The GAP-Sheet should indicate if the displayed information was provided by the applicant OR was revised by the zRMS (due to the product label and Annex III data). The zRMS has to verify the presented information and to ask (the applicant) for clarification of missing details (e.g. BBCH stages, EC-codes of crops). All abbreviations in the GAP-Sheet used must be explained. Use separate worksheet for each product. Make use of existing standards like EPPO and BBCH.

Product: Please indicate the specific variant of the active substance if relevant. If additional components have to be added to the applied product (tankmixtures), all relevant information must be provided in the column remarks. As the product usually will be determined either for professional or non professional use, this information should be given here. Otherwise to be indicated in column 4 of the GAP-sheet (conditions/location of use).

Formulation:

Type: e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

Refer to:

- GCPF Codes - GIFAP Technical Monograph No 2, (1989), 6th Edition – Revised May 2008 – Catalogue of pesticide formulation types and international coding system.
- Technical Monograph n°2, 6th Edition - Revised May 2008 - Catalogue of pesticide formulation types and international coding system (CropLife International) ¹⁾.

Conc. of as: g/kg or g/L

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Safener/Synergist: Since safeners and synergists are in scope of REG 1107/2009, information about safeners/synergists should be included in the GAP table as well.

Zone(s): All relevant zone(s) should be indicated. For interzonal uses (e.g. greenhouse, seed treatment, etc.) "EU" should be chosen.

Explanations to the particular columns:

No.: Numeration would be important when references are necessary e.g. to the dossier or to the authorisation certificate.

Member state(s): For a better general view of the valid uses for the particular zones/MS it would be helpful to mention both (the zone as well as the MS) in the column. However, to keep the table clearly arranged it seems dispensable to cite the zone; each MS is distinctly allocated to one zone; moreover the zone(s) are cited in the head of the table. Desirably MS are put in order according to the zone they belong.

Crop and/or situation: The common name(s) of the crop and the EC (EPPO)-Codes or at least the scientific name(s) [EU and Codex classifications (both)] should be used, where relevant, the situation should be described (e.g. fumigation of a structure). In case of crop groups all single crops belonging to that group should be mentioned, (either in the respective table element or – in case of a very extensive crop group - at least in a footnote).

If it is not possible to mention all single crops belonging to a crop group (e.g. for horticulture), it should be referred to appropriate crop lists (e.g. EPPO, residue (codex). It would be desirable to have a "joint list" of crop groups for the zones. Exceptions of specific crops/products/objects or groups of these and restrictions to certain uses (e.g. only for seed production, fodder) must be indicated. This column should also include when indicated information concerning "crop destination or purpose of crop" and which part of plants will be used / processed (e.g. for medicinal crops roots or leaves or seeds).

Conditions / location of use: Outdoor or field use (F), glasshouse application (G) or indoor application (I) "Glasshouse" indicates that the respective trials are acceptable for all zones. As results achieved in compartments without controlled conditions (temperature, light exposure), e.g. simple plastic tunnels [for those GAPs field trials have to be conducted in the respective zone the use is applied for], are not considered to be applicable for use in other zones the kind of glasshouse should be clearly indicated. [Remark: Greenhouse definitions are at the moment under evaluation]. Conditions include also information concerning the substrate (natural soil, artificial substrate).

Pests or Group of pests controlled: Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. If necessary – in case of pest groups - exceptions (e.g. sucking insects excluding scale insects) should be indicated. In some cases, the set of pests concerned for a given crop may vary in different parts of the EU region (where appropriate the pests should be specified individually). If the product is used as growth regulator the target organism is the specific crop, whose development should be influenced; the aim could also be e.g. an empty room for treatment.

Application details:

Method / Kind:

Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, drilling, high precision drilling (with or without pneumatic systems).

Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used (e.g. ultra low volume equipment (ULVA) or low volume equipment (LVA)) should be indicated if relevant.

Timing of Application / Growth stage of crop & season:

Time(s), period, first and last treatment, e.g. autumn or spring pre- or post-emergence, at sufficient pest density or begin of infection, including restrictions (e.g. not during flowering). Growth stage of crop (BBCH-code) – period, first and last treatment. Since the BBCH-codes are accomplished in the individual member states at different time periods the month(s) of application should be indicated in addition. BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
It seems sensible to constrain specifications in this column only to the crop, - information concerning the pest should be dealt in column “pest or group of Pests controlled”. In certain circumstances it might be helpful to give information about the expected rate of interception related to the BBCH codes. In many minor crops no BBCH/interception rate scenarios have been specified so far. This could also simplify grouping for the envelope approach.

Number of applications and interval between applications

- a) Maximum number of applications per growing season used for the named crop/pest combination possible under practical conditions of use.
- b) The proposed maximum number in the crop including applications on all pests/targets on the same crop in a growing season should be given. It should be clearly indicated whether the displayed number of applications is per season, per crop cycle or per pest generation.

Minimum interval (in days) between applications of the same product. The figure for the interval between the applications is to be set in brackets.

Application rate:

Application rate of the product per ha:

- a) (Maximum) product rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m² in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
- b) Maximum product rate per growing season (especially if limited) or per crop cycle should be cited.

Especially in three dimensional crops other dose expressions (kg/l per 10,000 m² leaf wall area or kg/l per ha per meter crown (canopy) height) should be given additionally.

For seed treatment also the load of product (l/g, kg) per kg, 100 kg or unit treated seed should be stated beside the application rate per hectare. The number of seeds per (seed) unit is to be given. The maximum seed drilling rate (=number of seed sown/maximum seed volume) per row and ha should be indicated.

Information concerning the sowing method (precision drilling, ...) would be advantageous.

See also Eppo-Guideline PP 1/239 Dose expression for plant protection products (please note, additional Eppo-guidelines may be developed).

Application rate of the active substance per ha:

- a) (Maximum) as rate per treatment (usually kg active substance / ha). For specific uses other specifications might be possible, e.g.: g/m² in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
- b) Maximum as rate per growing season (especially if limited) or per crop cycle should be cited.

The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg active substance / ha).

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Water L/ha:

It should be clearly indicated if a stated water volume range depends upon the developmental stage of the crop (low volume – early crops stage, high volume – late crop stage) which causes a consistent concentration of the spray solution, or if a water volume range indicates different spray solution concentrations. In the last mentioned case extremely low water volumes (indicating high concentrated spray solutions) need to be covered within selectivity trials. If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.

PHI (days) – minimum pre harvest interval: PHI - minimum pre-harvest interval For some crop situations a specific PHI may not be relevant. If so an explanation (e.g. the PHI is covered by the time remaining between application and harvest.) should be given in the remarks column (e.g. crop harvest at maturity or specific growth stages).

Remarks: Remarks may include: amount of safener/synergist per ha or extent of use/economic importance/restrictions, e.g. limiting the number of uses per crop and season, if several target pests/diseases are controlled with the same product. If additional components (other ppp or adjuvant) should be used with the applied product (tankmixtures), all relevant information must be provided in the column remarks. In addition, it should be mentioned as well those mixtures are recommended or mandatory.

**REGISTRATION REPORT
Part B**

**Section 6: Ecotoxicological studies
Detailed summary of the risk assessment**

Product code: Detia Mäuse Giftkörner
Active Substance: Zinc phosphide, 25 g/kg

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Detia Freyberg GmbH
Date: January 2015, updated April 2018

Table of Contents

SEC 6	ECOTOXICOLOGICAL STUDIES (MIIIA 10).....	5
6.1	GAP AND OVERALL CONCLUSIONS	6
6.1.1	Table of intended uses.....	6
6.1.2	Grouping of intended uses for risk assessment	10
6.1.3	Consideration of metabolites.....	10
6.2	EFFECTS ON BIRDS (MIIIA 10.1, KPC 10.1, KPC 10.1.1).....	11
6.2.1	Justification for new endpoints	12
6.2.2	Risk assessment (MIIIA 10.1.3, MIIIA 10.1.4, MIIIA 10.1.5) for baits, pellets, granules, prills or treated seeds.....	12
6.2.3	Biomagnification in terrestrial food chains.....	14
6.2.4	Overall conclusions.....	14
6.3	EFFECTS ON TERRESTRIAL VERTEBRATES OTHER THAN BIRDS (MIIIA 10.3, KPC 10.1, KPC 10.1.2).....	15
6.3.1	Justification for new endpoints	16
6.3.2	Risk assessment (MIIIA 10.3.1) for baits, pellets, granules, prills or treated seeds.....	16
6.3.3	Biomagnification in terrestrial food chains.....	18
6.3.4	Overall conclusions.....	18
6.4	EFFECTS ON OTHER TERRESTRIAL VERTEBRATE WILDLIFE (REPTILES AND AMPHIBIANS) (KPC 10.1.3).....	19
6.5	EFFECTS ON AQUATIC ORGANISMS (MIIIA 10.2, KPC 10.2, KPC 10.2.1).....	20
6.5.1	Justification for new endpoints	20
6.5.2	Toxicity to exposure ratios for aquatic species (MIIIA 10.2.1).....	20
6.5.3	Overall conclusions.....	21
6.6	EFFECTS ON BEES (MIIIA 10.4, KPC 10.3.1).....	21
6.7	EFFECTS ON ARTHROPODS OTHER THAN BEES (MIIIA 10.5, KPC 10.3.2)	22
6.7.1	Risk assessment.....	22
6.7.2	Overall conclusions.....	22
6.8	EFFECTS ON NON-TARGET SOIL MESO- AND MACROFAUNA (MIIIA 10.6, KPC 10.4, KPC 10.4.1, KPC 10.4.2).....	22
6.8.1	Justification for new endpoints	22
6.8.2	Toxicity exposure ratios for earthworms and other soil macro- and mesofauna, TER _A and TER _{LT} (MIIIA 10.6.1).....	23
6.8.3	Higher tier risk assessment.....	23
6.8.4	Overall conclusions.....	23
6.9	EFFECTS ON SOIL MICROBIAL ACTIVITY (MIIIA 10.7, KPC 10.5).....	24
6.9.1	Justification for new endpoints	24
6.9.2	Risk assessment.....	24
6.9.3	Overall conclusions.....	25
6.10	EFFECTS ON NON-TARGET PLANTS (MIIIA 10.8, KPC 10.6).....	25
6.10.1	Effects on non-target terrestrial plants (MIIIA 10.8.1).....	25
6.10.2	Justification for new endpoints	25
6.11	EFFECTS ON OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA) (KPC 10.7).....	26
6.12	MONITORING DATA (KPC 10.8)	26
6.13	AVAILABLE PRELIMINARY DATA (IIIA 10.9).....	26
6.14	OTHER/SPECIAL STUDIES (IIIA 10.10).....	26
APPENDIX 1	LIST OF DATA SUBMITTED IN SUPPORT OF THE EVALUATION	27
APPENDIX 2	DETAILED EVALUATION OF THE NEW STUDIES.....	29
APPENDIX 3	TABLE OF INTENDED USES IN THE CENTRAL ZONE (GAP TABLE).....	32

Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

This document reviews the ecotoxicological studies for the product Detia Mäuse Giftkörner containing the active substance zinc phosphide, which is currently approved under Reg. (EC) No 1107/2009 (repealing Directive 91/414/EEC) and fulfils the criteria according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2.

Detia Mäuse Giftkörner was not the representative formulation considered in the EU review process as part of the approval of the zinc phosphide.

The studies with the relevant endpoints for each non-target organism group were agreed during EU review process and are used for the risk assessment. Reference is made to the following documents, if not otherwise labelled with an asterisk:

EFSA Journal (2010) 8(7):1671 (Conclusion on the peer review of zinc phosphide)

Full details of toxicity studies are provided in the respective EU DAR and AR for zinc phosphide and final addenda (November 2009 and April 2010) and the EC Review Report for zinc phosphide (SANCO/12548/2010 final, 28 October 2010). The applicant did not provide further studies with the formulation Detia Mäuse Giftkörner and for the active substance zinc phosphide or its major metabolite phosphine.

6.1 GAP and overall conclusions

6.1.1 Table of intended uses

Table 6.1-1: GAP and overall conclusions

Intended use	F/G	Timing (months, BBCH)	Max number appl. (interval in days)	Application per treatment		Overall conclusions										
				kg a.s./ha max	Rate/season [kg a.s./ha] max	Birds	Aquatic organisms	Mammals	Bees	Non-target arthropods	Soil organisms	Non-target plants				
1, agricultural crops	F	all stages	n.a.#	0.05	0.15	X1			X1							
2, agricultural crops	F	all stages	n.a.#	0.05	0.15	X1			X1							
3, vegetable crops	F	all stages	n.a.#	0.05	0.15	X1			X1							
4, vegetable crops	F	all stages	n.a.#	0.05	0.15	X1			X1							
5, Fruit crops	F	all stages	n.a.#	0.05	0.15	X1			X1							
6, Fruit crops	F	all stages	n.a.#	0.05	0.15	X1			X1							
7, Vinicultural crops	F	all stages	n.a.#	0.05	0.15	X1			X1							
8, Vinicultural crops	F	all stages	n.a.#	0.05	0.15	X1			X1							

Intended use	F/G	Timing (months, BBCH)	Max number appl. (interval in days)	Application per treatment		Overall conclusions									
				kg a.s./ha max	Rate/season [kg a.s./ha] max	Birds	Aquatic organisms	Mammals	Bees	Non-target arthropods	Soil organisms	Non-target plants			
9, Grassland, lawns and meadows	F	all stages	n.a.#	0.05	0.15	X1		X1							
10, Grassland, lawns and meadows	F	all stages	n.a.#	0.05	0.15	X1		X1							
11, Ornamental crops	F	all stages	n.a.#	0.05	0.15	X1		X1							
12, Ornamental crops	F	all stages	n.a.#	0.05	0.15	X1		X1							
13, Coniferous and deciduous trees	F	all stages	n.a.#	0.05	0.15	X1		X1							
14, Coniferous and deciduous trees	F	all stages	n.a.#	0.05	0.15	X1		X1							
15, Vegetable crops (home and garden use)	F	all stages	n.a.#	0.05	0.15	X1		X1							

Intended use	F/G	Timing (months, BBCH)	Max number appl. (interval in days)	Application per treatment		Overall conclusions									
				kg a.s./ha max	Rate/season [kg a.s./ha] max	Birds	Aquatic organisms	Mammals	Bees	Non-target arthropods	Soil organisms	Non-target plants			
16, Vegetable crops (home and garden use)	F	all stages	n.a.#	0.05	0.15	X1		X1							
17, Fruit crops (home and garden use)	F	all stages	n.a.#	0.05	0.15	X1		X1							
18, Fruit crops (home and garden use)	F	all stages	n.a.#	0.05	0.15	X1		X1							
19, Ornamental crops (home and garden use)	F	all stages	n.a.#	0.05	0.15	X1		X1							
20, Ornamental crops (home and garden use)	F	all stages	n.a.#	0.05	0.15	X1		X1							

F: Field use; G: Glasshouse use



Safe use identified

Remarks: Further refinement and/or risk mitigation measures are needed

No safe use identified and considered possible

Explanations:

The colours in the Table 6-1 are intended to reflect the outcome of the assessments including the available and valid refinement steps and risk mitigations measures.

Remarks “X1”: Acceptable risk for birds and mammals can only be approved when risk mitigation is considered. Favorable risk mitigation would be application with suitable bait stations (here quality criteria have to be set) or securing the hidden application deep in the vole hole by using suitable application technique (e.g. application gun). Additionally, member states may consider a separate risk assessment for non-professional use. For German evaluation of these intended uses please refer to the National Addendum..

6.1.2 Grouping of intended uses for risk assessment

The following table lists the grouping of the intended uses in order to perform a risk envelope approach. Intended uses may be grouped according to soil relevant application rate, drift rate and with respect to the exposure of non-target organisms (i.e. maximum daily dose for birds and mammals). The soil relevant application rate is based on the effective cumulative application rate including interception. Grouping according to drift scenarios is not applicable in this case. With respect to the exposure of non-target organisms (i.e. birds and mammals) the conditions of use (i.e. outdoor / field use, glasshouse application) and method/kind of application in combination with the remarks are considered for grouping.

Table 6.1-2: Critical use pattern of Detia Mäuse Giftkörner

Risk envelope approach for exposure assessment according to Section 5			
Group / use no.	Crop/growth stage/interception	Application method	Application rate, cumulative (g a.s./ha)
A (covers all intended uses in all use areas in the central zone)	Agriculture, Orchard, Vegetables, Ornamentals, Grassland, Forestry, grape vine / all stages	placing of baits in vole hole or placing of baits in bait stations	3 x 3 appl. per season , zinc phosphide max. 3 x 50, Soil effective application rate: Zinc phosphide max. 150
Grouping for overall environmental risk assessment (based on conditions of use, method/kind, crop/situation as stated above)			
Group	Crop/growth stage/interception	Application method/drift scenario	Application rate, cumulative (g a.s./ha)
A 1 / 1, 3, 5, 7, 9, 11, 13	Outdoor use in: Agricultural crops; vegetable crops; fruit crops; vinicultural crops; grassland, lawns and meadows; ornamental crops; coniferous and deciduous trees / not defined	in vole holes, 5 grains/hole	Zinc phosphide Max. 3 x 50 (subdivision into 3 x 3 x 16.6 possible)
A 2 / 2, 4, 6, 8, 10, 12, 14	Outdoor use in: Agricultural crops; vegetable crops; fruit crops; vinicultural crops; grassland, lawns and meadows; ornamental crops; coniferous and deciduous trees / not defined	in bait stations, 20 – 50 g/bait station	Zinc phosphide Max. 3 x 50 (subdivision into 3 x 3 x 16.6 possible)
A 3 / 15, 17, 19	Home and garden use (non-professional): Vegetable crops; fruit crops; ornamental crops / not defined	in vole holes, 5 grains/hole	Zinc phosphide Max. 3 x 50 (subdivision into 3 x 3 x 16.6 possible)
A 4 / 16, 18, 20	Home and garden use (non-professional): Vegetable crops; fruit crops; ornamental crops / not defined	in bait stations, 20 – 50 g/bait station	Zinc phosphide Max. 3 x 50 (subdivision into 3 x 3 x 16.6 possible)

6.1.3 Consideration of metabolites

The metabolites which require an ecotoxicological assessment according to the endpoint list are given below.

Table 6.1-3: Metabolites of zinc phosphide potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of a.s. and maximum of formation not yet reached at the end of the study)

Metabolite	Structural formula/Molecular formula	occurrence in compartments (Max. at day/	Status of Relevance (SANCO/12548/ 2010 – final, 28 October 2010) and LOEP April 2010 (EFSA-Conclusion)
Phosphine	PH ₃	* Recent, "state-of-the-art" investigations according to current guidelines for the elucidation of the degradation pathway of zinc phosphide in soil do not exist. Zinc phosphide is an inorganic molecule, and therefore evolution of carbon dioxide is not possible, but ultimate transformation to inorganic salts occurs. Hydrolysis leading to the evolution of phosphine and residual salts will prevail when soil matrix is present to mediate the reaction. The former is expected to either partition to the atmosphere due to its volatility, or become re-adsorbed onto soil. In both cases, oxidative processes are effective in finally transforming phosphine to phosphate anions.	Soil: relevant Water: not relevant Sediment: not relevant Groundwater: not relevant (Step 2/Step 3-4) ¹⁾

1) According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

6.2 Effects on birds (MIIA 10.1, KPC 10.1, KPC 10.1.1)

Table 6.2-1: Endpoints used for risk assessment for birds

Species	Substance	Exposure System	Results	Reference	Internal code
<i>Colinus virginianus</i>	Zinc phosphide	acute oral 1d Method EPA 850.2100, 71-1	LD50 = 12.9 mg/kg bw	██████████ 27.01.1978 MRID 00006032	46052
<i>Branta canadensis</i>	Zinc phosphide	acute oral 1d	LD50 = 12 mg/kg	██████████ 01.01.1983	57257

<i>Colinus virginianus</i>	Zinc phosphide	Short term Dietary with vehicle 5 d	LC50 468.5 mg/kg feed	██████████ 11.03.1978 MRID 00006031	46057
<i>Coturnix japonica</i>	Zinc phosphide	49 d	NOEL = 1.2 mg/kg bw/d (males) NOEL = 0.99 mg/kg bw/d (females) NOEL = 5 mg/kg feed	██████████ 18.09.1985 W 2 / 85	46065

6.2.1 Justification for new endpoints

New studies with the preparation/active substance/metabolite have not been submitted are not considered necessary.

6.2.2 Risk assessment (MIIIA 10.1.3, MIIIA 10.1.4, MIIIA 10.1.5) for baits, pellets, granules, prills or treated seeds

Referring to the uses according to the GAP table of Detia Mäuse Giftkörner two pathways of exposure as critical for the risk assessment:

- Primary poisoning - Feeding on bait (i.e. Detia Mäuse Giftkörner)
- Secondary poisoning - Feeding on animals that have incorporated Detia Mäuse Giftkörner

6.2.2.1 Primary poisoning

The applicant did not provide a full risk assessment (i.e. no core assessment was submitted), but concluded an acceptable risk in the overall summary.

The zRMS does not fully agree with this conclusion. The zRMS considers the risk of spillage not negligible as in difference to the representative product assessed in the DAR (Arrex E Köder) Detia Mäuse Giftkörner is a ready-to-use bait that comes as loose kernels. The product evaluated in the DAR was provided in foliated bags as part of the formulation and additionally laid out in hidden places not attractive for birds. The study of ██████████ (1982) has shown that foliated bags were not consumed and that when the kernels were provided loosely (i.e. without foliated bag) they were still eaten as second choice. Thus, the conclusion of the evaluation in the DAR was that a safe use was possible due to the combination of risk mitigation measures: laying out in hidden places and provision in foliated bags.

As ready-to-use bait Detia Mäuse Giftkörner are intended to be applied either in bait stations (20 -50 g loose bait per bait station, per application 50 g a.s./ha) or loosely in vole holes (5 grains per vole hole, per application 50 g a.s./ha). As worst case it is assumed that a maximum of 5 kernels (the amount applied into one hole) would be available for birds at once. According to the applicant a portion of 5 kernels contains 7.5 mg zinc phosphide. In consideration of the lowest available LD₅₀ of 12.9 mg/kg bw, this results in TER values < 1 (hence an unacceptable acute risk) for small granivorous or omnivorous birds of less than 581 g bodyweight (e.g. linnet, partridge, pigeon). It is acknowledged, that this scenario may be restricted to rare cases, as baits should ideally be rapidly consumed by target organisms and the applications in vole holes or

bait stations reduce the risk of exposure to birds. However, on individual level, risk cannot be excluded and in comparison to the representative use evaluated in the DAR, for the intended use groups A 1 and A 3 of Detia Mäuse Giftkörner risk mitigation corresponding to the complementary combination of provision in foliated bags and hidden placement is lacking.

For the intended uses with bait stations it has to be highlighted that suitable bait stations must be used since the provision of loose kernels in bait stations at amounts up to 50 g bait per bait station may bear the risk of spillage.

In conclusion, acceptable acute risk can only be approved when risk mitigation that ensures hidden application is considered.

For intended use groups A 1 and A 3 hidden application deep in the vole hole secured by using suitable application technique (e.g. application gun) is considered feasible.

For intended use groups A 2 and A 4 approval can only be supported when suitable bait stations are used. Criteria for suitable bait stations (e.g. tamper-proof, mechanically stable, resistance to weathering) have to be defined on member state level. For German criteria please refer to the National Addendum.

Additionally, member states may consider a separate risk assessment for non-professional use (intended use groups A 3 and A 4). For German evaluation of these intended uses please refer to the National Addendum.

In agreement with the DAR evaluation and the applicant's argumentation a lack of systematic continuous ingestion is presumed and thus the risk of short- and long-term exposure was not calculated.

6.2.2.2 *Drinking water exposure*

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals (see below), no specific calculations of exposure and TER are necessary for a puddle scenario when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg).

A comparison of the relevant endpoint with the effective application rate for zinc phosphide is presented below.

Table 6.2-2: Application rate to endpoint ratios for birds exposed to zinc phosphide

Intended use	Exposure Scenario	Application rate, cumulative # [g a.s./ha]	Koc [L/kg]	LD ₅₀ [mg a.s./kg bw]	Ratio Application Rate : endpoint
zinc phosphide					
All uses	Acute	150	162	12.9	11.6

cumulative application rate as worst case assumption

Leaf scenario

Since Detia Mäuse Giftkörner is not intended to be applied on leafy vegetables forming heads or other water collecting structures, the leaf scenario does not have to be considered.

6.2.2.3 *Effects of secondary poisoning (MIIIA 10.1.9)*

For the risk of secondary poisoning it can generally be referred to the risk assessment outlined in the EU DAR. It should however be considered that when considering owls or falcons as focal species in addition to the risk assessment outlined in the DAR, correctly, the consumption of the gastrointestinal tract (GI tract) of the voles should be taken into account as owls likewise falcons do not despise the GI tract.

When considering the consumption of the whole carcass and in reference to the findings of [REDACTED] (1995, see EU DAR for evaluation) assuming 36.2 % of the consumed zinc phosphide as whole carcass residues TER values of 1 would be achieved for e.g. a long eared owl with a bodyweight of 220 g as focal species (assuming the vole would have consumed one portion of bait = 5 grains = 7.5 mg a.s.). A comparable result can be assumed for falcons (i.e. *Falco tinnunculus*). This assumption is, however, a rather unrealistic worst case as the birds do not consume their prey at once and zinc phosphide and/or phosphine residues can be assumed to be much lower in the carcass under real life conditions than in the study of [REDACTED] (1995). After ingestion of zinc phosphide containing baits there is a rapid process of conversion in non-hazardous phosphite and phosphate by oxidising of the developing phosphine in the gastro-intestinal tract of the voles. Toxicological studies with mammals there is no indication for bioaccumulation of phosphine in organisms (EU DAR) and the study of [REDACTED], 1980, see EU DAR for evaluation) supports this assumption, as none of the birds fed exclusively on contaminated voles died or showed abnormal behaviour or signs of intoxication.

To date, no new data were made available that indicate that the risk assessment would underestimate the risk for birds from secondary poisoning.

However, to minimize the risk from secondary poisoning for birds, it is important that baits are placed hidden in the vole holes or bait stations to increase chances that the intoxicated voles die after consumption of the bait in the pathways without access for birds.

6.2.3 **Biomagnification in terrestrial food chains**

Bioaccumulation of any of the active substances under natural conditions is not expected to occur and a study to determine bioaccumulation in non-target organisms is not necessary (please refer to the EU DAR and EFSA Journal (2010) 8(7):1671)).

6.2.4 **Overall conclusions**

Dietary risk assessment

As worst case it is assumed that a maximum of 5 kernels (the amount applied into one hole) would be available for birds at once. According to the applicant a portion of 5 kernels contains 7.5 mg zinc phosphide. In consideration of the lowest available LD₅₀ of 12.9 mg/kg bw, this results in TER values < 1 (hence an unacceptable acute risk) for small granivorous or omnivorous birds of less than 581 g bodyweight (e.g. linnet, partridge, pigeon). It is acknowledged, that this scenario may be restricted to rare cases, as baits

should ideally be rapidly consumed by target organisms and the applications in vole holes or bait stations reduce the risk of exposure to birds.

For the intended uses with bait stations it has to be highlighted that suitable bait stations must be used since the provision of loose kernels in bait stations at amounts up to 50 g bait per bait station may bear the risk of spillage.

In conclusion, acceptable acute risk can only be approved when risk mitigation that ensures hidden application is considered.

For intended use groups A 1 and A 3 hidden application deep in the vole hole secured by using suitable application technique (e.g. application gun) is considered a feasible risk mitigation.

For intended use groups A 2 and A 4 approval can only be supported when suitable bait stations are used. Criteria for suitable bait stations (e.g. tamper-proof, mechanically stable, resistance to weathering) have to be defined on member state level. For German criteria please refer to the National Addendum.

Additionally, member states may consider a separate risk assessment for non-professional use (intended use groups A 3 and A 4). For German evaluation of these intended uses please refer to the National Addendum.

In agreement with the DAR evaluation and the applicant's argumentation a lack of systematic continuous ingestion is presumed and thus the risk of short- and long-term exposure was not calculated.

Risk assessment for exposure via drinking water

No specific calculations of exposure and TER are necessary. The risk for birds arising from the uptake of zinc phosphide via drinking water is considered to be low for birds exposed to the active substance zinc phosphide according to the GAP of the formulation Detia Mäuse Giftkörner.

Risk assessment for exposure via secondary poisoning

The overall risk arising from secondary poisoning for birds is considered to be acceptable, however it is important that baits are placed hidden in the vole holes or bait stations to increase chances that the intoxicated voles die after consumption of the bait in the pathways without access for birds.

6.3 Effects on Terrestrial Vertebrates Other Than Birds (MIIIA 10.3, KPC 10.1, KPC 10.1.2)

Table 6.3-1: EU agreed endpoints and new endpoints

Species	Substance	Exposure System	Results	Reference	Internal code
Rattus	Zinc phosphide	acute	LD50 = 37 (geometric mean value of five values (12, 43, 44, 54, 56 mg/kg bw), according to EFSA	██████████ (2000), TOX2006-19 ██████████ (1979),	

			Journal 2010; 8(7):1671)	TOX2002-167, TOX2002-166 (see also DAR chapter 6.2.1)	
Rattus	Zinc phosphide	oral 90 d	LOEC = 3.5		

6.3.1 Justification for new endpoints

New studies with the preparation/active substance/metabolite were not submitted and are not considered to be necessary.

6.3.2 Risk assessment (MIIIA 10.3.1) for baits, pellets, granules, prills or treated seeds

Referring to the uses according to the GAP table of Detia Mäuse Giftkörner two pathways of exposure are critical for the risk assessment:

- Primary poisoning - Feeding on bait (i.e. Detia Mäuse Giftkörner)
- Secondary poisoning - Feeding on animals that have incorporated Detia Mäuse Giftkörner

6.3.2.1 Primary poisoning

The applicant did not provide a full risk assessment (i.e. no core assessment was submitted), but concluded an acceptable risk in the overall summary.

The zRMS does not fully agree with this conclusion. The zRMS considers the risk of spillage not negligible as in difference to the representative product assessed in the DAR (Arrex E Köder) Detia Mäuse Giftkörner is a ready-to-use bait that comes as loose kernels. The product evaluated in the DAR was provided in foliated bags as part of the formulation and additionally laid out in hidden places. The conclusion of the evaluation in the DAR was that a safe use was possible due to the combination of risk mitigation measures: laying out in hidden places and provision in foliated bags.

As ready-to-use bait Detia Mäuse Giftkörner are intended to be applied either in bait stations (20 -50 g loose bait per bait station, per application 50 g a.s./ha) or loosely in vole holes (5 grains per vole hole, per application 50 g a.s./ha). For intended uses with envisaged application of portions of 5 kernels per vole hole, an amount of 7.5 mg zinc phosphide could be consumed at once as worst case assumption. Considering the EU-agreed LD₅₀ of 37 mg/kg bw, the amount of zinc phosphide contained in one portion of bait result in TER values <10 (or < 1, respectively) for mammals with a bodyweight of less than 2030 g (or 203 g, respectively). The actual protection goal according to the Guidance Document (EFSA Journal 2009; 7 (12):1438) is “clearly establishing that there will be no visible mortality and no-long-term repercussions for abundance and diversity”, thus strictly the acute risk for non-target mammals of less than 2030 g bodyweight is not acceptable. The often given argument, that during the long-term practice of applying zinc phosphide not many cases of intoxication of non-target animals have been reported, cannot account to disburden the risk, since – likewise the target animals whose carcasses are hardly ever found – non-target mammals, especially other non-target rodents, could also die in the pathways and thus their

carcasses would not be recognised. The cited strong emetic effect on non-target mammals may prevent mortality in cases of mammals that are able to regurgitate, yet hamsters or rabbits, for example, are not able to regurgitate. In conclusion, acceptable acute risk can only be approved when risk mitigation that ensures hidden application is considered.

For intended use groups A 1 and A 3 hidden application deep in the vole hole secured by using suitable application technique (e.g. application gun) is considered feasible to reduce accessibility for non-target mammals.

For the intended uses with bait stations it has to be highlighted that the provision of loose kernels in bait stations at amounts up to 50 g bait per bait station may bear the risk of spillage. Thus for intended use groups A 2 and A 4 approval can only be supported when suitable bait stations are used. Criteria for suitable bait stations (e.g. tamper-proof, mechanically stable, resistance to weathering) have to be defined on member state level. For German criteria please refer to the National Addendum.

Additionally, member states may consider a separate risk assessment for non-professional use (intended use groups A 3 and A 4). For German evaluation of these intended uses please refer to the National Addendum.

Short-term or long-term risk from dietary exposure is considered to be rather low in agreement with the EU DAR, as the envisaged use should secure that no long-term exposure is given. Baits are consumed in a short period of time and re-application until no more baits are consumed is possible. Consequently, repeated exposition of non-target animals is theoretically possible, but is assumed to be restricted to rare and individual cases with no adverse effects on the population level.

6.3.2.2 *Drinking water exposure*

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals (see below), no specific calculations of exposure and TER are necessary for a puddle scenario when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg).

A comparison of the relevant endpoint with the effective application rate for zinc phosphide is presented below.

Table 6.3-2: Application rate to endpoint ratios for mammals exposed to zinc phosphide

Intended use	Exposure Scenario	Application rate, cumulative # [g a.s./ha]	Koc [L/kg]	LD ₅₀ /NOEL [mg a.s./kg bw]	Ratio Application Rate : endpoint
zinc phosphide					
All uses	Acute	150	162	37	4

cumulative application rate as worst case assumption

Leaf scenario

Since Detia Mäuse Giftkörner is not intended to be applied on leafy vegetables forming heads or other water collecting structures, the leaf scenario does not have to be considered.

6.3.2.3 *Effects of secondary poisoning (MIIA 10.3.2.3)*

For the risk of secondary poisoning it can generally be referred to the risk assessment outlined in the EU DAR. However, it has to be pointed out, that TER values below the trigger are achieved when taking the consumption of the GI tract of the intoxicated voles into account.

As after ingestion of zinc phosphide there is a rapid process of conversion of the developing phosphine in the gastro-intestinal tract of the voles into non-hazardous phosphite and phosphate and toxicological studies with mammals did not find any indication for bioaccumulation of phosphine in organisms (EU DAR), it can be presumed that under real life conditions zinc phosphide and/or phosphine residues will be much lower in the carcass than in the worst case study of ██████████ (1995) (for review please refer to the EU DAR). Thus, in agreement with EU DAR the risk from secondary poisoning is considered to be overall acceptable.

To date, no new data were made available that indicate that the risk assessment would underestimate the risk for birds from secondary poisoning.

6.3.3 Biomagnification in terrestrial food chains

Bioaccumulation of any of the active substances under natural conditions is not expected to occur and a study is not necessary to determine bioaccumulation in non-target organisms (please refer to the EU DAR and EFSA Journal (2010) 8(7):1671)).

6.3.4 Overall conclusions

Dietary risk assessment

As ready-to-use bait Detia Mäuse Giftkörner are intended to be applied either in bait stations (20 -50 g loose bait per bait station, per application 50 g a.s./ha) or loosely in vole holes (5 grains per vole hole, per application 50 g a.s./ha). For intended uses with envisaged application of portions of 5 kernels per vole hole, an amount of 7.5 mg zinc phosphide could be consumed at once as worst case assumption. Considering the EU-agreed LD₅₀ of 37 mg/kg bw, the amount of zinc phosphide contained in one portion of bait in TER values <10 (or < 1, respectively) for mammals with a bodyweight of less than 2030 g (or 203 g, respectively).

In conclusion, acceptable acute risk can only be approved when risk mitigation that ensures hidden application is considered.

For intended use groups A 1 and A 3 hidden application deep in the vole hole secured by using suitable application technique (e.g. application gun) is considered feasible.

For intended use groups A 2 and A 4 approval can only be supported when suitable bait stations are used. Criteria for suitable bait stations (e.g. tamper-proof, mechanically stable, resistance to weathering) have to be defined on member state level. For German criteria please refer to the National Addendum.

Additionally, member states may consider a separate risk assessment for non-professional use (intended use groups A 3 and A 4). For German evaluation of these intended uses please refer to the National Addendum.

Short-term or long-term risk from dietary exposure is considered to be rather low in agreement with the EU DAR

Risk assessment for exposure via drinking water

No specific calculations of exposure and TER are necessary. The risk for mammals arising from the uptake of zinc phosphide via drinking water is considered to be low for mammals exposed to the active substance zinc phosphide according to the GAP of the formulation Detia Mäuse Giftkörner.

Risk assessment for exposure via secondary poisoning

The overall risk arising from secondary poisoning for mammals is considered to be acceptable.

6.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KPC 10.1.3)

Reptiles and amphibians are not yet considered explicitly in standard risk assessments thus far and have not been considered explicitly in the review process for Annex I inclusion of zinc phosphide either. Traditionally it has been assumed that reptiles and amphibians would be covered by the regular birds and mammals risk assessment. Research results recently questioned this assumption (Brühl et al. 2011; Fryday and Thompson, 2012; Brühl et al., 2013). In the case of zinc phosphide, an open literature search reveals that zinc phosphide bears potential to act especially toxic to lizards (Avery et al., 2011) with respect to primary poisoning. Moreover, the risk from secondary poisoning for snakes differs from other predators. In contrast to many other predators, snakes follow their prey into the pathways and hence can easily prey on poisoned voles where other predators would not have access. Also, they consume the whole animal and do not reject the gastrointestinal tract of their prey. Therefore, it seems advisable to consider the specific risk for reptiles to exposure of zinc phosphide, especially for intended uses in crop cultures that are known to provide and be related to special habitats for reptiles as e.g. vineyards.

The applicant was therefore asked to compile current knowledge on the risk for reptiles considering likelihood of exposure by crop culture, effects and possible risk mitigation for reptiles.

The applicant addressed this issue partly. With respect to the cited literature on effects of zinc phosphide on lizards, the applicant argues, that in the cited study the active substance was provided as attractive bait especially for lizards, hence would not be representative to judge risk on lizards. We acknowledge this argument; however, it has to be pointed out that to date there is no study known to us dealing with the exposure and risk of effects on lizards from zinc phosphide containing rodent bait, thus as sound conclusion of “no risk” is not possible. Based on current knowledge, only an acceptable minor risk can be concluded.

With respect to secondary poisoning of snakes the applicant argues that the type of prevalent snakes in our latitude were not likely to be found in active mouse burrows as it would not comply with their living

habits and additionally zinc phosphide would not be intended for the use in biotopes where our native snake types generally occur. Further they argue, that only direct oral ingestion of the rodent bait could be potentially harmful, which was no realistic pathway for amphibians and reptiles.

We follow the latter argument, yet highlight again that there is no study available giving clear evidence that secondary poisoning of snakes can be excluded, since the available studies have a different focus.

The applicant has not provided any further state-of-knowledge. Even though the overall risk is considered acceptable, some degree of uncertainty remains and members states should check whether the argument that the intended uses of zinc phosphide do not interfere with biotopes of snakes applies for their country and if risk mitigation measures may be needed.

For German risk assessment please refer to the National Addendum of this submission.

6.5 Effects on aquatic organisms (MIIIA 10.2, KPC 10.2, KPC 10.2.1)

Table 6.5-1: Endpoints used for risk assessment for aquatic organisms for zinc phosphide

Species	Substance	Exposure System	Results [mg a.s./L]	Reference	Internal code
<i>Leuciscus idus</i>	Zinc phosphide technical	4 d Semi-static OECD 203	LC50 > 0.0217 mg/L	██████████ 13.09.2001 20001426/01-AAli	46056
<i>Daphnia magna</i>	Zinc phosphide technical	2 d Static OECD 202	EC50 = 0.114 mg/L	Heintze, A. 13.09.2001 20001426/01-AADm	46067
<i>Desmodesmus subspicatus</i>	Zinc phosphide technical	3 d Static OECD 201	EbC50 = 0.00821 mg/L NOEbC = 0.00323 mg/L ErC50 = 0.00375 mg/L NOErC = 0.00140 mg/L Real	Dengler, D. 11.09.2001 20001426/01-AADs	46080

6.5.1 Justification for new endpoints

No new studies with the preparation/active substance/metabolite submitted and not considered necessary.

6.5.2 Toxicity to exposure ratios for aquatic species (MIIIA 10.2.1)

In agreement with the EU DAR, quantitative TER value calculation is not considered necessary, as the exposure is limited due to the mode of application. Exposure, however, is not totally excluded, i.e. in cases of heavy rainfall subsequent to bait placement for the reason that vole pathways are known to function as

flow paths. When the bait is not fully consumed by target species, rainfall may cause washing out of bait into surface waters.

6.5.2.1 Risk assessment for the product, valid for run-off and not run-off endangered areas (based on drift only)

The overall risk for aquatic biocenosis is expected to be low due to specific mode of application and the thereby limited exposure. However still, it has to be pointed out, that acute toxicity of zinc phosphide technical for fish, *Daphnia* and algae indicates labelling as “very toxic for aquatic organisms, may cause long-term adverse effects in the aquatic environment” (relevant endpoint *Desmodesmus subspicatus* E_rC50 = 3.75 µg/L).

Therefore, worst case exposure incidents such as run-off or wash out of remaining bait via vole pathways into continuous or short-term water-bearing ditches after heavy rainfall should be prevented by suitable risk management measures. Consideration of specific risk management options is in responsibility of the individual member states.

6.5.2.2 Consideration of Metabolites

There are no relevant metabolites of zinc phosphide occurring in surface water or sediment (please refer to Section 5 of the Core Assessment).

6.5.2.3 Accumulation in aquatic non-target organisms

Bioaccumulation of any of the active substances under natural conditions is not expected to occur and a study is not necessary to determine bioaccumulation in aquatic non-target organisms (please refer to the EU DAR and EFSA Journal (2010) 8(7):1671).

6.5.3 Overall conclusions

The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of Detia Mäuse Giftkörner according to the label. Run-off or wash out of remaining bait via vole pathways into continuous or periodically water-bearing ditches and streams after heavy rainfall should be prevented by suitable risk management measures. Consideration of specific risk management options is in responsibility of the individual member states.

6.6 Effects on bees (MIIIA 10.4, KPC 10.3.1)

In agreement with the conclusions of the EU review of zinc phosphide (EFSA Journal (2010) 8(7):1671), the risk to bees can be considered negligible since no exposure is expected from the use of zinc phosphide containing rodenticide baits such as Detia Mäuse Giftkörner. No data from bee toxicity tests are required.

6.7 Effects on arthropods other than bees (MIIIA 10.5, KPC 10.3.2)

Due to the discrete placement of baits, distribution of zinc phosphide deriving from Detia Mäuse Giftkörner is assumed to be patchy and restricted to cases where the bait is not fully consumed by target species. Thus, exposure for ground-living arthropods is not totally excluded, yet it is presumably limited to individual spots and in line with the EFSA conclusion (EFSA Journal (2010) 8(7):1671), no unacceptable risk for non-target arthropods is expected.

6.7.1 Risk assessment

In line with the EU DAR and the EC Review Report for zinc phosphide (SANCO/12548/2010 final, 28 October 2010) no quantitative risk assessment for non-target arthropods is considered necessary due to limited exposure as outlined above.

6.7.2 Overall conclusions

In-field and off-field

Based on the argumentation outlined above the risk for non-target arthropods due to the intended use of Detia Mäuse Giftkörner according to the label is assumed to be low.

6.8 Effects on non-target soil meso- and macrofauna (MIIIA 10.6, KPC 10.4, KPC 10.4.1, KPC 10.4.2)

Table 6.8-1: EU agreed endpoints and new endpoints for earthworms and other soil macro- and mesofauna

Species	Substance	Exposure System	Results	Reference	Internal code
<i>Eisenia foetida</i>	Zinc phosphide technical	Acute 14 d OECD 207	LC50 > 1000 mg a.s./kg soil dw	Föhring, H. and Schlüter, W. 15.03.1991 ARW2005-257	46085
<i>Eisenia foetida</i>	Preparation „Mäusegiftweizen“ (grain kernels coated with zinc phosphide)	14 d OECD 207	LC50 > 500 grains/kg soil dw (~ 600 mg a.s./kg soil dw) 500 grain: maximum test concentration, 5 grains = 250 mg test substance corresponding to 6 mg a.s.	Föhring, H. and Schlüter, W. 15.03.1991 ARW2005-257	46085

6.8.1 Justification for new endpoints

No new studies with the preparation/active substance/metabolite have been submitted.

6.8.2 Toxicity exposure ratios for earthworms and other soil macro- and mesofauna, TER_A and TER_{LT} (MIIIA 10.6.1)

The evaluation of the risk for earthworms and other soil macro-organisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

For the calculations of predicted environmental concentrations in soils (PEC soil), reference is made to the environmental fate section (Part B, Section 5) of this submission.

For risk assessment purposes the maximum rate of application of 2 kg product/ha and treatment, i.e. 50 g zinc phosphide/ha and treatment is considered.

The acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to Detia Mäuse Giftkörner / zinc phosphide as well as the major soil degradation products of zinc phosphide was assessed by comparing the maximum PEC_{SOIL} with the 14-day LC₅₀ value to generate acute TER values. The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50} \text{ (mg/kg)}}{PEC_{soil} \text{ (mg/kg)}}$$

The results of the risk assessment are summarized in the following table. Calculations were carried out for 5 cm soil depth and 1 cm soil depth assuming that remaining bait is laying on soil surface and would not be mixed into the soil.

Table 6.8-2: TER values for earthworms and other soil macro- and mesofauna (Tier-1), all uses, 3 x 50 g a.s./ha

Species	Test item	Time scale	Endpoint [mg/kg soil dw]	Max. PEC _{SOIL} [mg/kg soil dw]	TER
<i>Eisenia fetida</i>	zinc phosphide	Acute	1000	0.2 (5 cm)	5000
	zinc phosphide	Acute	1000	1.0 (1 cm)	1000
	Detia Mäuse Giftkörner	Acute	600	8.0 (5 cm)	75
	Detia Mäuse Giftkörner	Acute	600	40.0 (1 cm)	15

TER values shown in bold fall below the relevant trigger.

6.8.3 Higher tier risk assessment

Not relevant.

6.8.4 Overall conclusions

Based on the predicted concentrations of zinc phosphide in soils, the worst case TER values describing the acute risk for earthworms following exposure to zinc phosphide according to the GAP of the formulation Detia Mäuse Giftkörner achieve the acceptability criteria TER ≥ 10 according to commission implementing

regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The assessment of TER values for other soil non-target macro-organisms is not triggered.

The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of Detia Mäuse Giftkörner according to the label.

6.9 Effects on soil microbial activity (MIIIA 10.7, KPC 10.5)

Table 6.9-1: EU agreed endpoints and new endpoints for soil microorganisms

Substance	Test design	Results	Source	Internal code
zinc phosphide technical	N-mineralisation, 28 d	< 25 % effect at day 28 at 240 g/ha (0.32 mg/kg d.w.soil) ¹⁾	Dresbach, C. 06.09.1990	20500
zinc phosphide technical	C-mineralisation, 28 d	< 25 % effect at day 28 at 240 g/ha (0.32 mg/kg d.w.soil) ¹⁾	Dresbach, C. 06.09.1990	20500

A study with the formulated product Detia Mäuse Giftkörner has not been submitted, thus formally data requirements are not fulfilled. Ex post submission of a study will not be requested though for the reason that exposure is expected to be limited even though it cannot totally be excluded (for example when baits are not fully consumed). A worst case risk assessment is carried out based on the effect study with the technical substance.

6.9.1 Justification for new endpoints

New studies with the preparation/active substance/metabolite were not submitted and are not considered necessary.

6.9.2 Risk assessment

The evaluation of the risk for earthworms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

Please refer to above for the predicted environmental concentrations in soil (PEC_{SOIL}) of zinc phosphide and Detia Mäuse Giftkörner.

The results of the risk assessment are summarized in the following table.

Table 6.9-2: Risk assessment for effects on soil micro-organisms

Test substance	Test concentration (adverse effects < 25%) [mg /kg]	PEC _{SOIL} [mg/kg]	Risk acceptable [yes/no]
zinc phosphide	0.32	0.2 (5 cm)	Yes, MoS = 1.6

zinc phosphide	0.32	1.0 (1 cm)	<i>No (please refer to the argumentation below)</i>
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It should be noted that PEC_{soil} calculations are based on the assumption of a homogenous distribution of baits over the area. In reality, however, distribution is patchy due to the specific mode of application. Even though ideally, direct exposure of zinc phosphide from Detia Mäuse Giftkörner to the soil should be limited due to the specific mode of application. As worst case not fully consumed baits can lead to exposure of Detia Mäuse Giftkörner towards soil and the individual spots of application could be exposed to relatively high concentrations zinc phosphide. The area of influence, however, can be assumed to be limited due to the moderate release of zinc phosphide from remaining bait relatively and the rapid degradation and low mobility of released zinc phosphide in soils (for details on the behaviour in soils please refer to Section 5 of the Core Assessment). Thus the overall risk is considered to be acceptable.

6.9.3 Overall conclusions

The risk to soil microbial processes following exposure to zinc phosphide /Detia Mäuse Giftkörner according to the GAP of the formulation Detia Mäuse Giftkörner is considered to be acceptable due to the specific mode of application.

6.10 Effects on non-target plants (MIIIA 10.8, KPC 10.6)

6.10.1 Effects on non-target terrestrial plants (MIIIA 10.8.1)

As shown in the EU DAR, adverse effects on plants due to the zinc content of the baits are not expected. The mode of application at discrete sites prevents extensive contamination. Additionally, the area of influence can be assumed to be limited due to the moderate release of zinc phosphide from remaining bait relatively and the rapid degradation and low mobility of released zinc phosphide in soils (for details on the behaviour in soils please refer to Section 5 of the Core Assessment). Thus the risk is considered to be acceptable

6.10.2 Justification for new endpoints

New studies were not submitted and are not considered necessary.

6.10.2.1 Risk assessment

In line with the EU DAR and the EC Review Report for zinc phosphide (SANCO/12548/2010 final, 28 October 2010) no quantitative risk assessment for non-target arthropods is considered necessary due to limited exposure as outlined above.

6.10.2.2 Overall conclusions

The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of Detia Mäuse Giftkörner according to the label.

- 6.11** **Effects on other terrestrial organisms (flora and fauna) (KPC 10.7)**
- 6.12** **Monitoring data (KPC 10.8)**
- 6.13** **Available preliminary data (IIIA 10.9)**
- 6.14** **Other/special studies (IIIA 10.10)**

Appendix 1 List of data submitted in support of the evaluation

No new data submitted.

Reference is made to:

EFSA Journal (2010) 8(7):1671 (Conclusion on the peer review of zinc phosphide)

Full details of toxicity studies are provided in the respective EU DAR and the EC Review Report for zinc phosphide (SANCO/12548/2010 final, 28 October 2010).

Cited open literature

Avery, M.L., Eisemann, J.D., Keacher, K.L., Savarie, P.J. (2011): Acetaminophen and zinc phosphide for lethal management of invasive lizards *Ctenosaura similis*. *Current Zoology*, 57 (5): 625-629.

Abstract: Reducing populations of invasive lizards through trapping and shooting is feasible in many cases but effective integrated management relies on a variety of tools, including toxicants. In Florida, using wild-caught non-native black spiny-tailed iguanas *Ctenosaura similis*, we screened acetaminophen and zinc phosphide to determine their suitability for effective population management of this prolific invasive species. Of the animals that received acetaminophen, none died except at the highest test dose, 240 mg per lizard, which is not practical for field use. Zinc phosphide produced 100% mortality at dose levels as little as 25 mg per lizard, equivalent to about 0.5% in bait which is lower than currently used in commercial baits for commensal rodent control. We conclude that zinc phosphide has potential as a useful tool for reducing populations of invasive lizards such as the black spiny-tailed iguana provided target-selective delivery methods are developed.

Brühl, C. A., Pieper, S. and Weber, B. (2011): Amphibians at risk? Susceptibility of terrestrial amphibian life stages to pesticides. *Environmental Toxicology and Chemistry*, 30: 2465–2472. doi: 10.1002/etc.650

Abstract: Current pesticide risk assessment does not specifically consider amphibians. Amphibians in the aquatic environment (aquatic life stages or postmetamorphic aquatic amphibians) and terrestrial living juvenile or adult amphibians are assumed to be covered by the risk assessment for aquatic invertebrates and fish, or mammals and birds, respectively. This procedure has been evaluated as being sufficiently protective regarding the acute risk posed by a number of pesticides to aquatic amphibian life stages (eggs, larvae). However, it is unknown whether the exposure and sensitivity of terrestrial living amphibians are comparable to mammalian and avian exposure and sensitivity. We reviewed the literature on dermal pesticide absorption and toxicity studies for terrestrial life stages of amphibians, focusing on the dermal exposure pathway, that is, through treated soil or direct overspray. In vitro studies demonstrated that cutaneous absorption of chemicals is significant and that chemical percutaneous passage, P (cm/h), is higher in amphibians than in mammals. In vivo, the rapid and substantial uptake of the herbicide atrazine from treated soil by toads (*Bufo americanus*) has been described. Severe toxic effects on various amphibian species have been reported for field-relevant application rates of different pesticides. In general, exposure and toxicity studies for terrestrial amphibian life stages are scarce, and the reported data indicate the need for further research, especially in light of the global amphibian decline.

Brühl, C. A., Schmidt, T., Pieper, S. and Alscher, A. (2013): Terrestrial pesticide exposure of amphibians: An underestimated cause of global decline?. *Sci. Rep.*, 3, 1135. doi: 10.1038/srep01135

Abstract: Amphibians, a class of animals in global decline, are present in agricultural landscapes characterized by agrochemical inputs. Effects of pesticides on terrestrial life stages of amphibians such as juvenile and adult frogs, toads and newts are little understood and a specific risk assessment for pesticide exposure, mandatory for other vertebrate groups, is currently not conducted. We studied the effects of seven pesticide products on juvenile European common frogs (*Rana temporaria*) in an agricultural overspray scenario. Mortality ranged from 100% after one hour to 40% after seven days at the recommended label rate of currently registered products. The demonstrated toxicity is alarming and a large-scale negative effect of terrestrial pesticide exposure on amphibian populations seems likely. Terrestrial pesticide exposure might be underestimated as a driver of their decline calling for more attention in conservation efforts and the risk assessment procedures in place do not protect this vanishing animal group.

Fryday, S. and H. Thompson (2012): Toxicity of pesticides to aquatic and terrestrial life stages of amphibians and occurrence, habitat use and exposure of amphibian species in agricultural environments Supporting Publications 2012:EN-343. [348 pp.]. Available online: www.efsa.europa.eu/publication

Abstract: The aim of this study was to provide EFSA with information relating to assessment of the risk to amphibians posed by pesticide exposure. In the first part of the study the European amphibian species associated with agricultural habitats were identified with the aim of collating information for representative species such as body size and life-cycle. Also collated were the results of studies of amphibians in European agricultural habitats to provide information on activity in areas where they may be at risk of exposure to pesticides. Several studies of the use of agricultural habitats were found providing information on migration distances and associations with particular crops although the data is patchy. The second part of the study collated information useful to risk assessment for terrestrial habitats. Information was presented on possible assessment of dietary exposure but methods for estimating dermal exposure have not yet been developed due to lack of necessary information. Other routes of exposure such as soil ingestion and inhalation were considered but no methods specific to amphibians were found. Finally, toxicity data for both the aquatic and terrestrial stages were gathered for comparison with fish and bird/mammal data respectively. A substantial quantity of data was found for aquatic exposure and after quality assessment data for each time period were presented. Far less information was found for terrestrial amphibians and what is available is of variable quality. More information is required to allow the assessment of exposure, particularly dermal exposure and the relative toxicity of pesticides to terrestrial amphibians and other vertebrate groups.

Appendix 2 Detailed evaluation of the new studies

IIIA 10.1 Effects on birds

IIIA 10.1.3 Baits: Concentration of active substance in bait in mg/kg

IIIA 10.1.4 Pellets, granules, prills or treated seed

IIIA 10.1.4.1 Amount of active substance in or on each item

IIIA 10.1.4.2 Proportion of active substance LD₅₀ per 100 items and per gram of items

IIIA 10.1.5 Size and shape of pellet, granule or prill

IIIA 10.1.6 Acute toxicity of the formulation

IIIA 10.1.7 Supervised cage or field trials

IIIA 10.1.8 Acceptance of bait, granules or treated seeds (palatability testing)

IIIA 10.2 Effects on aquatic organisms

IIIA 10.2.2 Acute toxicity (aquatic) of the preparation

IIIA 10.2.2.1 Fish acute toxicity LC₅₀, freshwater, cold-water species

IIIA 10.2.2.2 Acute toxicity (24 & 48 h) for Daphnia preferably Daphnia magna

IIIA 10.2.2.3 Effects on algal growth and growth rate

IIIA 10.2.2.4 Marine or estuarine organisms acute toxicity LC₅₀/EC₅₀

IIIA 10.2.2.5 Marine sediment invertebrates, acute toxicity LC₅₀/EC₅₀

IIIA 10.2.3 Microcosm or mesocosm study

IIIA 10.2.4 Residue data in fish (long-term)

IIIA 10.2.5 Chronic fish toxicity data

IIIA 10.2.5.1 Chronic toxicity (28 day exposure) to juvenile fish. Analytical data on concentrations in the test media

IIIA 10.2.5.2 Fish early life stage toxicity test. Analytical data on concentrations in the test media

IIIA 10.2.5.3 Fish life cycle test. Analytical data on concentrations in the test media

IIIA 10.2.6 Chronic toxicity to aquatic invertebrates

IIIA 10.2.6.1 Chronic toxicity in Daphnia magna (21-day). Analytical data on concentrations in the test media

**IIIA 10.2.6.2 Chronic toxicity for a representative species of aquatic insects.
Analytical data on concentrations in the test media**

**IIIA 10.2.6.3 Chronic toxicity for a representative species of aquatic gastropod molluscs.
Analytical data on concentrations in the test media**

**IIIA 10.2.7 Accumulation in aquatic non-target organisms.
Analytical data on concentrations in the test media**

IIIA 10.3.2.1 Acute oral toxicity of the preparation

IIIA 10.3.2.2 Acceptance of bait, granules or treated seeds by terrestrial vertebrates (palatability test)

IIIA 10.3.3 Supervised cage or field trials or other appropriate studies

IIIA 10.4 Effects on bees

IIIA 10.4.2 Acute toxicity of the preparation to bees

IIIA 10.4.2.1 Acute oral toxicity

IIIA 10.4.2.2 Acute contact toxicity

IIIA 10.4.3 Effects on bees of residues on crops

IIIA 10.4.4 Cage tests

IIIA 10.4.5 Field tests

IIIA 10.4.6 Investigation of special effects

IIIA 10.4.6.1 Larval toxicity

IIIA 10.4.6.2 Long residual effects

IIIA 10.4.6.3 Disorienting effects on bees

IIIA 10.4.7 Tunnel testing to investigate effects of feeding on contaminated honey dew or flowers

MIIA 10.5 Effects on arthropods other than bees

IIIA 10.5.1 Effects on sensitive species already tested, using artificial substrate

IIIA 10.5.2 Effects on non-target terrestrial arthropods in extended laboratory tests

IIIA 10.5.3 Effects on non-target terrestrial arthropods in semi-field tests

IIIA 10.5.4 Field tests on arthropods species

IIIA 10.6 Effects on earthworms and other soil macro-organisms

IIIA 10.6.2 Acute toxicity to earthworms

- IIIA 10.6.3 Sublethal effects on earthworms**
- IIIA 10.6.4 Field tests (effects on earthworms)**
- IIIA 10.6.5 Residue content of earthworms**
- IIIA 10.6.6 Effects of other soil non-target macro-organisms**
- IIIA 10.6.7 Effects on organic matter breakdown**
- IIIA 10.7 Effects on soil microbial activity**
- IIIA 10.7.1 Laboratory test to investigate impact on soil microbial activity**
- IIIA 10.7.2 Further laboratory, glasshouse or field testing to investigate impact on soil microbial activity**
- III 10.8 Effects on non-target plants**
- III 10.8.1 Effects on non-target terrestrial plants**
- IIIA 10.8.1.1 Seed germination**
- IIIA 10.8.1.2 Vegetative vigour**
- IIIA 10.8.1.3 Seedling emergence**
- IIIA 10.8.1.4 Terrestrial field testing**
- MIII 10.8.2 Effects on non-target aquatic plants**
- IIIA 10.8.2.1 Aquatic plant growth – Lemna**
- IIIA 10.8.2.2 Aquatic field testing**
- Table A 1: Summary of findings of <product>**

Appendix 3 Table of Intended Uses in the central zone (GAP table)

The table below includes all individual GAP uses envisaged for the registration of Detia Mäuse Giftkörner in the Central Zone.

1 Use- No.	2 Member state(s)	3 Crop and/ or situation (crop destination / purpose of crop)	4 F G or I	5 Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	6 Method / Kind		7 Application		8 Max. number (min. interval between applications) a) per use b) per crop/ season	9 kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	10 Application rate		11 g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	12 Water L/ha min / max	13 PHI (days)	14 Remarks:
					Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max								
1	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Agricultural crops	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.				
2	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Agricultural crops	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.				
3	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vegetable crops	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.				

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application		Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	Application rate		PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season			g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
4	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vegetable crops	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g / bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded. Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
5	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Fruit crops	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
6	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Fruit crops	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.

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Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application		Max. number (min. interval between applications) a) per use b) per crop/ season	Application rate		PHI (days)	Remarks:	
					Timing / Growth stage of crop & season	Method / Kind		kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season			Water L/ha min / max
7	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vinicultural crops	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded. Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
8	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vinicultural crops	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
9	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Grassland, lawns and meadows	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.

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10	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Grassland, lawns and meadows	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded. Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
11	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Ornamental crops	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
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Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application		Max. number (min. interval between applications) a) per use b) per crop/ season	Application rate		PHI (days)	Remarks:	
					Method / Kind	Timing / Growth stage of crop & season		kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season			Water L/ha min / max
13	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Coniferous and deciduous trees	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded. Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
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15	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vegetable crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.

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Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled	Method / Kind	Timing / Growth stage of crop & season	Application	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
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17	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Fruit crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.	
18	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Fruit crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.	

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19	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Ornamental crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded. Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
20	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Ornamental crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.

**REGISTRATION REPORT
Part B**

**Section 6: Ecotoxicological studies
Detailed summary of the risk assessment**

Product code: Detia Mäuse Giftkörner
Active Substance: Zinc phosphide, 25 g/kg

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM

Applicant: Detia Freyberg GmbH
Date: January 2015, updated April 2018

Table of Contents

SEC 6	ECOTOXICOLOGICAL STUDIES (MIIIA 10).....	3
6.1	PROPOSED USE PATTERN AND CONSIDERED METABOLITES.....	4
6.1.1	Grouping of intended uses for risk assessment.....	4
6.1.2	Consideration of metabolites.....	5
6.2	EFFECTS ON BIRDS (MIIIA 10.1, KPC 10.1, KPC 10.1.1).....	6
6.3	EFFECTS ON TERRESTRIAL VERTEBRATES OTHER THAN BIRDS (MIIIA 10.3, KPC 10.1, KPC 10.1.2).....	7
6.4	EFFECTS ON OTHER TERRESTRIAL VERTEBRATE WILDLIFE (REPTILES AND AMPHIBIANS) (KPC 10.1.3).....	8
6.5	EFFECTS ON AQUATIC ORGANISMS (MIIIA 10.2, KPC 10.2, KPC 10.2.1).....	8
6.6	EFFECTS ON BEES (MIIIA 10.4, KPC 10.3.1).....	8
6.7	EFFECTS ON ARTHROPODS OTHER THAN BEES (MIIIA 10.5, KPC 10.3.2).....	9
6.8	EFFECTS ON NON-TARGET SOIL MESO- AND MACROFAUNA (MIIIA 10.6, KPC 10.4, KPC 10.4.1, KPC 10.4.2).....	9
6.9	EFFECTS ON SOIL MICROBIAL ACTIVITY (MIIIA 10.7, KPC 10.5).....	9
6.10	EFFECTS ON NON-TARGET PLANTS (MIIIA 10.8, KPC 10.6).....	9
6.10.1	Effects on non-target terrestrial plants (MIIIA 10.8.1).....	9
6.11	CLASSIFICATION AND LABELLING.....	9
6.11.1	GHS Classification and Labelling.....	9
6.11.2	National labelling and conditions of use in Germany.....	10
APPENDIX 1	TABLE OF INTENDED USES IN GERMANY (ACCORDING TO BVL 15.08.2013)	12

Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

A full risk assessment according to Uniform Principles for the plant protection product Detia Mäuse Giftkörner in its intended uses is documented in detail in the core assessment of the plant protection product Detia Mäuse Giftkörner dated from January 2014 performed by zRMS DE, updated in January 2015 (Section 6, chapter 6.4).

This document comprises specific risk assessment for some annex points for authorization of the plant protection product Detia Mäuse Giftkörner in Germany according to the uses listed in Appendix 2.

General information on the formulation Detia Mäuse Giftkörner can be found in Table 5.1-1 of Section 5 of the National addendum Germany (January 2014).

6.1 Proposed use pattern and considered metabolites

6.1.1 Grouping of intended uses for risk assessment

Full details of the proposed use pattern of the formulation Detia Mäuse Giftkörner that will be assessed are presented in Appendix 1 and summarized in the table below. The intended uses in Germany are covered by the core assessment performed by zRMS DE, however, the GAP table for Germany comprises slightly differently defined intended uses than the GAP table for the central zone. Hence, the following table lists the grouping of the intended uses for Germany.

Intended uses may be grouped according to soil relevant application rate, drift rate and with respect to the exposure of non-target organisms (i.e. maximum daily dose for birds and mammals). The soil relevant application rate is based on the effective cumulative application rate including interception. Grouping according to drift scenarios is not applicable in this case. With respect to the exposure of non-target organisms (i.e. birds and mammals) and the overall environmental risk assessment the conditions of use (i.e. outdoor / field use, glasshouse application) and method/kind of application in combination with the remarks are considered. Additionally, the crop/situation has been taken into account (i.e. cultivated land / non-cultivated land, professional use / non-professional use) for grouping.

Table 6.1-1: Critical use pattern of Detia Mäuse Giftkörner according to the GAP table for Germany

Risk envelope approach for exposure assessment according to Section 5			
Group / use no.	Crop/growth stage/interception	Application method	Application rate, cumulative (g a.s./ha)
A / covers all intended uses in all use areas in the central zone	Agriculture, Orchard, Vegetables, Ornamentals, Grassland, Forestry, grape vine / all stages	placing of baits in vole hole or placing of baits in bait stations	3 x 3 appl. per season , zinc phosphide max. 3 x 50, Soil effective application rate: Zinc phosphide max. 150
Grouping for overall environmental risk assessment (based on conditions of use, method/kind, crop/situation as stated above)			
Group /use no. 00-	Crop/growth stage/interception	Application method/drift scenario	Application rate, cumulative (g a.s./ha)
A 1 / 001, 002, 003, 005, 006, 008, 010	Outdoor use in: field crops; forst plants; vegetables; grassland, pasture, meadows; fruit crops; grape vine; ornamentals / if required	lay out poisoned cereal grains, 5 piece(s) per hole (hide)	Zinc phosphide Max. 3 x 50
A 2 / 011, 012, 013, 015, 016, 018, 020	Outdoor use in: field crops; forst plants; vegetables; grassland, pasture, meadows; fruit crops; grape vine; ornamentals / if required	lay out poisoned cereal grains, 50 g per bait station (hide)	Zinc phosphide Max. 3 x 50
A 3 / 004, 007, 009	Home and garden use (non-professional): Vegetables; fruit crops; ornamentals / if required	lay out poisoned cereal grains, 5 piece(s) per hole (hide)	Zinc phosphide Max. 3 x 50
A 4 / 014, 017, 019	Home and garden use (non-professional):	lay out poisoned cereal grains, 50 g per bait station (hide)	Zinc phosphide Max. 3 x 50

	Vegetables; fruit crops; ornamentals / if required		
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6.1.2 Consideration of metabolites

Please refer to the core assessment.

6.2 Effects on birds (MIIIA 10.1, KPC 10.1, KPC 10.1.1)

For details please refer to the core assessment.

In conclusion, acceptable acute risk can only be approved when risk mitigation is considered. For intended use groups A 1 hidden application deep in the vole hole secured by using suitable application technique (e.g. application gun) is considered a feasible.

For intended use groups A 2 approval can be supported when suitable bait stations are used.

For intended use groups A 3 to A 4, UBA does not support the intended use in amateur gardening due the following reasons: According to § 2 of PflSchG plant protection measures are bound to the principles of good agricultural practise. For any approval of products for non-professional use it has to be considered that for non-professional users not the same level of expertise can be presumed as for professional users. Thus only products that require low levels of expertise and/or only simple risk mitigation measures can be authorised for non-professional users (see also “Die Zulassung von Pflanzenschutzmitteln für nicht-berufliche Anwender und zur Anwendung im Haus- und Kleingartenbereich“, BVL 2013). In order to minimize the risk for non-target species a high standard in expertise is requested for safe usage of chemical rodent control. This includes the ability to clearly distinguish between target and non-target species (not relevant for risk for birds, yet for application of the product), clearly establish that the burrows are inhabited and to accomplish compliance with the risk mitigation measures (i.e. hidden application deep in the vole holes secured by using application technique (Legeflinte)), which cannot be required from non-professional users.. Thus safe usage of a product that is designed to kill vertebrates with the risk to harm or kill non-target vertebrates such as Detia Mäuse Giftkörner to be carried out by non-professional users cannot be approved from an environmental risk assessment perspective. In contrast to the intended uses for professional users the benefits do not prevail in this case. Also, non-professional users in amateur gardening should not reach a pest infestation that requires chemical pest control of rodents as there are non-chemical measures (such as wire mesh barriers) that can be applied as prevention or from an early stage on (consulting information e.g. available via www.bi-ozid.info).

In agreement with the DAR evaluation and the applicant’s argumentation a lack of systematic continuous ingestion is presumed and thus the risk of short- and long-term exposure was not calculated.

Consequences for authorization:

No authorization for intended use groups A 3 and A 4 (non-professional use).

For intended use group A 1 (for provision of loose kernels in vole holes):

NS 648, NT 659, NT 671, NT 865, NTneu(1), NTneu(2), NTneu(3), NTneu(4)

For intended use group A 2 (for use in bait stations):

NS648, NT 659, NT 671, NT 865, NTneu(1), NTneu(2), NTneu(4), NTneu(5)

6.3 Effects on Terrestrial Vertebrates Other Than Birds (MIIIA 10.3, KPC 10.1, KPC 10.1.2)

For details please refer to the core assessment.

In conclusion, acceptable acute risk can only be approved when risk mitigation that ensures hidden application is considered.

For intended use groups A 1 hidden application deep in the vole holes by using application technique (e.g. application gun) is feasible..

For intended use group A 2 approval can be supported when suitable bait stations are used.

For intended use groups A 3 and A 4, UBA does not support the intended use in amateur gardening due the following reasons: According to § 2 of PflSchG plant protection measures are bound to the principles of good agricultural practise. For any approval of products for non-professional use it has to be considered that for non-professional users not the same level of expertise can be presumed as for professional users. Thus only products that require low levels of expertise and/or only simple risk mitigation measures can be authorised for non-professional users (see also “Die Zulassung von Pflanzenschutzmitteln für nicht-berufliche Anwender und zur Anwendung im Haus- und Kleingartenbereich“, BVL 2013). In order to minimize the risk for non-target species a high standard in expertise is requested for safe usage of chemical rodent control. This includes the ability to clearly distinguish between target and non-target species, clearly establish that the burrows are inhabited and to accomplish compliance with the risk mitigation measures (i.e. hidden application deep in the vole holes secured by using application technique (Legeflinte)), which cannot be required from non-professional users. Thus safe usage of a product that is designed to kill vertebrates with the risk to harm or kill non-target vertebrates such as Detia Mäuse Giftkörner to be carried out by non-professional users cannot be approved from an environmental risk assessment perspective. In contrast to the intended uses for professional users the benefits do not prevail in this case. Also, non-professional users in amateur gardening should not reach a pest infestation that requires chemical pest control of rodents as there are non-chemical measures (such as wire mesh barriers) that can be applied as prevention or from an early stage on (consulting information e.g. available via www.biozid.info).

Due to the lack of systematic continuous ingestion, the risk from short- and long-term exposure was not calculated (see core assessment).

Consequences for authorization:

No authorization for intended use groups A 3 and A 4 (non-professionl use).

For intended use group A 1 (for provision of loose kernels in vole holes):

NS 648, NT 659, NT 671, NT 865, NTneu(1), NTneu(2), NTneu(3), NTneu(4)

For intended use group A 2 (for use in bait stations):

NS648, NT 659, NT 671, NT 865, NTneu(1), NTneu(2), NTneu(4), NTneu(5)

6.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KPC 10.1.3)

The applicant was asked to compile current knowledge on the risk for reptiles considering likelihood of exposure by crop culture, effects and possible risk mitigation for reptiles. The applicant partly fulfilled the request, for details please refer to the core assessment.

Even though the overall risk is considered acceptable, some uncertainties remain. These uncertainties, however, are considered to be addressed by the risk mitigation measures deduced for prevention of unacceptable effects on mammals (chapter 6.3).

6.5 Effects on aquatic organisms (MIIIA 10.2, KPC 10.2, KPC 10.2.1)

The overall risk for aquatic biocenosis is expected to be low due to specific mode of application and the thereby limited exposure, yet it has to be pointed out, that acute toxicity of zinc phosphide technical for fish, *Daphnia* and algae indicates labeling as “very toxic for aquatic organisms, may cause long-term adverse effects in the aquatic environment” (relevant endpoint *Desmodesmus subspicatus* E_rC₅₀ = 3.75 µg/L).

For details please refer to the core assessment.

In order to prevent exposure incidents via run-off or wash out after rainfall, there must be a buffer zone of at least 10 m between treated areas and surface waters - including periodically but excluding occasionally water-bearing surface waters - when applying the product.

Consequences for authorization:

For the authorization of the plant protection product Detia Mäuse Giftkörner following labeling and conditions of use are mandatory:

Required Labeling

NW 262 zinc phosphide: *Desmodesmus subspicatus* NOErC 0.00140 mg/L

NW 264 zinc phosphide: *Daphnia magna*. EC₅₀ = 0.114 mg/L; *Leuciscus idus*
LC₅₀ > 0.0217 mg/L

Conditions for use

All uses NW 467
NW 704 (or equivalent new condition for use) (10 m)

6.6 Effects on bees (MIIIA 10.4, KPC 10.3.1)

Please refer to the core assessment.

Consequences for authorization:

None

6.7 Effects on arthropods other than bees (MIIIA 10.5, KPC 10.3.2)

Please refer to the core assessment.

Consequences for authorization:

None

6.8 Effects on non-target soil meso- and macrofauna (MIIIA 10.6, KPC 10.4, KPC 10.4.1, KPC 10.4.2)

Please refer to the core assessment.

Consequences for authorization:

None

6.9 Effects on soil microbial activity (MIIIA 10.7, KPC 10.5)

Please refer to the core assessment.

Consequences for authorization:

None

6.10 Effects on non-target plants (MIIIA 10.8, KPC 10.6)

6.10.1 Effects on non-target terrestrial plants (MIIIA 10.8.1)

Please refer to the core assessment.

Consequences for authorization:

None

6.11 Classification and Labelling

6.11.1 GHS Classification and Labelling

Classification and labelling

Relevant toxicity	Active substance: zink phosphide (content 0.8 %) 72-h ErC50 of 0.00323 mg/L (<i>Desmodesmus subspicatus</i>) Acute M-factor = 100 NOErC 0.00140 mg/L (<i>Desmodesmus subspicatus</i>) Chronic M-factor: 10
Classification and labelling according to Directive 67/548/EC, 78/631/EC and 1999/45/EC	
Hazard symbol	N, dangerous for the environment
Risk phrases	R 50-53
Classification and labelling according to Regulation 1272/2008	
Hazard symbol	GHS09
Signal word	No signal word used
Hazard statement	H400, H410

6.11.2 National labelling and conditions of use in Germany

Table 6.11-1 Labelling requirements according to § 36 (3) PflSchG

NW 262	zinc phosphide: <i>Desmodesmus subspicatus</i> NOErC 0.00140 mg/L
NW 264	zinc phosphide: <i>Daphnia magna</i> . EC50 = 0.114 mg/L; <i>Leuciscus idus</i> LC50 > 0.0217 mg/L

Table 6.11-2 Mandatory conditions of use according to § 36 (1) PflSchG for use no. 00-001, 00-002, 00-003, 00-005, 00-006, 00-008, 00-010, 00-011, 00-012, 00-013, 00-0014, 00-015, 00-016, 00-0018, 00-0020

NS 648	Application only if sample trappings or other suitable prognosis methods have proven that control measures are necessary.
NT 659	Do not put in exposed places.
NT 671	The product is very toxic for birds and game.
NT 865	Not to be used on or next to areas which are inhabited by hamsters.
NTneu(1)	Proposal: No application in bird sanctuaries and nature conservation areas.
NTneu(2)	Proposal: The operator should refrain from treatment if it is known that vertebrate species which are listed in Annex II or IV of Directive (EEC) 92/43 are present.
NTneu(4)	Proposal: The operator should refrain from treatment at known breeding and resting places of migrant birds during migration in reference to 2009/147/EG.
NW 467	The product and its remains, empty containers and packaging and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.
NW 704 (or equivalent new condition for use)	Due to the danger of run-off, there must be a buffer zone of at least 10 m between treated areas and surface waters - including periodically but excluding occasionally water-bearing surface waters - when applying the product.

Table 6.11-2 Additional mandatory conditions of use according to § 36 (1) PflSchG for uses no. 00-001, 00-002, 00-003, 00-005, 00-006, 00-008, 00-010

NTneu(3)	Proposal: The bait must be placed deep down in the rodent burrows by using suitable implements (i.e. application gun), to make it inaccessible for birds. There should be no bait left on the surface.
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Table 6.11-4 Additional mandatory conditions of use according to § 36 (1) PflSchG for uses no. 00-011, 00-012, 00-013, 00-015, 00-016, 00-018, 00-020

NTneu(5)	Proposal: Bait stations must be used that fulfill the following criteria: <ul style="list-style-type: none">- bait stations have to be mechanically stable, resistant to weathering and tamper-proof;- bait stations must be designed and placed in a way, that they are as inaccessible for non-target species as possible. The maximum diameter of the aperture is 6 cm for the target species common vole, field vole and bank vole;- only bait stations may be used that are legibly labelled with the following warnings: attention rodenticide, active substance, emergency number for poisonings, and „keep children and domestic animals away“
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Appendix 1 Table of Intended Uses in Germany (according to BVL 15.08.2013)

GAP rev. (No), date: 2013-08-15

PPP (product name/code)
active substance 1

Detia Mäuse Giftkörner
Zinkphosphid

Formulation type: type

Conc. of as 1: 25 g/kg

Applicant:
Zone(s):

Detia Fryberg GmbH
central

professional use x

non professional use x

Verified by MIS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
001	DE	Field crops (NNNAC)	F	Common vole (MICRAR)	lay out poi- soned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			5 piece(s) per hole (hide)
002	DE	Forest plants (NNNWW)	F	Common vole (MICRAR)	lay out poi- soned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			5 piece(s) per hole (hide)

003	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			5 piece(s) per hole (hide)
004	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			5 piece(s) per hole (hide) Amateur gardening
005	DE	Grassland, Pasture, Meadow (NNNFW)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			5 piece(s) per hole (hide)
006	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			5 piece(s) per hole (hide)
007	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			5 piece(s) per hole (hide) Amateur gardening
008	DE	Grape vine (VTIV)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			5 piece(s) per hole (hide)
009	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			5 piece(s) per hole (hide) Amateur gardening
010	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			5 piece(s) per hole (hide)
011	DE	Field crops (NNNAC)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			50 g per bait station (hide)

012	DE	Forest plants (NNNWW)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			50 g per bait station (hide)
013	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			50 g per bait station (hide)
014	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			50 g per bait station (hide) Amateur gardening
015	DE	Grassland, Pasture, Meadow (NNNFW)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			50 g per bait station (hide)
016	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			50 g per bait station (hide)
017	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			50 g per bait station (hide) Amateur gardening
018	DE	Grape vine (VITVI)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			50 g per bait station (hide)
019	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			50 g per bait station (hide) Amateur gardening
020	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned cereal grains	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			50 g per bait station (hide)

General remarks/explanations:

The GAP-Sheet should indicate if the displayed information was provided by the applicant OR was revised by the zRMS (due to the product label and Annex III data). The zRMS has to verify the presented information and to ask (the applicant) for clarification of missing details (e.g. BBCH stages, EC-codes of crops). All abbreviations in the GAP-Sheet used must be explained. Use separate worksheet for each product.

Make use of existing standards like EPPO and BBCH.

Product: Please indicate the specific variant of the active substance if relevant. If additional components have to be added to the applied product (tankmixtures), all relevant information must be provided in the column remarks. As the product usually will be determined either for professional or non professional use, this information should be given here. Otherwise to be indicated in column 4 of the GAP-sheet (conditions/location of use).

Formulation:

Type: e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

Refer to:

- GCPF Codes - GIFAP Technical Monograph No 2, (1989), 6th Edition – Revised May 2008 – Catalogue of pesticide formulation types and international coding system.
- Technical Monograph n°2, 6th Edition - Revised May 2008 - Catalogue of pesticide formulation types and international coding system (CropLife International) ¹⁾.

Conc. of as: g/kg or g/L

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Safener/Synergist: Since safeners and synergists are in scope of REG 1107/2009, information about safeners/synergists should be included in the GAP table as well.

Zone(s): All relevant zone(s) should be indicated. For interzonal uses (e.g. greenhouse, seed treatment, etc.) "EU" should be chosen.

Explanations to the particular columns:

No.: Numeration would be important when references are necessary e. g. to the dossier or to the authorisation certificate.

Member state(s): For a better general view of the valid uses for the particular zones/MS it would be helpful to mention both (the zone as well as the MS) in the column. However, to keep the table clearly arranged it seems dispensable to cite the zone; each MS is distinctly allocated to one zone; moreover the zone(s) are cited in the head of the table. Desirably MS are put in order according to the zone they belong.

Crop and/or situation: The common name(s) of the crop and the EC (EPPO)-Codes or at least the scientific name(s) [EU and Codex classifications (both)] should be used; where relevant, the situation should be described (e.g. fumigation of a structure). In case of crop groups all single crops belonging to that group should be mentioned, (either in the respective table element or – in case of a very extensive crop group - at least in a footnote). If it is not possible to mention all single crops belonging to a crop group (e.g. for horticulture), it should be referred to appropriate crop lists (e.g. EPPO, residue (codex). It would be desirable to have a "joint list" of crop groups for the zones. Exceptions of specific crops/products/objects or groups of these and restrictions to certain uses (e.g. only for seed production, fodder) must be indicated. This column should also include when indicated information concerning "crop destination or purpose of crop" and which part of plants will be used / processed (e.g. for medicinal crops roots or leaves or seeds).

Conditions / location of use: Outdoor or field use (F), glasshouse application (G) or indoor application (I) "Glasshouse" indicates that the respective trials are acceptable for all zones. As results achieved in compartments without controlled conditions (temperature, light exposure), e.g. simple plastic tunnels [for those GAPs field trials have to be conducted in the respective zone the use is applied for], are not considered to be applicable for use in other zones the kind of glasshouse should be clearly indicated. [Remark: Greenhouse definitions are at the moment under evaluation]. Conditions include also information concerning the substrate (natural soil, artificial substrate).

Pests or Group of pests controlled: Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. If necessary – in case of pest groups - exceptions (e.g. sucking insects excluding scale insects) should be indicated. In some cases, the set of pests concerned for a given crop may vary in different parts of the EU region (where appropriate the pests should be specified individually). If the product is used as growth regulator the target organism is the specific crop, whose development should be influenced; the aim could also be e.g. an empty room for treatment.

Application details:

Method / Kind:

Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, drilling, high precision drilling (with or without pneumatic systems).

Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used (e.g. ultra low volume equipment (ULVA) or low volume equipment (LVA)) should be indicated if relevant.

Timing of Application / Growth stage of crop & season:

Time(s), period, first and last treatment, e.g. autumn or spring pre- or post-emergence, at sufficient pest density or begin of infection, including restrictions (e.g. not during flowering).

Growth stage of crop (BBCH-code) – period, first and last treatment. Since the BBCH-codes are accomplished in the individual member states at different time periods the month(s) of application should be indicated in addition. BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

It seems sensible to constrain specifications in this column only to the crop, - information concerning the pest should be dealt in column "pest or group of Pests controlled". In certain circumstances it might be helpful to give information about the expected rate of interception related to the BBCH codes. In many minor crops no BBCH/interception rate scenarios have been specified so far. This could also simplify grouping for the envelope approach.

Number of applications and interval between applications

- a) Maximum number of applications per growing season used for the named crop/pest combination possible under practical conditions of use.
 b) The proposed maximum number in the crop including applications on all pests/targets on the same crop in a growing season should be given. It should be clearly indicated whether the displayed number of applications is per season, per crop cycle or per pest generation.
 Minimum interval (in days) between applications of the same product. The figure for the interval between the applications is to be set in brackets.

Application rate:

Application rate of the product per ha:

a) (Maximum) product rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).

b) Maximum product rate per growing season (especially if limited) or per crop cycle should be cited.

Especially in three dimensional crops other dose expressions (kg/l per 10.000 m² leaf wall area or kg/l per ha per meter crown (canopy) height) should be given additionally.

For seed treatment also the load of product (l/g, kg) per kg, 100 kg or unit treated seed should be stated beside the application rate per hectare. The number of seeds per (seed) unit is to be given. The maximum seed drilling rate (=number of seed sown/maximum seed volume) per row and ha should be indicated.

Information concerning the sowing method (precision drilling, ...) would be advantageous.

See also EPPQ-Guideline PP 1/239 Dose expression for plant protection products (please note, additional EPPQ-guidelines may be developed).

Application rate of the active substance per ha:

a) (Maximum) as rate per treatment (usually kg active substance / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).

b) Maximum as rate per growing season (especially if limited) or per crop cycle should be cited.

The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg active substance / ha).

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Water L/ha:

It should be clearly indicated if a stated water volume range depends upon the developmental stage of the crop (low volume – early crops stage, high volume – late crop stage) which causes a consistent concentration of the spray solution, or if a water volume range indicates different spray solution concentrations. In the last mentioned case extremely low water volumes (indicating high concentrated spray solutions) need to be covered within selectivity trials. If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.

PHI (days) – minimum pre harvest interval: PHI - minimum pre-harvest interval For some crop situations a specific PHI may not be relevant. If so an explanation (e. g. the PHI is covered by the time remaining between application and harvest.) should be given in the remarks column (e.g. crop harvest at maturity or specific growth stages).

Remarks: Remarks may include: amount of safener/synergist per ha or extent of use/economic importance/restrictions, e.g. limiting the number of uses per crop and season, if several target pests/diseases are controlled with the same product. If additional components (other ppp or adjuvant) should be used with the applied product (tankmixtures), all relevant information must be provided in the column remarks. In addition, it should be mentioned as well those mixtures are recommended or mandatory.

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product Code: Detia Mäuse Giftkörner

Reg. No.: 007851-00/00

Active Substance: zinc phosphide 25 g/kg

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Detia Freyberg GmbH

Date: December 2012

Evaluator: Julius Kühn-Institut

Date: 2018-02-06

Table of Contents

List of tables	3
Abbreviations	3
IIIA1 6	Efficacy Data and Information on the Plant Protection Product..... 4
	General information..... 4
	Recent registration situation/history of the PPP 4
	Information on the active ingredients (Uptake and mode of action) 4
	Information on crops and pests 5
IIIA1 6.1	Efficacy data..... 7
IIIA1 6.1.1	Preliminary range-finding tests 7
IIIA1 6.1.2	Minimum effective dose tests 7
IIIA1 6.1.3	Efficacy tests 7
IIIA1 6.1.4	Effects on yield and quality..... 11
IIIA1 6.1.4.1	Impact on the quality of plants and plant products 11
IIIA1 6.1.4.2	Effects on the processing procedure 11
IIIA1 6.1.4.3	Effects on the yield of treated plants and plant products..... 12
IIIA1 6.2	Adverse effects 12
IIIA1 6.2.1	Phytotoxicity to host crop..... 12
IIIA1 6.2.2	Adverse effects on health of host animals 12
IIIA1 6.2.3	Adverse effects on site of application 12
IIIA1 6.2.4	Adverse effects on beneficial organisms (other than bees)..... 12
IIIA1 6.2.5	Adverse effects on parts of plant used for propagating purposes 12
IIIA1 6.2.6	Impact on succeeding crops..... 13
IIIA1 6.2.7	Impact on other plants including adjacent crops 13
IIIA1 6.2.8	Possible development of resistance or cross-resistance 13
IIIA1 6.3	Economics 13
IIIA1 6.4	Benefits 13
IIIA1 6.4.1	Survey of alternative pest control measures 13
IIIA1 6.4.2	Compatibility with current management practices including IPM..... 13
IIIA1 6.4.3	Contribution to risk reduction..... 13
IIIA1 6.5	Other/special studies..... 13
IIIA1 6.6	Summary and assessment of data according to points 6.1 to 6.5..... 14
IIIA1 6.7	List of test facilities including the corresponding certificates 15
Appendix 1:	Lists of data considered in support of the evaluation..... 19
Appendix 2:	GAP table..... 68
Appendix 2:	GAP table central zone 74

List of tables

Table 6-1:	Identity of the active substance zinc phosphide contained in ‘Detia Mäuse Giftkörner’	5
Table 6-2:	Physical and chemical properties of active substance zinc phosphide contained in ‘Detia Mäuse Giftkörner’	6
Table 6-3:	Spectrum of activity of ‘Detia Mäuse Giftkörner’	7
Table 6-4:	Classification of agricultural uses and pest organism <i>M. arvalis</i> in the rapporteur and other member states	8
Table 6-5:	Number of efficacy trials in the EPPO Climatic Zones	17
Table 6-6:	Classification of agricultural uses and pest organism <i>M. arvalis</i> in the rapporteur and other member states	18

Abbreviations

as	active substances
PPP	plant protection product
w/w	weight by weight, mass percent

IIIA1 6 Efficacy Data and Information on the Plant Protection Product

General information

'Detia Mäuse Giftkörner' is formulated grain with a zinc phosphide and dying coat, ready for use bait to be applied underground in the common voles' holes or applied on the surface in sheltered locations or in bait stations. After ingestion of the granules and in contact with the acid milieu in the gastro-intestinal area, phosphine gas is released.

Recent registration situation/history of the PPP

The active substance zinc phosphide is registered in Germany and in countries of zone B in different rodenticidal products. 'Detia Mäuse Giftkörner' is a rodenticide approved in Germany since 1970. It is registered in Germany under the BVL authorization No 040902-00 to be used against damage by common voles (*Microtus arvalis*) by application in the voles holes.

In Germany, various zinc phosphide-containing rodenticides are permitted. Further information can be found on the BVL homepage: <https://apps2.bvl.bund.de/psm/jsp/index.jsp>.

Information on the active ingredients (Uptake and mode of action)

The old bait formulations of 'Detia Mäuse Giftkörner' had an active ingredient content of 3.0%. 'Detia Mäuse Giftkörner' is a ready to use bait containing 2.5% w/w zinc phosphide intended for the control of common voles in agricultural crops, vegetable crops, fruit crops, vinicultural crops, grassland, lawns and meadows, ornamental crops and forestry.

Information on the active substances is given in Table 6-1 and Table 6-2.

Table 6-1: Identity of the active substance zinc phosphide contained in Detia Mäuse Giftkörner

Common name	Zinc phosphide
Code number	0003
Content number	2.5
Mode of action	In an acidic environment (e.g. after ingestion), zinc phosphide develops the toxic gas phosphine (PH ₃). The gas is highly toxic to organisms undergoing oxidative respiration. As a strong reducing agent, it inhibits intracellular oxidative processes by reducing the central iron ion in hemoglobin.
Chemical structure	-
Chemical name (IUPAC)	Trizinc diphosphide
Chemical name (CA)	Zinc phosphide
Empirical formula	Zn ₃ P ₂
Molecular weight	258.1 g/mol
CAS registry number	1314-84-7
EEC number	215-244-5
CIPAC number	69

Mode of action

Detia Mäuse Giftkörner contains 25 g/kg zinc phosphide, which develops the toxic gas phosphine (PH₃). The gas is highly toxic to organisms undergoing oxidative respiration. As a strong reducing agent, it inhibits intracellular oxidative processes by reducing the central iron ion in haemoglobin. 'Detia Mäuse Giftkörner' is used as a bait agent that degasses phosphine after ingestion of the bait. It is used to control common voles in-

festing fields and meadows, orchards, forests, agricultural crops, ornamental crops, vegetable crops, viticulture including amateur gardening.

Detia Mäuse Giftkörner as a bait rodenticide, degassing phosphine after ingestion of the bait, is intended to be used in open field, either underground in holes or as surface application in bait stations or in sheltered locations.

Table 6-2: Physical and chemical properties of active substance zinc phosphide contained in 'Detia Mäuse Giftkörner'

Appearance	Solid (grain baits)
Odour	Garlic-like odour
Explosive and oxidising properties	None
Flammability, auto-flammability	The test item is not a highly flammable solid. The relative self-ignition temperature is 395°C.
Relative density	Pour density: 0.820 g/ml Tap density: 0.832 g/ml
Surface tension	Not applicable
Vapour pressure (Pa, 25°C)	Not applicable
Henry's law constant (Pa m³ mol⁻¹)	Not applicable
Water solubility (mg/l, 20°C)	Not applicable
Coefficient of partition (log P_{ow}, 25 °C)	Not applicable
Dissociation constant	Not applicable

The data presented in this registration report fully support the label claim for 'Detia Mäuse Giftkörner' for the control of common vole (*Microtus arvalis*) in agricultural areas.

Proposed uses for this product are supplied in GAP-Table. For the spectrum of activity of 'Detia Mäuse Giftkörner' see Table 6-3. 'Detia Mäuse Giftkörner' is effective against all stages of the common vole, which can feed on the bait. The rodenticidal effect of each application can be expected to last for up to seven days.

Table 6-3: Spectrum of activity of 'Detia Mäuse Giftkörner'

Crops	Agricultural areas (Agricultural crops, vegetable crops, fruit crops, viticultural crops, grassland, lawns and meadows, ornamental crops and coniferous and deciduous trees)
Pest	Common vole (<i>Microtus arvalis</i>)
Method of application	Spreading in vole holes or bait stations
Timing of application	Not defined
Application doses	5 grains/hole or 20 – 50 grains/bait station
Spray volume	Not applicable
PHI	Not required

Information on crops and pests

Fields and meadows, orchards, forests, agricultural crops, ornamental crops, vegetable crops, viticulture and amateur gardening may be infested by common voles (*Microtus arvalis*). They are described in the following.

Periodically recurrent massive proliferation of the common vole (*Microtus arvalis*) makes the animal a major pest in arable farming, grassland and specialised cultivation in Germany like vegetable crops, viticultural crops, ornamental crops, fruit crops and agricultural crops which

are all major crops. In particularly catastrophic years such as 2012, up to 80 % of winter sowing was destroyed by the animals in many areas, resulting in a consideration of the problem by the Ministers of Agriculture Conference (AMK) of the federation and the federal states. Expert discussions, involving the Federal Ministry of Food and Agriculture (BMEL), the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB), the federal state authorities, the body for authorisation of plant protection products as well as affected associations, took place with the aim of developing strategies for management of the common vole. Problems caused by this pest in Germany are described in detail in the literature (JACOB et al., 2014; NACHTIGALL, 2013; LAUENSTEIN, 2009).

***Microtus arvalis* (MICRAR)**

Common name: common voles

Description: Common voles are rodents similar to mice, but with a stouter body, a shorter tail, a slightly rounder head, smaller ears and eyes. They have a length of up to 20 cm (without tail). They are mostly active in the night or during twilight. They dig shallow galleries below the soil surface, but can also utilize old abandoned mole tunnels.

Life cycle: Common voles can have 3-10 litters per year with 4-8 young, each. Gestation lasts for 3 weeks and the young common voles reach sexual maturity within 14 days. As a result of this exponential growth, common vole populations can grow very large within a very short period of time.

Habitat and food source(s): Common voles can be found in most parts of Europe, North America and northern Asia. Common voles are strict vegetarian feeders. Their diet consists of seeds, grass, leaves, tubers, conifer needles, nuts.

Detia Mäuse Giftkörner are formulated grain with a zinc phosphide and dying coat, ready for use bait to be applied underground in the common voles' holes or applied on the surface in sheltered locations or in bait stations. After ingestion of the grains and in contact with the acid milieu in the gastro-intestinal region phosphine gas is released.

Table 6-4: Classification of agricultural uses and pest organism *M. arvalis* in the rapporteur and other member states

	EPPO code	Classification	
		major	minor
<u>Agricultural use</u> ¹⁾			
Agricultural crops	-	AT, BE, CZ, DE, PL, SK	-
Vegetable crops	-	Not available	Not available
Fruit crops	-	-	AT, BE, CZ, DE, PL, SK
Vinicultural crops	-	-	AT, BE, CZ, DE, PL, SK
Grassland, lawns and meadows	-	AT, BE, CZ, DE, PL, SK	-
Ornamental crops in the field	-	-	AT, BE, CZ, DE, PL, SK
Coniferous and deciduous trees	-	Not available	Not available
<u>Pest organism</u> ²⁾			
<i>Microtus arvalis</i>	MICRAR	AT, BE, CZ, DE, PL, SK	-

¹⁾ https://www.eppo.int/PPPRODUCTS/zonal_efficacy/zonal_efficacy.htm

²⁾ Briner et al., 2005

IIIA1 6.1 Efficacy data

IIIA1 6.1.1 Preliminary range-finding tests

The rodenticide action of the active substance and formulations based thereon has been established for more than 40 years. Reference KIIIA 6.1 refers to the effective dose of zinc phosphide for the common vole (*Microtus arvalis*). Given a body weight of 25 g for a vole and a LD50 = 440 mg/kg (acute toxicity, rat), 1 mg zinc phosphide would be sufficient to kill a vole. This dose is equivalent to the amount contained in one zinc phosphide-coated wheat grain ("Mäusegiftweizen"). One vole is able to consume 1 - 5 bait grains, but consumption of 1 - 2 grains may already be lethal. With regard to Detia Mäuse Giftkörner, which contains 1.5 mg zinc phosphide per grain, the consumption of one grain is already lethal for voles. (FÖHRING, H. 1991)

IIIA1 6.1.2 Minimum effective dose tests

No investigations were carried out with 'Detia Mäuse Giftkörner' according to EPPO standard PP 1/225 (2) Minimum effective dose. The applicant refers instead only to the publication of JACOB et al. 2009. A laboratory trial was performed in Germany in 2009 to determine the minimum effective dose of zinc phosphide against common vole. The study was published in the scientific journal Pest Management Science: Jacob, J., Budde, M., Leukers, A. (2009): Efficacy and attractiveness of zinc phosphide bait in common voles (*Microtus arvalis*), Pest Management Science 66:132-136, October 01, 2009.

Minimising the concentration of active substance in the rodenticide bait is economically desirable and preferable for the protection of the agro-ecosystem. The study aimed to identify a zinc phosphide concentration that balances palatability and efficacy for common vole management and to compare the attractiveness of two bait carriers. For this purpose, zinc phosphide-treated dyed husked wheat kernels with zinc phosphide concentrations of 0.4%, 0.8%, 1.6% and 3.2% were tested along with zinc phosphide-treated pellets containing 0.4% and 0.8% zinc phosphide.

A concentration of 2.1 % zinc phosphide seemed to balance bait uptake and bait efficacy best.

Conclusions

The examination of Jacob points, that a more or less clear dose response to the respective target organism. The applicant has set an active substance concentration of 2.5% for Detia Mäuse Giftkörner.

IIIA1 6.1.3 Efficacy tests

Zinc phosphide has been widely used as rodenticide since 1942, when other rodenticides like strychnine became limited during World War II (TIMM, 1983), and it is the most important active substance for managing pest rodents in fields and forests in Germany (JACOB et al., 2009). Already in the past, Zn₃P₂ has been considered less damaging to non-target animals when compared to strychnine (BELL and DIMMICK, 1975; SCHITOSKEY, 1975; TIETJEN, 1976; RUDD and GENELLY, 1956; HEGDAL et al., 1981; WOOD, 1965). Its successful use as an active substance in baits is reported in several publications. Results from STERNER et al. (1996) for example

demonstrated the efficacy and low hazards to non-target passerines of a single Zn_3P_2 baiting to control vole populations in alfalfa. Worldwide, zinc phosphide is also applied in pest control against several other rodents such as house mice (ADVANI, 1995), different rat species (SHEIKHER and JAIN, 1991; LEFEBVRE et al., 1985) and jirds (KHAN and AHMAD, 1991), but also against golden hamsters (BRADFIELD and GILL, 1984), ground squirrels (MATSCHKE et al., 1983), Western ghats squirrels (BHAT and MATHEW, 1981), black-tailed prairie dogs (URESK et al., 1986; HYGSTROM, et al., 1998) and others.

For the preparation of this submission, four trials were carried out to evaluate the efficacy of 'Detia Mäuse Giftkörner' for the control of common vole in agricultural areas. All trials were conducted according to GEP and followed the appropriate EPPO standards. The distribution of trials by location and year are described in Table 6-5.

Table 6-5: Number of efficacy trials in the EPPO Climatic Zones

Country	EPPO Zone		
	Maritime	South-east	North-east
Czech Republic	1	0	0
Germany	3	0	0

As shown in Table 6-5, all presented trials were conducted in the EPPO Maritime zone. However, the target organism *M. arvalis* is present all over Europe in comparable habitats. Furthermore, grain baits applied in vole holes or bait stations are protected from different climatic conditions and thus can be expected to have the same efficacy throughout the different EPPO zones. Due to these reasons, trial results can be extrapolated to the EPPO North-east and EPPO South-east zone.

Furthermore, in all presented trials baits were directly applied into vole holes. The environmental conditions for baits provided in bait stations are comparable. Thus, results from the trials, in which 'Detia Mäuse Giftkörner' is applied into vole holes can be extrapolated to an application in bait stations.

Conclusions

The applicant derives the efficacy against field mice from the toxicology of the active substance. In doing so, it is ignored that the effectiveness also depends significantly on the attractiveness and acceptance of the respective bait. The examination from Jacob et al. pointed, that a more or less clear dose response to the respective target organism.

The applicant supplementary presented four examination to this in accordance with EPPO standard PP1 169 (2) Field rodents (*Microtus*, *Arvicola*) from the years 2012 (quantity 1) and 2013 (quantity 3). The application technique was the hole treatment in all investigations. No attempts were made with the application technology bait station.

The efficacy tests were all carried out in the maritime EPPO climate zone. No efficacy studies are available for the other EPPO climatic zones.

Table 6-6: Classification of agricultural uses and pest organism *M. arvalis* in the rapporteur and other member states

		degree of efficiency [Henderson & Tilton]				
		15 DAA	14 DAA	14DAA	14 DAA	Ø
Detia Mäuse-giftkörner		83,28	94	88,5	73,9	84,92
Ratron Giftweizen		75,17	76	98,2	93,2	85,64
Testing Center		HETTERICH 2012	KONVALINKOVÁ 2013	REH 2013/08	REH 2013/12	

IIIA1 6.1.3.1 Efficacy of ‘Detia Mäuse Giftkörner’ in agricultural crops

One field trial was carried out in the Czech Republic in 2013 and a second was carried out in Germany in 2013 to assess the efficacy of the rodenticide ‘Detia Mäuse Giftkörner’ in agricultural crops. The trials were carried out according to GEP by officially recognized testing organizations and the guideline EPPO PP1 169 (2) was used. At all assessment timings, a good to very good control efficacy of common vole could be achieved by using Detia Mäuse Giftkörner. Data demonstrated that ‘Detia Mäuse Giftkörner’ at the proposed rate of 5 grains/hole was superior to the efficacy of reference product (5 grains/hole) against common vole.

Furthermore, one field trial was conducted in 2012 with ‘Detia Mäuse Giftkörner’ in a former fruit orchard in Germany and a second was carried out on grassland in Germany in 2013. Results from these trials are presented in Table 6-6, respectively and can be extrapolated to support the use in agricultural crops, because the agricultural situations are supposed to be comparable in this context.

IIIA1 6.1.3.2 Efficacy of ‘Detia Mäuse Giftkörner’ in vegetable crops

One field trial was carried out in the Czech Republic in 2013 and a second was carried out in Germany in 2013 to assess the efficacy of the rodenticide ‘Detia Mäuse Giftkörner’ in agricultural crops. The results presented in Table 6-6 can be extrapolated to support the use in vegetable crops, because the agricultural situations are supposed to be comparable in this context.

Furthermore, one field trial was conducted in 2012 with ‘Detia Mäuse Giftkörner’ in a former fruit orchard in Germany and a second was carried out on grassland in Germany in 2013. Results from these trials are presented in Table 6-6, respectively and can be extrapolated to support the use in vegetable crops, because the agricultural situations are supposed to be comparable in this context.

IIIA1 6.1.3.3 Efficacy of ‘Detia Mäuse Giftkörner’ in fruit crops

One field trial was carried out in Germany in 2012 to assess the efficacy of the rodenticide ‘Detia Mäuse Giftkörner’ in a former fruit orchard. The trial was carried out according to GEP by an officially recognized testing organization and the guideline EPPO PP1 169 (2) was used. At all assessment timings, a good to very good control efficacy of common vole could be achieved by using Detia Mäuse Giftkörner.

Furthermore, one field trial was carried out in the Czech Republic in 2013 and a second was carried out in Germany in 2013 to assess the efficacy of the rodenticide ‘Detia Mäuse Giftkörner’ in agricultural crops. In addition, one field trial was carried out in Germany in 2013 to assess the efficacy of the rodenticide ‘Detia Mäuse Giftkörner’ on grassland. The results presented in Table 6-6, respectively and can be extrapolated to support the use in fruit crops, because the agricultural situations are supposed to be comparable in this context.

IIIA1 6.1.3.4 Efficacy of ‘Detia Mäuse Giftkörner’ in vinicultural crops

One field trial was carried out in the Czech Republic in 2013 and a second was carried out in Germany in 2013 to assess the efficacy of the rodenticide ‘Detia Mäuse Giftkörner’ in agricultural crops. The results are presented in Table 6-6 and can be extrapolated to support the use in vinicultural crops, because the agricultural situations are supposed to be comparable in this context.

Furthermore, one field trial was conducted in 2012 with ‘Detia Mäuse Giftkörner’ in a former fruit orchard in Germany and a second was carried out on grassland in Germany in 2013. Results from these trials are presented in Table 6-6, respectively and can be extrapolated to support the use in vinicultural crops, because the agricultural situations are supposed to be comparable in this context.

IIIA1 6.1.3.5 Efficacy of ‘Detia Mäuse Giftkörner’ in grassland, lawns and meadows

One field trial was carried out in Germany in 2013 to assess the efficacy of the rodenticide ‘Detia Mäuse Giftkörner’ in grassland.

Furthermore, one field trial was carried out in the Czech Republic in 2013 and a second was carried out in Germany in 2013 to assess the efficacy of the rodenticide ‘Detia Mäuse Giftkörner’ in agricultural crops. The results are presented in Table 6-6 and can be extrapolated to support the use in grassland, lawns and meadows, because the agricultural situations are supposed to be comparable in this context.

Furthermore, one field trial was conducted in 2012 with ‘Detia Mäuse Giftkörner’ in a former fruit orchard in Germany. The results are presented in section Table 6-6 and can be extrapolated to support the use in grassland, lawns and meadows, because the agricultural situations are supposed to be comparable in this context.

IIIA1 6.1.3.6 Efficacy of ‘Detia Mäuse Giftkörner’ in ornamental crops

One field trial was carried out in the Czech Republic in 2013 and a second was carried out in Germany in 2013 to assess the efficacy of the rodenticide ‘Detia Mäuse Giftkörner’ in agricultural crops. The results are presented in Table 6-6 and can be extrapolated to support the use in ornamental crops, because the agricultural situations are supposed to be comparable in this context.

Furthermore, one field trial was conducted in 2012 with ‘Detia Mäuse Giftkörner’ in a former fruit orchard in Germany and a second was carried out on grassland in Germany in 2013. Results

from these trials are presented in Table 6-6, respectively and can be extrapolated to support the use in ornamental crops, because the agricultural situations are supposed to be comparable in this context.

IIIA1 6.1.3.7 Efficacy of ‘Detia Mäuse Giftkörner’ in coniferous and deciduous trees

One field trial was carried out in the Czech Republic in 2013 and a second was carried out in Germany in 2013 to assess the efficacy of the rodenticide ‘Detia Mäuse Giftkörner’ in agricultural crops. The results are presented in Table 6-6 and can be extrapolated to support the use in coniferous and deciduous trees, because the agricultural situations are supposed to be comparable in this context.

Furthermore, one field trial was conducted in 2012 with ‘Detia Mäuse Giftkörner’ in a former fruit orchard in Germany and a second was carried out on grassland in Germany in 2013. Results from these trials are presented in Table 6-6, respectively and can be extrapolated to support the use in coniferous and deciduous trees, because the agricultural situations are supposed to be comparable in this context.

IIIA1 6.1.3.8 Justification for the use of data from other countries/zones

Data from Germany and the Czech Republic have been used for compilation of the core European Biological Assessment Dossier for Detia Mäuse Giftkörner.

IIIA1 6.1.3.9 Effects of climate

The applicant notes that no indications or test results are available to him, that the climatic, edaphic or agronomic conditions in the other EU zones have a negative effect on the efficacy of Detia Mäuse Giftkörner. Detia Mäuse Giftkörner, when applied per label directions and use precautions, will provide the expected control levels of the target species.

IIIA1 6.1.3.10 Procedures for cleaning application equipment

Clean application equipment after treatment carefully with dry fabric under observance of personal safety measures.

IIIA1 6.1.4 Effects on yield and quality

IIIA1 6.1.4.1 Impact on the quality of plants and plant products

The investigation of potential effects on the quality of plants or plant products following the use of the product ‘Detia Mäuse Giftkörner’ is not considered to be required, for the following reasons: If applied in accordance with the manufacturer’s instructions, and due to the formulation type, no plant or plant product can possibly be contaminated by the active substance. Therefore, ‘Detia Mäuse Giftkörner’ will not affect the quality of plants. See also section IIIA1 6.1.4.3.

IIIA1 6.1.4.2 Effects on the processing procedure

The investigation of effects on processing procedure for the product ‘Detia Mäuse Giftkörner’ is not considered to be required, for the following reasons: Besides for the reasons given in IIIA1 6.1.4.3, no influence on processing procedure is expected.

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

The investigation of potential effects on the yield of treated plants or plant products in terms of quantity and/or quality for the product 'Detia Mäuse Giftkörner' is not considered to be required, for the following reasons:

Detia Mäuse Giftkörner is not intended for direct application to growing crops, and thus no residues in plants or in plant food stuffs are expected. Unlike conventional crop protection products, which must be applied over relatively large crop areas, zinc phosphide rodenticides like 'Detia Mäuse Giftkörner' are predominantly applied to discrete sites in the form of baits directly in the holes or onto the soil surface in bait stations. Due to the non-solubility of the active ingredient in water, zinc phosphide will not be washed out, and any relevant uptake by plants is excluded. In soil, zinc phosphide is degraded to zinc cautions and phosphine. Whereas the first is a normal constituent of soil, phosphine is a gas subject either to rapid atmospheric degradation upon volatilization, or it may be re-adsorbed onto soil and subsequently be degraded to phosphate. Therefore, no soil accumulation is expected to occur. In the soil, zinc and phosphate are taken up and metabolized by plants as trace nutrients.

IIIA1 6.2 Adverse effects

IIIA1 6.2.1 Phytotoxicity to host crop

The performance of a test on phytotoxicity to target plants (including different cultivars), or to target plant products following the use of the product 'Detia Mäuse Giftkörner' is not considered to be required for the reasons given above (IIIA1 6.1.4.3).

IIIA1 6.2.2 Adverse effects on health of host animals

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.2.3 Adverse effects on site of application

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

The product will be used as rodenticide bait. Therefore, a direct contact of soil-dwelling or ground active beneficial organisms (ground beetle, rove beetle or spiders of the genus *Pardosa*) might be possible with the product (e.g. accidental consumption of the bait). Results to the effects of Detia Mäuse Giftkörner on these beneficial organisms were not submitted. Hence, an assessment of the effect of Detia Mäuse Giftkörner on soil-dwelling or ground active beneficial organisms is not possible, when it is applied according to the recommended use pattern. Due to the proposed use pattern of the test product, populations of plant dwelling beneficial organisms will not be at risk.

Adverse effects on soil quality indicators (e. g. microorganisms, earthworms) are considered in Section 6 Ecotoxicological Studies in the Registration Report.

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

Not required for reasons given above (please refer to section IIIA1 6.1.4.3), and because of lack of exposure of other plants or adjacent crops.

IIIA1 6.2.6 Impact on succeeding crops

The submission of data or the investigation of potential residues of zinc phosphide in succeeding crops following the use of 'Detia Mäuse Giftkörner' is not considered to be required, since there is no longer that significant residues (> 10 % of the applied active substance as a total of unchanged zinc phosphide and its relevant metabolites or degradation product) remain in soil or in plant materials up to sowing or planting time of succeeding crops and which could lead to any residues at harvest. Instead, based on soil degradation studies with zinc phosphide, it is expected that degradation will be complete within approx. one month after contact with soil (if any).

IIIA1 6.2.7 Impact on other plants including adjacent crops

Not required for reasons given above (KIIIA1 6.1.4.3), and because of lack of exposure of any plants or adjacent crops.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

The applicant is not aware of any occurrence of resistance against zinc phosphide in relevant susceptible pests, despite explicit literature searches to obtain any such data. This lack of development of resistance of voles to the product is assumed to be related to the inorganic nature of the active ingredient. However, it was considered relevant to briefly summarize the existing information on reported cases of bait-shyness.

It has been reported that voles grow shy to bait after the uptake of a sub-toxic dose of zinc phosphide (BHARDWAJ and PRAKASH, 1982; BÄUMLER, 1992). Furthermore, young voles can also become bait-shy by learning from their parents (BÄUMLER, 1992). These animals show the same effect in a new test after one year with the same active substance zinc phosphide. This phenomenon could not be reversed by starving pauses or changing to other formulations with the same active substance. BHARDWAJ et al. (1984) found out that besides poison-shyness to the active substance, rodents can also grow shy to the food base of the bait.

IIIA1 6.3 Economics

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4 Benefits

IIIA1 6.4.1 Survey of alternative pest control measures

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4.2 Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4.3 Contribution to risk reduction

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.5 Other/special studies

No further information is provided

IIIA1 6.6 Summary and assessment of data according to points 6.1 to 6.5

This dossier presents a summary of the trials performed with 'Detia Mäuse Giftkörner' in the Central administrative zone (laboratory and field trials in Germany and the Czech Republic).

The Central zone has been defined based on comparable climates in the form of a 'Climatic Justification' paper as approved by EPPO and found within the standard PP 1/241(1). The applicant notes that no indications or test results are available to him, that the climatic, edaphic or agronomic conditions in the other EU zones have a negative effect on the efficacy of Detia Mäuse Giftkörner. Detia Mäuse Giftkörner, when applied per label directions and use precautions, will provide the expected control levels of the target species.

'Detia Mäuse Giftkörner' is a ready to use bait containing 2.5% w/w zinc phosphide intended for the control of common voles in agricultural crops, vegetable crops, fruit crops, vinicultural crops, grassland, lawns, meadows, ornamental crops, coniferous trees and deciduous trees.

A total of four trials were conducted between 2009 and 2013 in order to assess the efficacy of 'Detia Mäuse Giftkörner' against common vole.

'Detia Mäuse Giftkörner' showed a good effectiveness against common vole. It is recommended to use 'Detia Mäuse Giftkörner' up to three times per season resulting in a maximum amount of 6.00 kg/ha to obtain a steady efficacy. The application rate of 2.00 kg/ha per use can be divided into three single applications of 0.66 kg/ha resulting in nine applications per season. The maximum of 2.00 kg/ha per use must not be exceeded.

'Detia Mäuse Giftkörner' is a rodenticide against field mice that was been approved in Germany for more than 50 years. There are no indications of lack effectiveness of the product on the part of the plant protection service. To avoid duplication testing of vertebrate animals, no new efficacy trials requested.

There is no risk of resistance development due to the mode of action of zinc phosphide.

Detia Mäuse Giftkörner is effective bait for common vole control (*Microtus arvalis*). Its efficacy was clearly demonstrated in trials (see ref. KIIIA 6.1.1-6.1.3 and table 6.1.3-1), and by its use for more than 40 years. An impact on plants in any way is not to be expected, as zinc phosphide is degraded to soil components and plant nutrients. Besides, the active ingredient concentration of the product and the application rate are very low. Risk to non-target organisms cannot be totally excluded, but is minimized by an appropriate use of the bait, according to recommendation given on the label. There is no evidence for development of resistance against zinc phosphide, but it has been reported that voles can grow bait-shy after consumption of a sub-lethal dose. However, alternative rodenticides are available for elimination of voles and preventing a spread of zinc phosphide bait shyness. In the majority of cases, Detia Mäuse Giftkörner is potent bait with several advantages compared to other rodenticides. The lethal dose for voles is very small and the formulation type as pellets or grains minimizes the risk of fatal accidents to operators or other humans, as well as for wildlife animals.

Due to the proposed use pattern of the test product, populations of plant dwelling beneficial organisms will not be at risk.

IIIA1 6.7 List of test facilities including the corresponding certificates

Official testing station	Address	GEP certificate	Concerned studies and year
JKI Institute for cultivated plants, Vertebrate Research, Münster and Institute for Landscape Ecology, Westphalian Wilhelms University, Münster, Germany	Toppheideweg 88, 48161 Münster, Germany and Robert-Koch-Strasse 26-28, 48149 Münster, Germany	- -	Reference 6.1.2, 2009
Ingenieurbüro für landwirtschaftliche Feldversuche, Andreas Hetterich	Bamberger Strasse 50, 97359 Schwarzach, Germany	yes	Reference 6.1.3, 2012
Versuchswesen Pflanzenschutz, Dr. Paul Reh	Ehlbeek 2, 30938 Burgwedel, Germany	yes	
Testing Station Rýmařov s.r.o.	8. května 61 79501 Rýmařov, Czech Republic	yes	



Bescheinigung

Die Anerkennung der Versuchseinrichtung

Ingenieurbüro für landwirtschaftliche
Feldversuche **Andreas Hetterich**
Bamberger Str. 50, OT Düllstadt
97359 Schwarzach

mit dem Hauptsitz in

und zwei Zweigstellen in

Gerhardshagen Hof 31, 18276 Lohmen;
Dorfstr. 34, Altenberge, 49733 Haren/Ems

ist auf Antrag vom 02. März 2009 und nach Prüfung der vorgelegten Unterlagen durch die Bayerische Landesanstalt für Landwirtschaft, Institut für Pflanzenschutz, Freising, LD Wolfgang Kreckl,

am 18. Juni 2009 für

5 Jahre bis zum 19. Juni 2014

im Sinne des § 1c Abs. 3 der Pflanzenschutzmittelverordnung für die Kategorien **Ackerbau, Wiesen und Weiden, Gemüsebau, Obstbau, Weinbau verlängert worden.**

Certificate

Following the application for renewal dated from March 2, 2009 and after the audit of the documents

by the Bayerische Landesanstalt für Landwirtschaft, Institut für Pflanzenschutz, Freising, LD Wolfgang Kreckl,

the recognition of the testing facility

Ingenieurbüro für landwirtschaftliche
Feldversuche **Andreas Hetterich**

with its headquarter in

Bamberger Str. 50 OT Düllstadt
97359 Schwarzach

and two subsidiary testing units in


Gerhardshagen Hof 31, 18276 Lohmen;
Dorfstr. 34, Altenberge, 49733 Haren/Ems

has been renewed under paragraph (3) of Article 1c of the Plant Protection Products Ordinance

for 5 years to June 19, 2014

for arable farming, meadows and pastures, vegetable growing, fruit growing, viticulture,

Freising, 18. Juni 2009


Dr. Wolfgang Kreckl, Landwirtschaftsdirektor

Anerkennungsbescheinigung

Der Versuchseinrichtung: Versuchswesen Pflanzenschutz
mit Hauptsitz in: Dr. Paul Reh
30938 Burgwedel, Ehlbeek 2

und organisatorisch zugehörigen
Arbeitseinheiten in: 74933 Neidenstein, Josef-Umdasch-Str. 1

des Trägers der Versuchseinrichtung: Versuchswesen Pflanzenschutz, Dr. Paul Reh

wird auf Antrag vom: 27.08.2013

vom der: Landwirtschaftskammer Niedersachsen,
mit durchgeführter Besichtigung vom: 17.09.2013
durch: Frau G. Warnecke-Busch

das Zertifikat ist gültig bis September 2018,

eine amtliche Versuchseinrichtung im Sinne des § 8 Abs. 6 der Pflanzenschutzmittelverordnung vom 15. Januar 2013 (BGBl. I S. 74) und gemäß Verordnung (EU) Nr. 545/2011 zu sein.

Recognition Certificate

the testing facility: Versuchswesen Pflanzenschutz
with headquarter in: Dr. Paul Reh
and subsidiary testing units in: 30938 Burgwedel, Ehlbeek 2
74933 Neidenstein, Josef-Umdasch-Str. 1

supported by: Versuchswesen Pflanzenschutz, Dr. Paul Reh

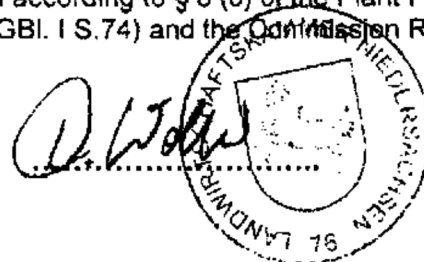
following its application dated: August 28 th, 2013

from the: Landwirtschaftskammer Niedersachsen
and pre inspection of: September 17th 2013
by: G. Warnecke-Busch

This certificate is valid until: September 2018

has been officially recognized as an organisation according to § 8 (6) of the Plant Protection Products Ordinance from 15 th January 2013 (BGBl. I S.74) and the Ordinance on Regulation (EU) Nr. 545/2011.

Hannover, 19.09.2013



STÁTNI ROSTLINOLÉKAŘSKÁ SPRÁVA

Sekce přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

V Brně dne 27. 4. 2009
Č.j.: SRS 010362/2009

OSVĚDČENÍ

č. OR/07/2009

o způsobilosti k provádění zkoušek
v souladu se zásadami správné pokusnické praxe

Official Recognition Certificate / GEP - Certificate

právníká osoba: **Zkušební stanice Rýmařov s.r.o.**

sidlo právnické osoby: 8. května 61, 795 01 Rýmařov

IČ právnické osoby: 25816322

je způsobilá k provádění zkoušek za účelem zjišťování biologické účinnosti přípravků na ochranu rostlin v souladu se zásadami správné pokusnické praxe podle § 45 odst. 2 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 91/414/EHS.

oblasti zkoušení / categories of official recognition:

- polní plodiny a zelenina / field crops and vegetables

Ing. Pavel Mlnář, Ph.D.
vedoucí sekce POR

Appendix 1: Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 3.4.2	Sterner, R.T.	1996	Efficacy of zinc phosphide baits to control voles in alfalfa - an enclosure study k.A. Crop Protection 15, 727-734 N/N J 2442690/321928	N	N		
KIIA 3.4.2	Khan, A.A., Ahmad, M.	2005	Field efficacy of the second generation anticoagulants, zinc phosphide and bromethalin against <i>Meriones hurrianae</i> Jerdon k.A. Indian J. Plant Prot. 19, 43-48 N/N J 2442691/321929	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 3.4.2	Advani, R.	1995	Mouse populations and their control in New York City k.A. Int. Biodet. Biodegr. 36, 135-141 N/N J 2442692/321930	N	N		
KIIA 3.4.2	Sheikher, C., Jain, S.D.	1991	Damage and hoarding by rodents and their control in standing wheat in Himachal Pradesh (India) k.A. Trop. Pest Managem. 37, 298-300 N/N J 2442693/321931	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 3.4.2	Bradfield, A.A.G., Gill, J.E.	1984	Laboratory trials of five rodenticides for the control of <i>Mesocricetus auratus</i> Waterhouse k.A. J. Hyg. Camb. 93, 389-394 N/N J 2442694/321932	N	N		
KIIA 3.4.2	Bhat, S.K., Mathew, D.N.	1981	Comparative toxicity of two acute rodenticides to the Western Ghats Squirrels, (<i>Funambulus tristriatus</i> , Waterhouse) k.A. Int. Pest Control 23, 132 N/N J 2442695/321933	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 3.4.2	Hygnstrom, S.E., et al.	1998	Efficacy of three formulations of zinc phosphide for managing black-tailed prairie dogs k.A. Int. Biodet. Biodegr. 42, 147-152 N/N J 2442696/321934	N	N		
KIIA 3.4.2	Uresk, D.W., et al.	1986	Efficacy of zinc phosphide and strychnine for black-tailed prairie dog control k.A. J. Range Management 39, 298-299 N/N J 2442697/321935	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 3.4.2	Matschke, G.H., et al.	1983	Efficacy of zinc phosphide broadcast baiting for controlling Richardson's ground squirrels on rangeland k.A. J. Range Management 36, 504-506 N/N J 2442698/321936	N	N		
KIIA 3.4.2	Lefebvre, L.W., et al.	1985	Efficacy of aerial application of a 2% zinc phosphide bait on roof rats in sugarcane k.A. Wildlife Soc. Bull. 13, 324-327 N/N J 2442699/321937	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 3.4.2	Koehler, A.E., et al.	1995	Weatherability and acceptance of selected commercial zinc phosphide rodent baits k.A. Int. Biodet. Biodegr. 36, 35-50 N/N J 2442700/321938	N	N		
KIIA 3.4.2	Gill, J.E., Redfern, R.	1983	Laboratory tests of seven rodenticides for the control of <i>Meriones shawi</i> k.A. J. Hyg. Camb. 91, 351-357 N/N J 2442701/321939	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 3.4.2	Tongtavee, K., et al.	1987	The safety and efficacy of brodifacoum (Klerat) wax blocks and zinc phosphide for rodent control in Thailand k.A. In: Richards, C.G.J.; Ku, T.Y. (Eds.): Control of mammal pests, 173-180 N/N J 2442702/321940	N	N		
KIIA 3.4.2	Sugihara, R.T., et al.	1995	Zinc phosphide baits and prebaiting for controlling rats in Hawaiian sugarcane k.A. J. Wildl. Manage. 59, 882-889 N/N J 2442703/321941	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 3.4.2	Proulx, G.	1998	Evaluation of strychnine and zinc phosphide baits to control northern pocket gophers (<i>Thomomys talpoides</i>) in alfalfa fields in Alberta, Canada k.A. Crop Protection 17, 135-138 N/N J 2442704/321942	N	N		
KIIA 3.4.2	Khan, A.A.	1981	Field trial of some rodenticides against the collared pika, <i>Ochotona rufescens</i> in apple orchards k.A. Int. Pest Control 23, 12-13+26 N/N J 2442705/321943	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 3.4.2	Apa, A.D., et al.	1990	Black-tailed prairie dog populations one year after treatment with rodenticides k.A. Great Basin Nat. 50, 107-114 N/N J 2442706/321944	N	N		
KIIA 3.5.1	Stephenson, J.B.P.	1967	Zinc phosphide poisoning k.A. Arch. Environ. Health 15, 83-88 N/N J 2442707/321945	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 3.5.1	Chin, K.L., et al.	1992	The interaction of phosphine with haemoglobin and erythrocytes k.A. Xenobiotica 22, 599-607 N/N J 2442708/321946	N	N		
KIIA 3.5.1	Chaudhry, M.Q., Price, N.R.	1990	A spectral study of the biochemical reactions of phosphine with various hemoproteins k.A. Pest. Biochem. Physiol. 36, 14-21 N/N J 2442709/321947	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 3.5.1	Hsu, C.-H., et al.	1998	Phosphine-induced oxidative stress in hepa 1c1c7 cells k.A. Toxicol. Sci. 46, 204-210 N/N J 2442710/321948	N	N		
KIIA 3.5.1	Hsu, C.H., et al.	2000	Phosphine induced oxidative damage in rats: attenuation by melatonin k.A. Free Radical Biol. Med. 28, 636-642 N/N J 2442711/321949	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 3.6	Baeumler, W.	1992	Bait shyness of voles (Microtinae) - Engl. transl. of German doc.: Köderscheu bei Wühlmäusen (Microtinae) k.A. Anz. Schädlingssk. Pflanzensch. Umweltsch. 65, 65-67 N/N J 2442712/321950	N	N		
KIIA 3.6	Bhardwaj, D., et al.	1984	Mitigating poison and bait-shyness developed by wild rats (Rattus rattus L.) k.A. Z. Angew. Zool. 71, 339-346 N/N J 2442713/321951	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 3.6	Bhardwaj, D., Prakash, I.	1982	Mitigation of poison aversion in the house rat <i>Rattus rattus rufescens</i> (Gray) through acclimatization k.A. Indian J. Exp. Biol. 20, 396-398 N/N J 2442714/321952	N	N		
KIIA 3.10	Anonymous	2009	Safety data sheet according to article 31 and annex II of regulation (EC) No. 1907/2006 - Zinc Phosphide k.A. k.A. N/N N 2442719/321953	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 8.12	Boawn, L.C. Rasmussen, P.E.	1971	Crop response to excessive zinc fertilization of alkaline soil k.A. Agr. J. N/N J 2442837/321954	N	N		
KIIA 8.14.1	Paul, W.	1980	Testing of secondary hazards to birds feeding on poisoned mice - Engl. transl. of German doc.: Prüfung der Sekundärgefährdung von Vögeln durch vergiftete Mäuse 52100-464-001 k.A. N/N N 2442838/321955	J	J		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 8.14.1	Ramey, C.A. Sterner, R.T.	1995	Mortality of gallinaceous birds associated with 2 percent zinc phosphide baits for control of voles in alfalfa k.A. Int. Biodet. Biodegr. N/N J 2442839/321956	J	N		
KIIA 8.14.1	Bell, H.B. Dimmick, R. W.	1975	Hazards to predators feeding on prairie voles killed with zinc phosphide k.A. J. Wildl. Manage. N/N J 2442840/321957	J	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 8.14.1	Schitoskey, F.	1975	Primary and secondary hazards of three rodenticides to kit fox k.A. J. Wildl. Manage. 39, 416-418 N/N J 2442841/321958	J	N		
KIIA 8.14.1	Tkadlec, E. Rychnovsky, B.	1990	Residues of Zn3P2 in the common vole (<i>Microtus arvalis</i>) and secondary poisoning hazards to predators k.A. Folia Zoologica N/N J 2442842/321959	J	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 8.14.1	Hill, E.F. Carpenter, J.W.	1982	Responses of siberian ferrets to secondary zinc phosphide poisoning J. Wildl. Manage. N/N J 2442843/321960	J	N		
KIIA 8.14.1	Oehme, F.W.	1970	Species differences: The basis for and importance of comparative toxicology Clin. Toxicol. 3, 5-10 N/N J 2442844/321961	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 8.14.1	Wangenheim, M. et al.	1971	Rodenticide poisonings of animals in Switzerland (Deutsche Version) k.A. Schweiz. Arch. Tierheilk. N/N J 2442845/321962	N	N		
KIIA 8.14.1	Clarke, M.L. et al.	1981	Zinc phosphide Veterinary Toxicology, 2nd Ed., 77-78 N/N J 2442846/321963	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 8.14.1	Sample, B.E. Arenal, C.A.	1999	Allometric models for interspecies extrapolation of wildlife toxicity data Bull. Environ. Contam. Toxicol. N/N J 2442847/321964	N	N		
KIIA 8.14.1	Drolet, R., et al.	1996	Zinc phosphide poisoning in a horse Equine Vet. J. N/N J 2442848/321965	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 8.14.1	Casteel, S.W. Bailey, E.M.	1986	A review of zinc phosphide poisoning Vet. Hum. Toxicol. 28, 151-154 N/N J 2442849/321966	N	N		
KIIA 8.14.1	Sterner, R.T. Mauldin, R.E.	1995	Regressors of whole-carcass zinc phosphide/phosphine residues in voles: Indirect evidence of low hazards to predators/scavengers Arch. Environ. Contam. Toxicol. 28, 519-523 N/N J 2442850/321967	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 8.14.1	Jörmann, G. Gemmcke, H.	1994	Reported pesticide poisonings of wildlife - Engl. transl. of German doc.: Meldungen über Pflanzenschutzmittelvergiftungen von Wirbeltieren (Reported pesticide poisonings of wildlife) Nachrichtenbl. Pflanzenschutzd., N/N J 2442851/321968	J	N		
KIIA 8.14.1	Jörmann, G.	1998	Reported pesticide poisonings in vertebrates (1994-1997) - Engl. transl. of German doc.: Meldungen über Pflanzenschutzmittelvergiftungen von Wirbeltieren Nachrichtenbl. Pflanzenschutzd., N/N J 2442852/321969	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 8.14.1	Anonymous	2004	Reported pesticide poisonings in vertebrates (1998-2003) - Engl. transl. of German doc.: Meldungen über Pflanzenschutzmittelvergiftungen von Wirbeltieren (1998-2003) BVL, Germany, online: www.bvl.bund.de/pflanzenschutz/Monitoring N/N J 2442853/321970	N	N		
KIIA 8.14.1	Shivaprasad, H.L. Galey, F.	2001	Diphacinone and zinc phosphide toxicity in a flock of peafowl Avian Pathology N/N J 2442854/321971	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIA 8.14.1	Bayer, U.	1982	Acceptance test in pheasants (<i>Phasianus colchicus</i>) in aviaries, with 3 different types of "Arrex" mouse baits - Engl. transl. of German doc. 1-9-345-82 k.A. N/N N 2442855/321972	J	J		
MIIA Sec 1	Anonymus	2005	MIIA - Section 1, Tier II, Annex II k.A. k.A. N/N N 2442877/321977	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
MIIA Sec 1	Anonymous	2005	Attachment: MIIA - Section 1 k.A. k.A. N/N N 2442878/321978	N	N		
MIIA Sec 1	Anonymous	2009	MIIA - Section 1, Tier II, Annex II- Amendment 1 k.A. k.A. N/N N 2442879/321979	N	N		
MIIA Sec 6	Anonymous	2005	MIIA - Section 6, Tier II, Annex II k.A. k.A. N/N N 2442890/321981	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
Document MIIIA1	Anonymous	2012	Document MIIIA1 Section 1 O/O N 2447302/321985	N	O		
MIIIA1 Sec 6	Anonymous	2012	Document MIIIA1 Section 6 O/O N 2447306/321987	N	O		
MIIIA1 Sec 7	Anonymous	2012	Document MIIIA1 Section 7 O/O N 2447307/321988	N	O		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
Document N	Anonymous	2012	Document N1, the active substance, its properties, uses, proposed classification and labelling O/O N 2448511/321990	N	O		
Document N	Anonymous	2012	Document N2, methods of analysis O/O N 2448564/321991	N	O		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
Document N	Anonymous	2012	Document N3, impact on human and animal health O/O N 2448565/321992	N	O		
Document N	Anonymous	2012	Document N 4, Residues O/O N 2448566/321993	N	O		
Document N	Anonymous	2012	Document N 5, fate and behaviour in the environment O/O N 2448567/321994	N	O		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
Document N	Anonymous	2012	Document N6, effects on non-target species O/O N 2448568/321995	N	O		
Document N	Anonymous	2012	Document N7, efficacy data O/O N 2448569/321996	N	O		
Document N	Anonymous	2012	Document N final O/O N 2448570/321997	N	O		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 4.1.1	Thiels, J.	2012	Produktinformation Agro Pack Dual 250 ml HDPE UN 1350801 Kautex Textron GmbH & Co.KG, Bonn- Duisdorf, DE N/O J 2453157/322002	N	N		
Document C	Anonymus	2012	Etikett-Entwurf: 1 kg-Eimer: Detia Mäuse Giftkörner N/N N 2453597/322007	N	N		
Document C	Anonymus	2012	Etikett-Entwurf: 5 kg-Eimer: Detia Mäuse Giftkörner N/N N 2453598/322008	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
Document C	Anonymus	2012	Etikett-Entwurf: 25 kg-Sack: Detia Mäuse Giftkörner N/N N 2453599/322009	N	N		
Document C	Anonymus	2012	Etikett-Entwurf: 180 g- Kunststoffdose: Detia Mäuse Giftkörner N/N N 2453600/322010	N	N		
KIIIA1 6.1.2	Jakob, J.; Budde, M.; Leukers, A.	2009	Efficacy and attractiveness of zinc phosphide bait in common voles (<i>Microtus arvalis</i>) N/J N 2453601/322011	N	J		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.3	Lindemann, A.; Hetterich, A.	2012	Efficacy of rodenticides Detia Mäuse Giftkörner against <i>Microtus arvalis</i> Detia2012Het01 N/J N 2453602/322012	N	J		
KIIIA1 3.9	Anonymus	2012	Gebrauchsanleitung Etikett-Entwurf: 1 kg-Eimer: Detia Mäuse Giftkörner N/N N 2500984/322013	N	N		
KIIIA1 3.9	Anonymus	2012	Gebrauchsanleitung Etikett-Entwurf: 5 kg-Eimer: Detia Mäuse Giftkörner N/N N 2500986/322014	N	N		

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 3.9	Anonymus	2012	Gebrauchsanleitung Etikett-Entwurf: 25 kg-Sack: Detia Mäuse Giftkörner N/N N 2500987/322015	N	N		
KIIIA1 3.9	Anonymus	2012	Gebrauchsanleitung Etikett-Entwurf: 180 g-Kunststoffdose: Detia Mäuse Giftkörner N/N N 2500988/322016	N	N		
KIIIA1 6	Nachtigall, G.	2013	Expertengespräch am Julius Kühn-Institut zieht Bilanz zu Feldmaus-Massenvermehrung und Schäden im Jahr 2012 JKI-Homepage N/N J 2720738/373383	N	N		LIT

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA16	Lauenstein, G.	2009	Die nächste Mäuseplage kommt bestimmt Top agrar O/O J 2720739/373385	N	N		LIT
KIIIA16	Mackin-Rogalska, R., Nabaglo, L.	1990	Geographical Variation in cyclic periodicity and synchrony in the common vole, <i>Microtus arvalis</i> Oikos O/O J 2720742/373387	N	N		LIT

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA16	Truszowski, J.	1982	The Impact of the Common Vole on the Vegetation of Agroecosystems Acta Theriologica O/O J 2720743/373389	N	N		LIT
KIIIA16	Jacob, J., Manson, P., Barfknecht, R., Fredricks, T.	2013	Common vole (Microtus arvalis) ecology and Management: Implications for risk assessment of plant protection products N/N J 2720744/373391	N	N		LIT

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.3	Bhat, S.K., Mathewt, D.N.	19 81	Comparative toxicity of two acute rodenticides to the Western Ghats Squirrel, (Funambulus tristriatus Waterhouse) N/N J 2720913/373393	N	N		LIT
KIIIA1 6.1.3	Advani, R.	19 95	Mouse Population and their control in New York City N/N J 2720914/373395	N	N		LIT

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.3	Bell, H., Dimmick, R.	19 75	Hazards to predators feeding on prairie voles killed with zinc phosphide The Journal of Wildlife Management O/O J 2720915/373396	N	N		LIT
KIIIA1 6.1.3	Bradfield, A. Gill, J.	19 84	Laboratory Trials of five rodenticides for the control of Mesocricetus auratus Journal of Hygiene (Cambridge) O/O J 2720916/373397	N	N		LIT

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.3	Hegdal, P., Gatz, T., Fite, E.	1981	Secondary effects of rodenticides on mammalian predators the Worldwide Furbearer Conference Proceedings O/O N 2720917/373399	N	N		LIT
KIIIA1 6.1.3	Hygnstrom, S., McDonald, P., Dallas, R.	1998	Efficacy of three formulations of zinc Phosphide for Managing black-tailed prairie dogs International Biodeterioration & Biodegradation O/O J 2720918/373401	N	N		LIT

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.3	Khan, A., Ahmad, M.	19 91	Field efficacy of the second Generation anticoagulants, zinc Phosphide and bromethalin against Meriones hurrianae Jerdon Indian Journal of Plant Protection O/O J 2720919/373403	N	N		LIT
KIIIA1 6.1.3	Lefebvre, L., Holler, N., Decker, D.	19 85	Efficacy of Aerial application of 2 % zinc Phosphide bait on Roof rats in surgarcane Wildlife Society Bulletin O/O J 2720920/373405	N	N		LIT

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.3	Matschke, G, Marsh, M. Otis, D.	1983	Efficay of Zinc Phosphide Broatcast Baiting for Controlling Richardson's Ground Squirrels on Rangeland Journal of Range Management O/O J 2720921/373407	N	N		LIT
KIIIA1 6.1.3	Rudd, R., Genelly, R.	1956	Pesticides: Their use and toxicity in relation to Wildlife O/O J 2720922/373409	N	N		LIT

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.3	Schitoskey, F.	1975	Primery and Secondary hazards of three Rodenticides to kit Fox The Journal of Wildlife Management O/O J 2720923/373411	N	N		LIT
KIIIA1 6.1.3	Sugihara, R., Tobin, M., Koehler, A.	1995	Zinc Phosphide baits and prebaiting for Controlling rats in Hawaiian sugarcane The Journal of Wildlife Manangement O/O J 2720926/373413	N	N		LIT

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.3	Bhardwaj, D., Prakash, I.	1982	Mitigation of Poison Aversion in the house rat <i>Rattus rattus rufescens</i> (grey) through acclimatization Indian Journal of Experimental Biology O/O J 2720931/373415	N	N		LIT
KIIIA1 6.1.3	Reh, P.	2013	An Evaluation of the efficacy of baits, containing zinc Phosphide, against field mouse (<i>Microtus arvalis</i>) in Germany 2013 VP-13-4-81D2 N/J N 2721060/373421	N	J		Detia Freyberg

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.3	Reh, P.	2013	An Evaluation of the efficacy of baits, containing zinc Phosphide, against field mouse (<i>Microtus arvalis</i>) in Germany 2013 - First Amendment - VP-13-4-81D2 N/J N 2721061/373423	N	J		Detia Freyberg
KIIIA1 6.1.3	Reh, P.	2013	An Evaluation of the efficacy of baits, containing zinc Phosphide, against field mouse (<i>Microtus arvalis</i>) in Germany 2013 VP-13-4-81D3 N/J N 2721062/373426	N	J		Detia Freyberg

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.3	Ruzicka, A.	20 13	An Evaluation of the efficacy of Stutox II and Detia Mäuse Giftkörner for the control of Common Voles (<i>Microtus arvalis</i>) in the Czech Republic DELIRYMI13/0709 N/J N 2721063/373428	N	J		Detia Freyberg
KIIIA1 6	Anonymo us	20 14	Biological Assessment Dossier N/N N 2721075/373430	N	N		Detia Freyberg

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
MIIA Sec 1	Anonymus	2014	Document M Section 1 - Detia Mäuse Giftkörner N/N N 2721117/373432	N	J		DEL
MIIIA1 Sec 6	Detia Freyberg GmbH	2014	M-III, Sektion 6 O/O N 2721118/373434	N	O		Detia Freyberg
MIIIA1 Sec 7	Anonymus	2014	Registration Report - Part B - N/N N 2721119/373436	N	J		Detia Freyberg

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.3	Sheikher, C., Jain, S.D.	1991	Damage and hoarding by rodents and their control in wheat in Himachal Pradesh Tropical Pest Management N/N J 2721379/373438	N	J		LIT
KIIIA1 6.1.3	Sterner, R.T., Ramey, C.A., Edge, W.D., Manning, T.	1996	Efficacy of Zinc phosphide baits to control voles in Alfalfa - an enclosure study Crop Protection N/N J 2721383/373440	N	N		LIT

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.1.3	Tietjen, H.P.	20 14	Zinc Phosphide - Its development as a control agent for black-tailed prairie dogs N/N J 2721386/373443	N	N		LIT
KIIIA1 6.1.3	Wood, J.E.	19 65	Response of rodent populations to controls Journal of Wildlife Management N/N J 2721390/373445	N	N		LIT

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 6.2.8	Bäumler, W.	19 92	Köderscheu bei Wühlmäusen _ Microtinae Anzeiger für Schädlingskunde Pflanzenschutz Umweltschutz N/N J 2721393/373447	N	N		LIT
KIIIA1 6.1.2	Tkadlec, E., Rychnovsky, B.	19 90	Residues of Zinc Phosphide in (Microtus arvalis) and secondary poisoning hazards to predators Folia Zoologia N/N J 2721658/373449	N	N		LIT

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner

List of data submitted by the applicant and not relied on

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner

List of data relied on and not submitted by the applicant but necessary for evaluation

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner

Appendix 2: GAP table

Reg.-No. 007851-00/00
 PPP (product name/code): Detia Mäuse Giftkörner
 Active substance 1: Zinkphosphid
 Active substance 2:
 Active substance 3:
 Active substance 4:
 Active substance 5:
 Applicant: Detia Freyberg GmbH
 Zone(s): central/interzonal (d)
 Verified by MS: Yes

GAP rev.1, date: 2018-01-22
 RB (a,b)
 Formulation type: 25.00 g/kg (c)
 Conc. of as 1: 0 (c)
 Conc. of as 2: 0 (c)
 Conc. of as 3: 0 (c)
 Conc. of as 4: 0 (c)
 Conc. of as 5: 0 (c)
 Professional use: Yes
 Non professional use: Yes
 Field of use: Rodenticide

1 Use- No. (e)	2 Member state(s)	3 Crop and/ or situation (crop destina- tion / purpose of crop)	4 F, Fn, Fpn G, Gn, Gp n or l	5 Pests or Group of pests controlled (Additionally: develop- mental stages of the pest or pest group)	6			7		8		9		10		11		12		13 PHI (days)	14 Remarks: e.g. g safen- er/synergist per ha (f)	15 Conclusion (efficacy)
					Method Kind	Timing Growth stage of crop & season	Timing /	Max. number of use & per crop/ season	Min. interval between applications (days)	kg or L prod- uct / ha per appl. a) max. rate b) max. total rate crop/season	g or kg as/ha per appl. a) max. rate b) max. total rate crop/season	Water L/ha min / max	Application rate	Application rate	Application rate	Application rate	Application rate					
001	DE	field crops (NNNAC)	F	Common vole (MI- CRAR)	lay hide poisoned cereal grains / until up- take stops	if required	a) b)	a) b)	a) b)	a) b)	a) b)	a) b)	a) b)	a) b)	a) b)	a) b)	a) b)	a) b)	a) b)	-	Rate App. com- ment: treatments can be split into three separate partial treatments at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 5 pieces per hole	A
002	DE	forest plants (NNNWW)	F	Common vole (MI- CRAR)	lay hide poisoned cereal grains / until up- take	if required	a) b)	a) b)	a) b)	a) b)	a) b)	a) b)	a) b)	a) b)	a) b)	a) b)	a) b)	a) b)	a) b)	-	Rate App. com- ment: treatments can be split into three separate partial treatments	A

003	DE	vegetables (NNNVV)	F	Common vole (MI-CRAR)	stops lay out / hide poisoned cereal grains / until up- take stops	if required	a) b) 3	3		a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 5 pieces per hole	A
004	DE	vegetables (NNNVV)	F	Common vole (MI-CRAR)	stops lay out / hide poisoned cereal grains / until up- take stops	if required	a) b) 3	3		a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	Rate App. com- ment: treatments can be split into three separate partial treatments at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 5 pieces per hole	A
005	DE	grassland, pas- ture, meadow (NNNFW)	F	Common vole (MI-CRAR)	stops lay out / hide poisoned cereal grains / until up- take stops	if required	a) b) 3	3		a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	Rate App. com- ment: treatments can be split into three separate partial treatments at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 5 pieces per hole	A
006	DE	fruit (NNNOO)	F	Common vole (MI-CRAR)	stops lay out / hide	if required	a) b) 3	3		a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	Rate App. com- ment: treatments can be split into three separate partial treatments at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 5 pieces per hole	A

007	DE	fruit (NNNOO)	vine (VITV)	F	Common vole (MIVOLE)	poisoned cereal grains / until uptake stops	lay out / hide poisoned cereal grains / until uptake stops	if required	a) 3 b) 3	a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	ment: treatments can be split into three separate partial treatments at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 5 pieces per hole	A
008	DE	grape (VITV)	vine (VITV)	F	Common vole (MIVOLE)	poisoned cereal grains / until uptake stops	lay out / hide poisoned cereal grains / until uptake stops	if required	a) 3 b) 3	a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	Rate App. comment: treatments can be split into three separate partial treatments at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 5 pieces per hole	A
009	DE	ornamentals (NNNZZ)	vine (VITV)	F	Common vole (MIVOLE)	poisoned cereal grains / until uptake stops	lay out / hide poisoned cereal grains / until uptake stops	if required	a) 3 b) 3	a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	Amateur gardening Rate App. comment: treatments can be split into three separate partial treatments at 0.66 kg/ha each	A

010	DE	ornamentals (NNNZZ)	F	Common vole (MI-CRAR)	lay out / hide / poisoned cereal / grains / until up- take stops	if required	a) b) 3	3		a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	Notes on dose rate: the dose corresponds to 5 pieces per hole Rate App. comment: treatments can be split into three separate partial treatments at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 5 pieces per hole	A
011	DE	field crops (NNNAC)	F	Common vole (MI-CRAR)	lay out / hide / poisoned cereal / grains / until up- take stops	if required	a) b) 3	3		a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	Rate App. comment: treatments can be split into three separate partial treatments at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 50 g per bait station	A
012	DE	forest plants (NNNWW)	F	Common vole (MI-CRAR)	lay out / hide / poisoned cereal / grains / until up- take stops	if required	a) b) 3	3		a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	Rate App. comment: treatments can be split into three separate partial treatments at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 50 g per bait station	A
013	DE	vegetables (NNNVV)	F	Common vole (MI-CRAR)	lay out / hide / poisoned cereal / grains / until up-	if required	a) b) 3	3		a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	Rate App. comment: treatments can be split into three separate partial treatments	A

014	DE	vegetables (NNNVV)	F	Common vole (MI-CRAR)	take stops lay out / hide poisoned cereal grains / until up- take stops	if required a) 3 b) 3	a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 50 g per bait station	A
015	DE	grassland, pas- ture, meadow (NNNFW)	F	Common vole (MI-CRAR)	lay out / hide poisoned cereal grains / until up- take stops	if required a) 3 b) 3	a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	Rate App. com- ment: treatments can be split into three separate partial treatments at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 50 g per bait station	A
016	DE	fruit crops (NNNOO)	F	Common vole (MI-CRAR)	lay out / hide poisoned cereal grains / until up- take stops	if required a) 3 b) 3	a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	Rate App. com- ment: treatments can be split into three separate partial treatments at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 50 g per bait station	A
017	DE	fruit crops (NNNOO)	F	Common vole (MI-CRAR)	lay out / hide poisoned cereal grains / until up- take stops	if required a) 3 b) 3	a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	Rate App. com- ment: treatments can be split into three separate partial treatments at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 50 g per bait station	A

018	DE	grape (VITV)	vine	F	Common vole (MIL-CRAR)	poisoned cereal grains / until up-take stops	lay out / hide poisoned cereal grains / until up-take stops	If required	a) 3 b) 3	a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	ing Rate App. comment: treatments can be split into three separate partial treatments at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 50 g per bait station	A
019	DE	ornamentals (NNZZ)	ornamentals	F	Common vole (MIL-CRAR)	poisoned cereal grains / until up-take stops	lay out / hide poisoned cereal grains / until up-take stops	If required	a) 3 b) 3	a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	Rate App. comment: treatments can be split into three separate partial treatments at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 50 g per bait station	A
020	DE	ornamentals (NNZZ)	ornamentals	F	Common vole (MIL-CRAR)	poisoned cereal grains / until up-take stops	lay out / hide poisoned cereal grains / until up-take stops	If required	a) 3 b) 3	a) 2 kg/ha b) 6.00 kg/ha	a) 0.05kg/ha b) 0.15kg/ha	-/ kg/ha	-	Amateur gardening Rate App. comment: treatments can be split into three separate partial treatments at 0.66 kg/ha each Notes on dose rate: the dose corresponds to 50 g per bait station	A

													Notes on dose rate: the dose corresponds to 50 g per bait station
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Remarks table heading:

- (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 (b) Catalogue of pesticide formulation types and international coding system Crop Life International Technical Monograph n°2, 6th Edition Revised May 2008
 (c) g/kg or g/l
- (d) Select relevant
 (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
 (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

- Numeration necessary to allow references
- Use official codes/nomenclatures of EU Member States
- For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
- F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
- Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
- Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 38263-3152-4), including where relevant, information on season at time of application
- The maximum number of application possible under practical conditions of use must be provided.
 9 Minimum interval (in days) between applications of the same product
 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
 12 If water volume range depends on application equipment (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
 13 PHI - minimum pre-harvest interval
 14 Remarks may include: Extent of use/economic importance/restrictions
 15 A: Acceptable
 R: Acceptable with further restriction
 C: To be confirmed by cMS
 N: Not acceptable / evaluation not possible
 n.r.: Not relevant for section 3

Appendix 2: GAP table central zone

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-Member	state(s)	Crop	and/ F	Pests or Group of	Application			Application rate	PHI	Remarks:		

No.	or situation (crop destination / purpose of crop)	G or I	pests controlled (additionally: developmental stages of the pest or pest group)	Method Kind	Timing Growth stage of crop & season	Max. number interval between applications) a) per use b) per crop/season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	(days)	e.g. safener/synergist per ha
1	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
2	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
3	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
4	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop or (crop destination purpose of crop)	F G or I	Pests or Group of pests (additionally: devel- opmental stages of the pest or pest group)	Application		Max. number interval between appli- cations) a) per use b) per crop/ season	Application rate		PHI (days)	Remarks:	
					Method / Kind	Timing / Growth stage of crop & season		kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season			Water L/ha min / max
5	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Fruit crops	F	Common vole (<i>Microtus arvalis</i>)	in holes	in vole holes	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.
6	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Fruit crops	F	Common vole (<i>Microtus arvalis</i>)	in stations	in bait stations	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.
7	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vinicultural crops	F	Common vole (<i>Microtus arvalis</i>)	in holes	in vole holes	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop or (crop destination purpose of crop)	F G or I	Pests or Group of pests (additionally: devel- opmental stages of the pest or pest group)	Application		number interval between appli- cations) a) per use b) per crop/ season	Application rate		PHI (days)	Remarks:	
					Method Kind	Timing Growth stage of crop & season		kg, L product / ha a) max. rate b) max. total rate per crop/season	g, kg as/ha a) max. rate b) max. total rate per crop/season			Water L/ha min / max
8	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vinicultural crops	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
9	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Grassland, lawns and meadows	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
10	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Grassland, lawns and meadows	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
11	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Po-	Ornamental crops	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop or (crop destination purpose of crop)	F G or I	Pests or Group of pests (additionally: devel- opmental stages of the pest or pest group)	Application		Max. interval between appli- cations) a) per use b) per crop/ season	Application rate		PHI (days)	Remarks:	
					Method / Kind	Timing / Growth stage of crop & season		kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season			Water L/ha min / max
	land, Romania, Slovakia, Slovenia, United King- dom)											e.g. g safener/synergist per ha applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
12	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxem- bourg, Netherlands, Po- land, Romania, Slovakia, Slovenia, United King- dom)	Ornamental crops	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
13	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxem- bourg, Netherlands, Po- land, Romania, Slovakia, Slovenia, United King- dom)	Coniferous and deci- duous trees	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
14	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxem- bourg, Netherlands, Po- land, Romania, Slovakia, Slovenia, United King- dom)	Coniferous and deci- duous trees	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop or (crop destination purpose of crop)	F G or I	Pests or Group of pests (additionally: devel- opmental stages of the pest or pest group)	Application		Max. interval between appli- cations) a) per use b) per crop/ season	Application rate		PHI (days)	Remarks:	
					Method / Kind	Timing / Growth stage of crop & season		kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season			Water L/ha min / max
15	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vegetable crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in holes	in vole holes	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.
16	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Vegetable crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in stations	in bait stations	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.
17	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Fruit crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in holes	in vole holes	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded.

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop or (crop destination purpose of crop)	F G or I	Pests or Group of pests (additionally: devel- opmental stages of the pest or pest group)	Application		Max. interval between appli- cations) a) per use b) per crop/ season	Application rate		PHI (days)	Remarks:	
					Method Kind	Timing Growth stage of crop & season		kg, L product / ha a) max. rate b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season			Water L/ha min / max
18	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Fruit crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
19	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Ornamental crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in vole holes	Not defined	a) 3 b) 9	5 grains / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
20	Central zone (Austria, Belgium, Czech Republic, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, United Kingdom)	Ornamental crops (home and garden use)	F	Common vole (<i>Microtus arvalis</i>)	in bait stations	Not defined	a) 3 b) 9	20-50 g /bait station a) 2.00kg/ha b) 6.00kg/ha	a) 50 g as/ha b) 150 g as/ha	n.a.	Not required	Type/formulation: RB The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. The maximum of 2.00kg/ha per use must not be exceeded. A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.

Remarks: (a) In case of group of crops the Codex classification should be used

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting,

-
-
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and sucking insects, soil born insects, foliar fungi
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) Use CIPAC/FAO Codes where appropriate
- (f) All abbreviations used must be explained
- drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants
- (i) g/kg or g/l
- (j) Growth stage at last treatment
- (k) PHI = Pre-harvest interval
- (l) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications