REGISTRATION REPORT
Part A

Risk Management

Product name: **Arvalin Forte (Stutox II)**

Active Substance: **25 g/kg zinc phosphide**

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant: **Detia Freyberg GmbH**

Date: **12/06/2018**

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of Arvalin Forte (Stutox – II) 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/registration by the EU review. It also includes assessment of data and information relating to Arvalin Forte where that data has not been considered in the EU review. Otherwise assessments for the safe use of Arvalin Forte 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 registration of Arvalin Forte.

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

Appendix 2 of this document is a copy of the approved product label for Germany
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 made 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.
Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

1 Details of the application

1.1 Application background

This application was submitted by Detia Freyberg GmbH on 16 July 2013.

The application was for approval of Arvalin Forte, a Ready to use bait containing 25 g/kg zinc phosphide for use as a rodenticide.

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 approval the product Arvalin Forte 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 first approval of this product in Germany in accordance with the above.

1.4 Data protection claims

Where data protection is being claimed regarding information supporting registration of Arvalin Forte, 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	Arvalin Forte (Stutox – II)
Authorization Number (for re-registration)	008023-00/00
Function	Rodenticide
Applicant	Detia Freyberg GmbH
Composition	25 g/kg zinc phosphide
Formulation type	Ready to use bait [Code: RB]
Packaging	10 kg buckets cardboard (containing 2 PE bags a 5 kg)

2.2 Classification and labelling

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

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

Hazard classes and categories:	
Acute Tox. 4, Aquatic acute 1, Aquatic chronic 1	
Hazard pictograms:	
GHS07	exclamation mark
GHS09	environment
Signal word:	
Warning	
Hazard statements:	
H302	Harmful if swallowed.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Precautionary statemtents:	
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 no eat, drink or smoke when using this product.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312+P330	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.
P391	Collect spillage.
P404	Store in a closed container.
P405	Store locked up.
P501	Dispose of contents/container to ...
Additional labelling phrases:	
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.

2.2.2 R and S phrases under Regulation (EC) 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 the reach of children.
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 prod-ucts" 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.
SF531	Protective gloves (plant protection) must be worn when collecting remaining baits and when cleaning bait stations.
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.
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)

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 – 014

NT802 Not to be used in nature reserves and bird protection areas.
Uses: 001 – 014

NT803 Not to be used in resting areas of migratory birds on their migratory routes.
Uses: 001 – 014

NT820 Not to be used in areas inhabited by European hamster, hazel dormouse, northern birch mouse or Bavarian pine vole.
Uses: 001 – 014

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, 007, 009, 011, 013

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: 002, 004, 006, 008, 010, 012, 014

2.3 Product uses

GAP-Table of intended uses for Germany

GAP rev. 1, date: 2017-03-17

PPP (product name/code)	**Arvalin Forte**	**Formulation type:**	**RB**
active substance 1	**Zinkphosphid**	**Conc. of as 1:**	**25 g/kg**
Applicant:	**Detia Freyberg GmbH**	**professional use**	**x**
Zone(s):	**central**	**non professional use**	

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)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					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		
001	DE	Field crops (NNNAC)	F	Common vole (MICRAR)	lay out |from poison-onous pellets / hidden / in burrow systems or per hole/ until uptake stops	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*	The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. * The PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product 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
002	DE	Field crops (NNNAC)	F	Common vole (MICRAR)	lay out |from poison-onous pellets / hidden / in suitable bait stations / until uptake stops	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	The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. NT680, NT802, NT803, NT820, NW704 No authorisation possible, because efficacy trails are missing
003	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out |from poison-onous pellets / hidden / in burrow systems or per hole/ until uptake stops	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	The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. NT664, NT802, NT803, NT820, NW704
004	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out |from poison-onous pellets / hidden / in suitable bait stations / until uptake stops	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	The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. NT680, NT802, NT803, NT820, NW704 No authorisation possible, because efficacy trails are missing.
005	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out	if required	a) 3	a) 2 kg/ha	a) 50 g as/ha		F	The dose corresponds to 4

					|from poison-onous pellets / hidden / in burrow systems or per hole/ until uptake stops		b) 3	b) 6 kg/ha	b) 150 g as/ha			pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. NT664, NT802, NT803, NT820, NW704
006	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out |from poison-onous pellets / hidden / in suitable bait stations / until uptake stops	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	The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. NT680, NT802, NT803, NT820, NW704 No authorisation possible, because efficacy trails are missing
007	DE	Grape vine (VITVI)	F	Common vole (MICRAR)	lay out |from poison-onous pellets / hidden / in burrow systems or per hole/ until uptake stops	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	The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. NT664, NT802, NT803, NT820, NW704
008	DE	Grape vine (VITVI)	F	Common vole (MICRAR)	lay out |from poison-onous pellets / hidden / in suitable bait stations / until uptake stops	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	The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. NT680, NT802, NT803, NT820, NW704

												No authorisation possible, because efficacy trails are missing
009	DE	Grassland, pasture, meadow (NNNFW)	F	Common vole (MICRAR)	lay out |from poison-onous pellets / hidden / in burrow systems or per hole/ until uptake stops	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	The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. NT664, NT802, NT803, NT820, NW704
010	DE	Grassland, pasture, meadow (NNNFW)	F	Common vole (MICRAR)	lay out |from poison-onous pellets / hidden / in suitable bait stations / until uptake stops	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	The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. NT680, NT802, NT803, NT820, NW704 No authorisation possible, because efficacy trails are missing
011	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out |from poison-onous pellets / hidden / in burrow systems or per hole/ until uptake stops	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*	The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. *The setting of a PHI is without any relevance. NT664, NT802, NT803, NT820, NW704
012	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out |from poison-	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	The dose corresponds to 50 g per bait station The application rate of

					onous pellets / hidden / in suitable bait stations / until uptake stops							2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. NT680, NT802, NT803, NT820, NW704 No authorisation possible, because efficacy trails are missing
013	DE	Forest plants (NNNWW)	F	Common vole (MICRAR)	lay out |from poison-onous pellets / hidden / in burrow systems or per hole/ until uptake stops	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	The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. NT664, NT802, NT803, NT820, NW704
014	DE	Forest plants (NNNWW)	F	Common vole (MICRAR)	lay out |from poison-onous pellets / hidden / in suitable bait stations / until uptake stops	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	The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha. NT680, NT802, NT803, NT820, NW704 No authorisation possible, because efficacy trails are missing

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 has the appearance of inhomogeneous, flecked with grey pellets with a cereal like odour. It is not explosive, has no oxidising properties and a self ignition temperature of 388 °C. The pour and tap density of the formulation is 0.712 g/mL and 0.763 g/mL respectively.The stability data indicate a shelf life of at least 2 years at ambient temperature.
The technical characteristics are acceptable for ready to use bait formulation.

Implications for labelling:

None

Compliance with FAO specifications:
There is no FAO specification for zinc phosphide.

Compliance with FAO guidelines:
The product Arvalin Forte complies with the general requirements according to the FAO/WHO manual (2010).

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 Arvalin Forte 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)

An analytical method for determination of the active substance zinc phosphide in the formulation is available. However, further information on accuracy and specifity is missing.

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 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 phosphane, the toxicologically active compound, will be quickly exhaled or metabolised to phosphates, which would not be found in analysis.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

The product Arvalin Forte contains the active substance zinc phosphide and more than 90% non-toxic bait formulants (foodstuff). In contrast to other metal phosphides, zinc phosphide is practically insoluble in water or organic solvents. It is degraded hydrolytically to phosphine only in acidic medium (e.g. in the stomach following ingestion). Given the inert nature of the co-formulants in Arvalin Forte, no studies on the toxicity of the product were conducted. Instead, study results for zinc phosphide were used for the evaluation of product toxicity. The justifications for waiving the studies are given in Part B Section 3, Appendix 2.

3.1.3.2 Operator Exposure

Operator exposure was assessed against the AOEL systemic (0.042 mg/kg bw/d) applying an approach typically used for biocidal products. A detailed evaluation report is provided in Part B.
The estimated worst case exposure for a professional operator exceeds the systemic AOEL. Hence, gloves have to be worn for handling the product as well as for disposal and cleaning. Assuming a protection factor of 99 % for wearing protective gloves the operator exposure will be below the AOEL-S with 6.9 %.

3.1.3.3 Bystander Exposure

Bystander and resident exposure is considered to be negligible. The application of the product into holes/burrows will prevent any potential for direct exposure with the product. In contrast to other phosphide active substances, the release of phosphine will only occur in acidic environments (i.e. in the stomach of the target organism) and therefore there is little or no potential for bystander/resident exposure to evolved phosphine. The potential for dust exposure is considered low with respect to the formulation as ready-to-use grain bait. Ingestion of bait pellets by children can be excluded provided that the bait is securely deposited.

3.1.3.4 Worker Exposure

Worker exposure is considered to be negligible. The application of the product into holes/burrows will prevent any potential for direct exposure with the product. In contrast to other phosphide active substances, the release of phosphine will only occur in acidic environments (i.e. in the stomach of the target organism) and therefore there is little or no potential for worker exposure to evolved phosphine.

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

Please refer to chapter 2.2.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

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 this conclusion.

3.1.4.2 Consumer exposure

The envisaged uses are not relevant in terms of consumer health protection. Thus, risk assessment is made for long term exposure only.

Substance	ADI/ARfD	Model / Diet	ADI/ARfD Consumption
Zinc phosphide	ADI: 0.042 mg /kg bw/d d (zinc phosphide) 0.011 mg phosphine/kg bw/d	TMDI, EFSA PRIMo, WHO cluster diet B	23 %
	ARfD: 0.073 mg/kg bw (zinc phosphide) 0.019 mg phosphine/kg bw	not required	

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

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

Arvalin Forte was not the representative formulation considered in the EU review process as part of the approval of the zinc phosphide.

A full exposure assessment for the plant protection product Arvalin Forte 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 Arvalin Forte 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 Arvalin Forte 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 Arvalin Forte 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 Arvalin Forte 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, Section5, chapter 5.5.

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

3.1.5.2 Predicted Environmental Concentration in Ground Water (PEC_{GW}) (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 Arvalin Forte 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)

Arvalin Forte was not the representative formulation considered in the EU review process as part of the approval of the zinc phosphide.

A full risk assessment according to Uniform Principles for the plant protection product Arvalin Forte in its intended uses is documented in detail in the core assessment performed by zRMS Germany. The intended uses in Germany are covered by the core assessment performed by zRMS DE, how-ever, the GAP table for Germany comprises slightly differently defined intended uses than the GAP table for the central zone.

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

For reasons of better readability the intended uses in of the plant protection product Arvalin Forte 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/ 001 to 024	Agriculture, orchards, 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 = max. 150

Grouping for overall environmentals 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, 003, 005, 007, 009, 011, 013	Outdoor use in: Field crops; vegetables; fruit crops; grape vine; grassland, pasture and meadows; ornamentals; forest plants / if required	Lay out poisoned pellets, the dose corresponds to 4 pellets per hole	3 x per season Zinc phosphide: max. 3 x 50 (subdivison into 3 x 3 x 16.6 possible) = max. 150
A 2 / 002, 004, 006, 008, 010, 012, 014	Outdoor use in: Field crops; vegetables; fruit crops; grape vine; grassland, pasture and meadows; ornamentals; forest plants / if required	Lay out poisoned pellets, the dose corresponds to 50 g pellets per bait station	3 x 3 appl. per season Zinc phosphide: max. 3 x 50 (subdivison into 3 x 3 x 16.6 possible)= max. 150

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 Arvalin Forte 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 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. 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.

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

Consequences for authorisation:
For the authorisation of the plant protection product Arvalin Forte 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 µg/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 Arvalin Forte 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 mg/L; *Leuciscus idus* LC_{50} > 0.0217 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

Arvalin Forte (25 g/kg zinc phosphide) is applied to discrete sites in form of baits with low concentration of active substance. Due to the mode of application, only rodents can obtain any relevant access to the pellets. No data from bee toxicity tests are required.

It is concluded that Arvalin Forte will not adversely affect bees or bee colonies when used as recommended.

NB663	Due to the manner in which authorisation governs application of the product, bees are not endangered. (B3)

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 Marco-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 Arvalin Forte achieve the acceptability criteria TER ≥ 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 Arvalin Forte 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 Arvalin Forte 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 Arvalin Forte the following labelling and conditions of use are mandatory:

Classification and labelling

Relevant toxicity	Active substance: zink phosphide (content 0.8 %) 72-h E_rC_{50} of 0.00323 mg/L (*Desmodesmus subspicatus*) Acute M-factor = 100 NOE_rC 0.00140 mg/L (*Desmodesmus subspicatus*) Chronic M-factor:10
Classification and labelling according to Regulation (EC) No 1272/2008	
Hazard sysmbol	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)

The number of efficacy tests submitted by the applicant does not comply with EPPO Standard PP 1/226 'Number of efficacy trials'. The applicant submitted a total of only 3 experiments from more recent times. These data demonstrate that Arvalin forte is sufficiently effective when it is placed directly inside the holes openings. An extrapolation for comparability of ´Arvalin Forte` with other authorized plant protection products according to the EPPO standard PP 1/257 ´Efficacy and crop safety extrapolations for mi-nor uses` was not submitted.
The applicant also did not carry out any separate investigations for the application technology bait stations, nor did they carry out any extrapolation according to the EPPO standard PP 1/257. There is thus no reliable information about the acceptance behavior of common vole (*Microtus arvalis*) from bait stations, the distance between the bait stations, and also the delay in effect after application. Therefore, proposed uses in bait stations can not be authorized (002, 004, 006, 008, 010, 012 and 014).
If applied in accordance with the instructions, and due to the formulation type, no phytotoxicity, effects on neighbouring or following crops, can be observed.

Beneficials

Beneficial arthropods may have access to the application sites but are not expected to feed on the baits containing vegetable and dairy ingredients. Limited exposure cannot be excluded when the product is applied in burrow systems or holes in moist soil. The gases formed are probably toxic to arthropods. The risk is not quantifiable but should be limited to soil-dwelling or ground active beneficial organisms.

3.2 Conclusions

With respect to identity, physical, chemical, technical properties, packaging and further information as well as 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 for uses 001, 003, 005, 007, 009, 011 and 013 (application placed directly inside the holes openings).

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

Harmful effects on ground water consequent to the intended uses of the product Arvalin Forte have not to be apprehended. The environmental risk assessment shows that the intended field uses 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.

An authorisation can be granted for uses 001, 003, 005, 007, 009, 011 and 013.

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 made 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.

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Dienstsitz Braunschweig • Postfach 15 64 • 38005 Braunschweig

Detia Freyberg GmbH
Dr.-Werner-Freyberg-Straße 11
69514 Laudenbach

Dr. Susanne Luttmann
Referentin

TELEFON +49 (0)531 299-3612
TELEFAX +49 (0)531 299-3002
E-MAIL susanne.luttmann@bvl.bund.de

IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.008023-00/00.86460
(bitte bei Antwort angeben)

DATUM 25. Juni 2018

ZV1 008023-00/00

Arvalin Forte

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit dem Wirkstoff:	25 g/kg	Zinkphosphid
Zulassungsnummer:	008023-00	
Versuchsbezeichnungen:	DET-12345-R-0-RB	
Antrag vom:	16. Juli 2013	

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):

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008023-00/00-001	Feldmaus	Ackerbaukulturen	
008023-00/00-013	Feldmaus	Forstpflanzen	
008023-00/00-003	Feldmaus	Gemüsekulturen	
008023-00/00-005	Feldmaus	Obstkulturen	
008023-00/00-007	Feldmaus	Weinrebe	
008023-00/00-009	Feldmaus	Wiesen, Weiden	
008023-00/00-011	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 Arvalin forte 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 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 Primärvergiftung von Nicht-Zielarten nicht prinzipiell ausgeschlossen werden kann, muss das Risiko stattdessen durch entsprechende Risikominderungsmaßnahmen adressiert werden.
Da es sich bei dem Mittel Arvalin forte 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 Arvalin forte ist daher zu dokumentieren. Weitere Informationen sind den Bewertungsdokumenten (Part B, Sektion 6, Core Assessment und Nationales Addendum) zu entnehmen.

(NT659)
Nicht offen auslegen/ausbringen.
Begründung:
Der im Pflanzenschutzmittel Arvalin forte 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 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 Primärvergiftung von Nicht-Zielarten nicht prinzipiell ausgeschlossen werden kann, muss das Risiko stattdessen durch entsprechende Risikominderungsmaßnahmen adressiert werden.
Eine Ausbringung darf zur Minimierung der Risiken für Nicht-Zielorganismen nur verdeckt erfolgen. Bei Darreichung ohne Köderstation muss Arvalin forte 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 (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 kommu-

nalen Kläranlagen zurückzuführen ist, muss dieser Gefährdung durch die bußgeldbewehrte Anwendungsbestimmung durchsetzbar begegnet werden.

(SF531)
Bei der Entsorgung verbliebener Köder und bei der Reinigung von Köderstationen sind Schutzhandschuhe (Pflanzenschutz) zu tragen.
Begründung:
Im Ergebnis der Expositionsbewertung ist die Anwendungsbestimmung erforderlich, um den Referenzwert bei bestimmungsgemäßer Anwendung nicht zu überschreiten. Nur in Verbindung mit dieser Expositionsminderungsmaßnahme wird das Risiko als vertretbar beurteilt.

(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 Expositionsminderungsmaßnahme 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:

Verpackungs-art	Verpackungs-material	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Beutel	PE	2		5,00		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:

Kennzeichnungsauflagen:

(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 Kennzeichnungsauflagen 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.

(P301+P312+P330)

BEI VERSCHLUCKEN: Bei Unwohlsein GIFTINFORMATIONSZENTRUM oder Arzt anrufen. Mund ausspülen.

(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):

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008023-00/00-002	Feldmaus	Ackerbaukulturen	
008023-00/00-014	Feldmaus	Forstpflanzen	
008023-00/00-004	Feldmaus	Gemüsekulturen	
008023-00/00-006	Feldmaus	Obstkulturen	
008023-00/00-008	Feldmaus	Weinrebe	
008023-00/00-010	Feldmaus	Wiesen, Weiden	
008023-00/00-012	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

Zu KIIIA1 2.1:

Es liegen keine Informationen zum Formulierungsstandort vor.

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. Karsten Hohgardt
stellvertretender Abteilungsleiter

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

Anlage

Anlage 1 zugelassene Anwendung: 008023-00/00-001

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:	von Giftpellets / verdeckt / bis keine Annahme mehr erfolgt / in Gangsysteme bzw. pro Loch
Aufwand:	
-	2 kg/ha
- Erläuterungen:	Der Mittelaufwand entspricht 4 Pellets 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 Feldhamster 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 Arvalin Forte 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: 008023-00/00-003

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:	von Giftpellets / verdeckt / bis keine Annahme mehr erfolgt / in Gangsysteme bzw. pro Loch
Aufwand:	
-	2 kg/ha
- Erläuterungen:	Der Mittelaufwand entspricht 4 Pellets 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 Feldhamster 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 Arvalin Forte 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: 008023-00/00-005

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:	von Giftpellets / verdeckt / bis keine Annahme mehr erfolgt / in Gangsysteme bzw. pro Loch
Aufwand:	
-	2 kg/ha
- Erläuterungen:	Der Mittelaufwand entspricht 4 Pellets 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 Feldhamster 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 Arvalin Forte 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: 008023-00/00-007

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:	von Giftpellets / verdeckt / bis keine Annahme mehr erfolgt / in Gangsysteme bzw. pro Loch
Aufwand:	
-	2 kg/ha
- Erläuterungen:	Der Mittelaufwand entspricht 4 Pellets 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 Feldhamster 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 Arvalin Forte 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: 008023-00/00-009

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:	von Giftpellets / verdeckt / bis keine Annahme mehr erfolgt / in Gangsysteme bzw. pro Loch
Aufwand:	
-	2 kg/ha
- Erläuterungen:	Der Mittelaufwand entspricht 4 Pellets 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 Feldhamster 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 Arvalin Forte 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: 008023-00/00-011

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:	von Giftpellets / verdeckt / bis keine Annahme mehr erfolgt / in Gangsysteme bzw. pro Loch
Aufwand:	
-	2 kg/ha
- Erläuterungen:	Der Mittelaufwand entspricht 4 Pellets 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 Feldhamster 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 Arvalin Forte 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: 008023-00/00-013

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:	von Giftpellets / verdeckt / bis keine Annahme mehr erfolgt / in Gangsysteme bzw. pro Loch
Aufwand:	
-	2 kg/ha
- Erläuterungen:	Der Mittelaufwand entspricht 4 Pellets 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 Feldhamster 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 Arvalin Forte 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 2 nicht zugelassene Anwendung: 008023-00/00-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Ackerbaukulturen

Verwendungszweck:

2 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:	von Giftpellets / verdeckt / bis keine Annahme mehr erfolgt / in geeigneten Köderstationen
Aufwand:	
-	2 kg/ha
- Erläuterungen:	Der Mittelaufwand entspricht 50 g pro Köderstation

3 Begründung

Wirksamkeit

Nach Art. 33 Abs. 3 Buchst. a der Verordnung (EG) Nr. 1107/2009 sind dem Antrag für das Pflanzenschutzmittel ein vollständiges Dossier und eine Kurzfassung davon beizufügen, die jeden Punkt der Datenanforderungen für den Wirkstoff abdecken. Das vollständige Dossier enthält gemäß Art. 8 Abs. 2 S. 1 der Verordnung (EG) Nr. 1107/2009 den Volltext der einzelnen Versuchs- und Studienberichte bezüglich aller unter Art. 8 Abs. 1 Buchst. c der Verordnung (EG) Nr. 1107/2009 genannten Informationen. Hierfür gelten gemäß Art. 1 der Verordnung (EU) Nr. 545/2011 die Datenanforderungen im Anhang der Verordnung (EU) Nr. 545/2011.

Gemäß Punkt 6.2 im Anhang der Verordnung (EU) Nr. 545/2011 in Verbindung mit EPPO-Richtlinie PP 1/241(1) "Guidance on comparable climates" und EPPO-Richtlinie PP 1/226 (1) "Number of efficacy trials" sind 10 (6-15) Wirksamkeitsversuche inkl. Grenzaufwandversuche aus möglichst 2 Versuchsjahren je EPPO-Klimazone bei Anwendungen im Freiland vorzulegen. Die zentrale Zone beinhaltet drei klimatische Zonen (maritime, nordöstliche und südöst-

liche Zone).
Die von Ihnen eingereichten Studien bzw. das Biologische Wirksamkeitsdossier erfüllen diese Anforderungen nicht, weil nicht keine validen Versuche für die Anwendung des Produktes in Köderstationen eingereicht wurden. Da die genannten Unterlagen nicht vorliegen, ist Ihr Antrag unvollständig.

Anlage 2 nicht zugelassene Anwendung: 008023-00/00-004

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Gemüsekulturen

Verwendungszweck:

2 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Gemüsebau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	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:	von Giftpellets / verdeckt / bis keine Annahme mehr erfolgt / in geeigneten Köderstationen
Aufwand:	
-	2 kg/ha
- Erläuterungen:	Der Mittelaufwand entspricht 50 g pro Köderstation

3 Begründung

Wirksamkeit
Siehe Begründung zu Anwendung 008023-00/00-002.

Anlage 2 nicht zugelassene Anwendung: 008023-00/00-006

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Obstkulturen

Verwendungszweck:

2 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:	von Giftpellets / verdeckt / bis keine Annahme mehr erfolgt / in geeigneten Köderstationen
Aufwand:	
-	2 kg/ha
- Erläuterungen:	Der Mittelaufwand entspricht 50 g pro Köderstation

3 Begründung

Wirksamkeit
Siehe Begründung zu Anwendung 008023-00/00-002.

Anlage 2 nicht zugelassene Anwendung: 008023-00/00-008

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Weinrebe

Verwendungszweck:

2 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:	von Giftpellets / verdeckt / bis keine Annahme mehr erfolgt / in geeigneten Köderstationen
Aufwand:	
-	2 kg/ha
- Erläuterungen:	Der Mittelaufwand entspricht 50 g pro Köderstation

3 Begründung

Wirksamkeit
Siehe Begründung zu Anwendung 008023-00/00-002.

Anlage 2 nicht zugelassene Anwendung: 008023-00/00-010

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Wiesen, Weiden

Verwendungszweck:

2 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:	von Giftpellets / verdeckt / bis keine Annahme mehr erfolgt / in geeigneten Köderstationen
Aufwand:	
-	2 kg/ha
- Erläuterungen:	Der Mittelaufwand entspricht 50 g pro Köderstation

3 Begründung

Wirksamkeit
Siehe Begründung zu Anwendung 008023-00/00-002.

Anlage 2 nicht zugelassene Anwendung: 008023-00/00-012

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen

Verwendungszweck:

2 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:	von Giftpellets / verdeckt / bis keine Annahme mehr erfolgt / in geeigneten Köderstationen
Aufwand:	
-	2 kg/ha
- Erläuterungen:	Der Mittelaufwand entspricht 50 g pro Köderstation

3 Begründung

Wirksamkeit
Siehe Begründung zu Anwendung 008023-00/00-002.

Anlage 2 nicht zugelassene Anwendung: 008023-00/00-014

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Feldmaus

Pflanzen/-erzeugnisse/Objekte: Forstpflanzen

Verwendungszweck:

2 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:	von Giftpellets / verdeckt / bis keine Annahme mehr erfolgt / in geeigneten Köderstationen
Aufwand:	
-	2 kg/ha
- Erläuterungen:	Der Mittelaufwand entspricht 50 g pro Köderstation

3 Begründung

Wirksamkeit
Siehe Begründung zu Anwendung 008023-00/00-002.

REGISTRATION REPORT
Part B

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

Detailed summary of the risk assessment

Product code: Stutox – II

Active Substance: Zinc phosphide 25 g/kg

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: **Detia Freyberg GmbH**

Submission Date: **16/07/2013**

Date: **June 2016**

Table of Contents

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 plant protection product Stutox - II containing zinc phosphide which was included into Annex I of Directive 91/414 on 1st May 2011 (Commission Directive 2010/85/EU).

For the purposes of this Registration Report the product is referred to as Stutox – II which is its original name but it should be noted that the product will also be marketed under the trade name Arvalin Forte in various countries. The product trade name will be Stutox – II in Slovakia and the Czech Republic. The product will be known as Arvalin Forte in Germany, Austria and Belgium.

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 Stutox - II can be found in the confidential dossier of this submission (Registration Report - Part C).

IIIA 1 IDENTITY OF THE PLANT PROTECTION PRODUCT

IIIA 1.1 Applicant

Detia Freyberg GmbH

[redacted]

[redacted]

Germany

Contact person:	[redacted]
Tel.No.:	[redacted]
Fax No:	[redacted]
e-mail:	[redacted]

Alternative person:	[redacted]
Tel.No.:	[redacted]
Fax No:	[redacted]
e-mail:	[redacted]

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

IIIA 1.2.1 Manufacturer(s) of the preparation

Confidential information - data provided separately (Part C).

IIIA 1.2.2 Manufacturer(s) of the active substance(s)

Confidential information - data provided separately (Part C).

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

Zinc phosphide: minimum 800 g/kg

Further information/justification is provided in Part C.

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

Trade name: Stutox-II

Company code number:

IIIA 1.4 Detailed Quantitative and Qualitative Information on the Composition of the Preparation

IIIA 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:	18.75 – 31.25 g/kg

Technical active substance:

content of technical zinc phosphide at minimum purity (80.0%):	31.25 g/kg	(3.13 % w/w)

None of the active substances in the formulation are present in the form of a salt, ester, anion or cation.

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

IIIA 1.4.2 Certified limits of each component

This is not an EC data requirement/ not required by regulation (EU) No 545/2011.

IIIA 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	EINECS No.	215-244-5
1.4.3.2	CIPAC No.	69
1.4.3.2	ELINCS	
1.4.3.3	Salt, ester anion or cation present	Not relevant

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

CONFIDENTIAL information - data provided separately (Part C).

IIIA 1.4.5 Formulation process

IIIA 1.4.5.1 Description of formulation process

This is not an EC data requirement/ not required by regulation (EU) No 545/2011.

IIIA 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.

IIIA 1.5 Type of Preparation and Code

Type : Bait (ready for use) Code : RB

IIIA 1.6 Function

The product will be used as rodenticide.

IIIA 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.

Tabelle 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	Stutox – II Batch No. EXP DETIA 2 2.64% trizinc diphosphide	Inhomogeneous, flecked with grey pellets with a cereal-like odour. The mean dimensions of pellets were about 3-5 mm in length and 3.5-4 mm in diameter.	Y	Wilfinger,W., 2013a, S13-02926	Acceptable
		not available	dark brown to greyish green appearance	N	Anonymous, MSDS (2013)	Additional information
Explosive properties (IIIA 2.2.1)	EEC A 14	Stutox – II Batch No. EXP DETIA 2 2.64% trizinc diphosphide	The exothermic decomposition energy is more than 500 J/g. In the main test no mechanical (friction, shock) or thermal sensitivity could be detected. The test item has no explosive properties.	Y	Dornhagen, J.,2013a, 20130089.02	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Oxidizing properties (IIIA 2.2.2)	Theoretical assessment	Stutox – II Batch No. EXP DETIA 2 2.64% trizinc diphosphide	The test item has no oxidising properties.	Y	Dornhagen, J. 2013b, 20130089.04	Acceptable. Formulation has no oxidising properties.
Flash point (IIIA 2.3.1)			Not applicable for a solid, ready to use bait (RB) formulation.			Acceptable.
Flammability (IIIA 2.3.2)	EEC A 10	Stutox – II Batch No. EXP DETIA 2 2.64% trizinc diphosphide	The test item is not a highly flammable solid.	Y	Dornhagen, J. 2013c, 20130089.01	Acceptable.
Auto-flammability (IIIA 2.3.3)	EEC A 16	Stutox – II Batch No. EXP DETIA 2 2.64% trizinc diphosphide	Auto-ignition at 388 °C	Y	Dornhagen, J. 2013d, 20130089.03	Acceptable.
Acidity or alkalinity and pH (IIIA 2.4.1)			The test can not be conducted due to the dangerous nature of the active substance, zinc phosphide on contact with water. Upon contact with water, a violent reaction occurs and toxic gases are liberated. It is therefore deemed not safe to perform the test.			Acceptable.
pH of a 1% aqueous dilution, emulsion or			The test can not be conducted due to the dangerous nature of the active			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
dispersion (IIIA 2.4.2)			substance, zinc phosphide on contact with water. Upon contact with water, a violent reaction occurs and toxic gases are liberated. It is therefore deemed not safe to perform the test.			
Kinematic viscosity (IIIA 2.5.1)			Not required. The product is a solid, ready to use bait (RB) formulation. This parameter is only required for liquid formulations.			Acceptable.
Dynamic viscosity (IIIA 2.5.2)			Not required. The product is a solid, ready to use bait (RB) formulation. This parameter is only required for liquid formulations.			Acceptable.
Surface tension (IIIA 2.5.3)			Not required. The product is a solid, ready to use bait (RB) formulation			Acceptable.
Relative density (IIIA 2.6.1)			Not required. The product is a solid, ready to use bait (RB) formulation. This parameter is only required for liquid formulations.			Acceptable.
Bulk or tap density (IIIA 2.6.2)	CIPAC MT 159	Stutox – II Batch No. EXP DETIA 2 2.64% trizinc diphosphide	Pour density: 0.712 g/mL Tap density: 0.763 g/mL	Y	Dornhagen, J. 2013e, 20130089.05	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)			see IIIA 2.7.2.			Acceptable.
Stability after storage for other periods and/or temperatures (IIIA 2.7.2)	storage conditions: 30 °C for 18 weeks	Stutox – II Batch No. EXP DETIA 2 2.64% trizinc diphosphide	Storage material: Outer packaging: drum of cardboard with white PE-LD lids Inner packaging: PE bags Content of Zn_3P_2 (method is identical to method in Part B Section 2): before storage: 2.51 % (w/w) after storage: 2.39 % (w/w) (-4.8%) The changes of the physical and chemical properties appearance, dry sieve analysis, dustiness and friability/attrition are negligible. A weight decrease of 0.94 % was observed, the package was not damaged.	Y	Morlock, G., 2013a, 13D06126-01-ASFO Wilfinger,W., 2013a, S13-02926	Acceptable. The justification for the performance of the stability test at 30 °C is questionable.
Minimum content after heat stability testing (IIIA 2.7.3)			Not necessary, since the decrease of the active substance did not exceed 5%.			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Effect of low temperatures on stability (IIIA 2.7.4)			Not required for solid, ready to use bait (RB) formulations.			Acceptable.
Ambient temperature shelf life (IIIA 2.7.5)		Stutox – II Batch No. EXP DETIA 2 2.64% trizinc diphosphide	Storage material: Outer packaging: drum of cardboard with white PE-LD lids Inner packaging: PE bags Content of Zn_3P_2 (method is identical to method in Part B Section 2): before storage: 2.51 % (w/w) after storage: 2.40 % (w/w) (-4.4 %) The changes of the physical and chemical properties appearance, dry sieve analysis, dustiness and friability/attrition are negligible. A weight decrease of 0.57 % was observed and no damage to the container shape or size was observed.	Y	Walter, A., 2015, 13D06126-01-SSFO Wilfinger, W., 2015, S13-02927	Acceptable.
Shelf life in months (if less than 2 years) (IIIA 2.7.6)	-		Not necessary as sample is stable for 2 years.			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Wettability (IIIA 2.8.1)			Not required for a solid, ready to use bait (RB) formulation.			Acceptable.
Persistence of foaming (IIIA 2.8.2)			Not required for a solid, ready to use bait (RB) formulation.			Acceptable.
Suspensibility (IIIA 2.8.3.1)			Not required for a solid, ready to use bait (RB) formulation.			Acceptable.
Spontaneity of dispersion (IIIA 2.8.3.2)			Not required for a solid, ready to use bait (RB) formulation.			Acceptable.
Dilution stability (IIIA 2.8.4)			Not required for a solid, ready to use bait (RB) formulation.			Acceptable.
Dry sieve test (IIIA 2.8.5.1)	CIPAC MT 170	Stutox – II Batch No. EXP DETIA 2 2.64% trizinc diphosphide	Initial: ≤ 10 %: 5000 µm ≥ 90 %: 3350 µm after 18 weeks at 30 °C: ≤ 10 %: 5000 µm ≥ 90 %: 3350 µm	Y	Wilfinger, W., 2013a, S13-02926	Acceptable.
Wet sieve test (IIIA 2.8.5.2)			Not required for a solid, ready to use bait (RB) formulation.			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Particle size distribution (IIIA 2.8.6.1)			Not required for a solid, ready to use bait (RB) formulation.			Acceptable.
Nominal size range of granules (IIIA 2.8.6.2)	CIPAC MT 58.3		See IIIA 2.8.5.1			Acceptable.
Dust content (IIIA 2.8.6.3)	CIPAC MT 171	Stutox – II Batch No. EXP DETIA 2 2.64% trizinc diphosphide	Initial: 1.6 mg after 18 weeks at 30 °C: 1.9 mg Nearly dust free	Y	Wilfinger, W., 2013a, S13-02926	Acceptable.
Particle size of dust (IIIA 2.8.6.4)			Not relevant, the amount of dust formed is below the trigger value for determination of particle size.			Acceptable.
Friability and attrition (IIIA 2.8.6.5)	CIPAC MT 178	Stutox – II Batch No. EXP DETIA 2 2.64% trizinc diphosphide	Initial: 100% after 18 weeks at 30 °C: 99.9%	Y	Wilfinger, W., 2013a, S13-02926	Acceptable.
Emulsifiability (IIIA 2.8.7.1)			Not required for a solid, ready to use bait (RB) formulation.			Acceptable.
Flowability (IIIA 2.8.8.1)	CIPAC MT 172	Stutox – II Batch No. EXP DETIA 2 2.64% trizinc diphosphide	100% of the test item passed the sieve spontaneously	Y	Wilfinger, W. , 2013b, S13-02925	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 relevant as the formulation is a ready to use bait formulation and not a suspension.			Acceptable.
Dustability following accelerated storage (IIIA 2.8.8.3)			Not relevant as the formulation is not a dustable powder.			Acceptable.
Physical compatibility of tank mixes (IIIA 2.9.1)			Not applicable as formulation is a solid, ready to use bait formulation.			Acceptable.
Chemical compatibility of tank mixes (IIIA 2.9.2)			Not applicable as formulation is a solid, ready to use bait formulation.			Acceptable.
Distribution to seed (IIIA 2.10.1)			Not relevant as the formulation is not used for seed treatment.			Acceptable.
Adhesion to seeds (IIIA 2.10.2)			Not relevant as the formulation is not used for seed treatment.			Acceptable.
Miscibility (IIIA 2.11)			Not required by regulation (EU) No 545/2011.			Acceptable.
Dielectric breakdown (IIIA 2.12)			Not required by regulation (EU) No 545/2011.			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) No 545/2011.			Acceptable.
Container material (IIIA 2.14)			Not required by regulation (EU) No 545/2011.			Acceptable.
Other/special studies (IIIA 2.15)			Not required by regulation (EU) No 545/2011.			Acceptable.

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

Stutox – II is a ready to use bait formulation. The product has the appearance of inhomogeneous, flecked with grey pellets with a cereal like odour. It is not explosive, has no oxidising properties. It has a self ignition temperature of 388 °C. The pour and tap density of the formulation is 0.712 g/mL and 0.763 g/mL respectively.The stability data indicate a shelf life of at least 2 years at ambient temperature. Its technical characteristics are acceptable for ready to use bait formulation.

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

No sample has been tested in the laboratory.

Implications for labelling:

No labelling necessary due to physical or chemical properties described above.

IIIA 3 DATA ON APPLICATION OF THE PLANT PROTECTION PRODUCT

IIIA 3.1 Field of Use

Arvalin Forte, as a bait rodenticide degassing phosphine after ingestion of the bait, is intended to be used in agricultural areas, either underground in holes or as surface application in bait sta-tions.

IIIA 3.2 Nature of the Effects on Harmful Organisms

Zinc phosphide is a quick-acting acute poison and soluble in acids (such as gastric acid) or alka-lizes well. After the ingestion the decomposition is carried out in the stomach to phosphine. 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.

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

The pellets are packed in 2 x 5 kg polyethylene bags and stored in 10 kg buckets

.

5 kg bag	material:	PE
in 10 kg bucket:	shape/size:	cylindrical / approx. 230 mm diameter x 460 mm
	opening:	224 mm inner diameter
	closure:	bucket lid PE

IIIA 4.1.2 Suitability of the packaging and closures

Report:	No data from applicant

The packaging has been certified to UN standards and has been tested to ensure its suitability for the carriage of dangerous goods.

IIIA 4.1.3 Resistance of the packaging material to its contents

Report:	Wilfinger, W.
Title:	Physico-chemical Properties of the Formulation STUTOX over 2 years at 20 °C
Document No:	Study code: S13-02927
Guidelines:	n.a.
GLP	Yes

No damage to the container shape or size was observed after 24 months storage at 20 °C.

Package: Outer packaging: drum of cardboard with white PE-LD lids

Inner packaging: PE bags

Weight loss after 24 month ≤ 0.57 %.

The packaging in which Stutox - II 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/feedstuff nature, it is concluded that the packaging materials are suitable for packaging and transport of Stutox - II.

IIIA 4.2 Procedures for Cleaning Application Equipment

IIIA 4.2.1 Procedures for cleaning application equipment and protective clothing

Report:	No data from applicant

The submission of information on procedures for cleaning application equipment and protective clothing for the product Stutox - II is not considered to be required due to the application method.

IIIA 4.2.2 Effectiveness of the cleaning procedures

Report:	No data from applicant

Not relevant. Please refer to IIIA 4.2.1 above.

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

Report:	Anonymous, 2013
Title:	Safety data sheet - Arvalin Forte
Document No:	-
Guidelines:	EEC 1907/2006
GLP	No, not subject to GLP regulations

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

IIIA 4.4.1 Warehouse storage

Store in a cool, dry place at a temperature of below 30 °C. Do not store together with acids or alkalis.

IIIA 4.4.2 User level storage

Store in a cool, dry place at a temperature of below 30 °C. Do not store together with acids or alkalis.

IIIA 4.4.3 Transport

Land transport (ADR/RID)

UN number: UN3077

UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Transport hazard class(es): 9

Packing group: III

Hazard label: 9

Classification code: M7

Special Provisions: 274 335 601

Limited quantity: 5 kg

Transport category: 3

Hazard No: 90

Tunnel restriction code: E

Limited quantity: E1

Inland waterways transport (ADN)

UN number: UN3077

UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Transport hazard class(es): 9

Packing group: III

Hazard label: 9

Classification code: M7

Special Provisions: 274 601

Limited quantity: 5 kg

Limited quantity: E1

Marine transport (IMDG)

UN number: UN3077

UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Transport hazard class(es): 9

Packing group: III

Hazard label: 9

Special Provisions: 274, 335

Limited quantity: 5 kg

EmS: F-A, S-F

Limited quantity: E1

Air transport (ICAO)

UN number: UN3077

UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Transport hazard class(es): 9

Packing group: III

Hazard label: 9

Special Provisions: A97 A158 A179

Limited quantity Passenger: 30 kg G

IATA-packing instructions - Passenger: 956

IATA-max. quantity - Passenger: 400 kg

IATA-packing instructions - Cargo: 956

IATA-max. quantity - Cargo: 400 kg

Refer to the safety data sheet for Stutox - II provided in Registration Report (dRR Part C).

IIIA 4.4.4 Fire

Suitable extinguishing media:	Extinguishing powder and CO_2 dry sand or powder and then CO_2
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 released: phosphorous oxides (e.g. phosphorous pentoxide), phosphine corrosive phosphoric acid aerosols (phosphoric pentoxide)
Special protective equipment for fire fighting:	Wear self-contained breathing apparatus and chemical-protective clothing. Full mask with filters B2-P2 or self-contained breathing apparatus

IIIA 4.4.5 Nature of protective clothing proposed

General:	When using do not eat, drink or smoke.
Hand protection:	Chemical protective gloves according to EU-374-2, and EU374-3 PVC or PE (prior to use Integrity check), breakthrough (Value for permeation: Level 6,> 480 minutes; E374).
Eye protection:	If the instructions for use are adhered to, no protection is necessary.

Body protection:	If the instructions for use are adhered to, no protection is necessary.

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 nature of the preparation 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

Please refer to IIIA 4.4.6.

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

Not applicable.

IIIA 4.5.2 Decontamination of areas, vehicles and buildings

Not applicable.

IIIA 4.5.3 Disposal of damaged packaging, adsorbents and other materials

Not applicable.

IIIA 4.5.4 Protection of emergency workers and bystanders

Not applicable.

IIIA 4.5.5 First aid measures

General:	Remove contaminated clothes.
Inhalation:	Provide fresh air. Remove casualty to fresh air and keep warm and at rest. In case of inhalation of decomposition products, affected person should be moved into fresh air and kept still. In case of accident or unwellness, seek medical advice immediately; inhale products for acute treatment following exposition of smoke gas (e.g. beclometasone (Ventolair®) spray).
Eye contact:	1. Brush off loose particles from skin. , 2. thereafter apply eye drops with plenty of water. Call a physician immediately.
Skin contact:	Brush off loose particles from skin. Immerse in cool water/wrap in wet bandages.
Ingestion:	If swallowed, seek medical advice immediately and show this container or label.
Indication of immediate medical attention and special treatment needed.	A steroid-containing inhalation spray, such as 100 Ventolair®.
Symptoms:	Headache, dizziness, anxiety, difficulty breathing and nausea

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

Stutox - II does not require specific neutralisation. Small quantities should be picked up with suitable appliance and dispose in accordance with local regulations.

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 Stutox - II is not considered to be required, since the product is neither liquid nor soluble in water.

Large quantities pick up in dry form. 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.

IIIA 4.6.1 Details of proposed procedures for small quantities

Not applicable, no neutralization procedures are proposed.

IIIA 4.6.2 Evaluation of products of neutralization (small quantities)

Not applicable, no neutralization procedures are proposed.

IIIA 4.6.3 Procedures for disposal of small quantities of neutralized waste

Not applicable, no neutralization procedures are proposed.

IIIA 4.6.4 Details of proposed procedures for large quantities

Not applicable, no neutralization procedures are proposed.

IIIA 4.6.5 Evaluation of products of neutralization (large quantities)

Not applicable, no neutralization procedures are proposed.

IIIA 4.6.6 Procedures for disposal of large quantities of neutralized waste

Not applicable, no neutralization procedures are proposed.

IIIA 4.7 Pyrolytic Behaviour of the Active Substance

The pyrolytic behaviour of the Stutox - II is not required as zinc phosphide does not contain any halogens and all other major product constituents are of food/feed status. As the halogen content of Stutox - II is less than 60%, there is no need for a pyrolysis study.

IIIA 4.8 Disposal Procedures for the Plant Protection Product

IIIA 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).

IIIA 4.8.2 Methods other than controlled incineration for disposal

No other methods for disposal of Stutox - II than those described in chapter 4.8.1 are available.

Apart from disposal via controlled incineration, the product Stutox - II should be disposed of in accordance with regional legislation.

IIIA 4.9 Other/Special Studies

No additional studies were performed.

IIIA 11 FURTHER INFORMATION

IIIA 11.1 Information of Authorisations in Other Countries

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

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

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

IIIA 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 (-)	Dornhagen, J.,(2013a), 20130089.02
Oxidizing properties	Not oxidizing (-)	Dornhagen, J.,(2013b), 20130089.04
Flammability	Auto-ignition temperature is 388°C	Dornhagen, J. (2013d), 20130089.03

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	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*
IIIA 2.1 2.7.2 2.8.5.1 2.8.6.3 2.8.6.5	Wilfinger, W.	2013a	Physico-chemical Properties of the Formulation STUTOX before and after accelerated Storage at 30 °C for 18 weeks Eurofins Agroscience Services, EcoChem GmbH, Eutiner Str. 24 D-75223 Niefern Öschelbronn, Germany Lab Phase Code: S13-02926-L1_PCAS GLP Unpublished	Y	Detia Freyberg GmbH	1
IIIA 2.1	Anonymous	2013	Safety Data Sheet – Arvalin Forte Non-GLP Published	N	Detia Freyberg GmbH	5
IIIA 2.2.1	Dornhagen, J.	2013a	STUTOX. Batch No. EXP DETIA 2. Explosive Properties A.14. Siemens AG, Frankfurt am Main, Germany. 20130089.2 GLP Unpublished.	Y	Detia Freyberg GmbH	1
IIIA 2.2.2	Dornhagen, J.	2013b	see confidential Part C			1
IIIA 2.3.2	Dornhagen, J.	2013c	STUTOX. Batch No. EXP DETIA 2. Flammability (Solids) A.10. Siemens AG, Frankfurt am Main, Germany. 20130089.01 GLP Unpublished.	Y	Detia Freyberg GmbH	1

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*
IIIA 2.3.3	Dornhagen, J.	2013d	STUTOX. Batch No. EXP DETIA 2. Auto flammability (Solids-Determination of Relative Self Ignition Temperature A.16. Siemens AG, Frankfurt am Main, Germany. 20130098.03 GLP Unpublished.	Y	Detia Freyberg GmbH	1
IIIA 2.6.2	Dornhagen, J.	2013e	STUTOX. Batch No. EXP DETIA 2. Pour and Tap Density CIPAC MT 159. Siemens AG, Frankfurt am Main, Germany. 20130089.05 GLP Unpublished.	Y	Detia Freyberg GmbH	1
IIIA 2.7.2	Morlock, G.	2013a	Content Analysis of the formulation STUTOX before and after Accelerated Storage at 30 °C for 18 Weeks CIP Chemisches Institut Pforzheim GmbH, Schulberg 17 D-75175 Pforzheim, Germany CIP Study Code 13D06126-01-ASFO GLP Unpublished	Y	Detia Freyberg GmbH	1

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*
IIIA 2.7.5	Walter, A.	2015	Content Analysis of the Formulation STUTOX Over 2 Years at 20°C CIP Chemisches Institut Pforzheim GmbH, Schulberg 17 D-75175 Pforzheim, Germany CIP Study Code 13D06126-01-SSFO GLP Unpublished	Y	Detia Freyberg GmbH	1
	Wilfinger, W.	2015	Physico-chemical properties of the formulation STUTOX over 2 years at 20°C Eurofins Agroscience Services, EcoChem GmbH, Eutiner Str. 24 D-75223 Niefern Öschelbronn, Germany Lab Phase Code: S13-02927-L1_PCTY GLP Unpublished	Y	Detia Freyberg GmbH	1
IIIA 2.8.8.1	Wilfinger, W.	2013b	Flowability of the Formulation STUTOX Eurofins Agroscience Services, EcoChem GmbH, Eutiner Str. 24 D-75223 Niefern Öschelbronn, Germany Lab Phase Code: S13-02925-L1_PCFL GLP Unpublished	Y	Detia Freyberg GmbH	1
IIIA 4.4	Anonymous	2013	Safety Data Sheet – Arvalin Forte Non-GLP Published	N	Detia Freyberg GmbH	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: year-month-day

PPP (product name/code)	**product name / code**	**Formulation type: RB**	**type**
active substance 1	**active substance 1**	**Conc. of as 1:**	**conc.**
active substance 2	**active substance 2**	**Conc. of as 2:**	**conc.**
active substance …	**active substance ...**	**Conc. of as:…**	**conc.**
safener safener		**Conc. of safener:**	**conc.**
synergist	**synergist**	**Conc. of synergist:**	**conc.**
Applicant:	**company**	**professional use**	☐
Zone(s):northern/central/southern/EU		**non professional use**	☐

Verified by MS: yes/no

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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					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		
001												
002												
003												
004												
005												

REGISTRATION REPORT
Part B

Section 2: Analytical Methods
Detailed summary of the risk assessment

Product code: Stutox – II
(Arvalin Forte)
Active Substance: Zinc phosphide 25 g/kg

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Detia Freyberg GmbH
Submission Date: 16/07/2013
Date: January 2016

Table of Contents

IIIA 5 METHODS OF ANALYSIS

This document summarises the information related to the analytical methods for the product Stutor - II (Arvalin Forte) 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 Stutor - II (Arvalin Forte) 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

No samples were provided because there was no request.

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

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

Report:	5.2.1/2 Morlock, G., 2013
Title:	Validation of an Analytical Method for the Determination of Zinc phosphide in STUTOX
Document No:	13D0613D06126-01-VMFO
Guidelines:	SANCO/3030/99 rev. 4
GLP	Yes

Method description

The content of zinc phosphide was determined after hydrolysis of the test item with sulphuric acid. The released phosphan reacted with mercury (II) chloride to generate hydrogen chloride. The amount of this reaction product was determined by titration with potassium hydroxide solution 0.1 N.

Reaction equations:

$Zn_3P_2 + 6 H_2O = 2 PH_3 + 3 Zn(OH)_2$

$2 PH_3 + 6 HgCl_2 = 2 P(HgCl)_3 + 6 HCl$

$6 HCl + 6 NaOH = 6 H_2O + 6 NaCl$

According to these reaction equations one aliquot of zinc phosphide generates six aliquots of hydrochloric acid.

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 Stutox.

Table B.5.2.1 1: Determination of zinc phosphide in the plant protection product

Analyte	Specificity/ interferences	Linearity (R^2) (n = 6) (conc. range)	Accuracy (n = 4)		Repeatability (% RSD) (n = 5)
			fortification level (%)	mean recovery (%)	
Zinc phospide (determination of released phosphan)	No information	r = 1.000 10 – 130 mg reference item (2 mg - 25 mg active P)			2.1 (content =2.6 %)

Conclusion:

Phosphan released from the formulation Stutox 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 specifity are missing.

IIA 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 Stutox - II (Arvalin Forte) 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 Stutox - II (Arvalin Forte).

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 Fehler! Kein Text mit angegebener Formatvorlage im Dokument.**-1: Information on the active substance zinc phosphide**

Name of component of residue definiton substance code IUPAC name formula	**Structural formula**
Zinc phosphide	Zn_3P_2

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 Fehler! Kein Text mit angegebener Formatvorlage im Dokument.**-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 Fehler! Kein Text mit angegebener Formatvorlage im Dokument.**-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

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.

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.

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 Fehler! Kein Text mit angegebener Formatvorlage im Dokument.**-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 Fehler! Kein Text mit angegebener Formatvorlage im Dokument.**-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 phospine or 0.0025 mg/kg Zn_3P_2	headspace GC/NPD with ZB-1 column and ZB-35 column	confirmation of results with second GC column	BVL no 1859406 ASB2009-7434

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 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 Fehler! Kein Text mit angegebener Formatvorlage im Dokument.**-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 Fehler! Kein Text mit angegebener Formatvorlage im Dokument.**-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 MET2000-49
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 MET2002-40

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.

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).

5.3.1.8 Other Studies/ Information

Not required.

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. OECD	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 5.2.1/1	Morlock, G.		Study plan: Validation of an Analytical Method for the Determination of Zinc phosphide in STUTOX 13D06126-01-VMFO GLP, unpublished BVL no. 2495232	Y	Detia Freyberg GmbH	2
KIIIA1 5.2.1/2	Morlock, G.		Validation of an Analytical Method for the Determination of Zinc phosphide in STUTOX 13D0613D06126-01-VMFO GLP, unpublished BVL no. 2936136	Y	Detia Freyberg GmbH	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
KIIA 4.5	Shrimali, A.	2001	Determination of Phophine concentration in water treated with Aluminium Phosphide bag 3569 GLP: Yes (1) Open (5) 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

* 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 name: Arvalin Forte
Active Substance: Zinc phosphide 25 g/kg

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Detia Freyberg GmbH
Date: February 2018

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3 Mammalian Toxicology (IIIA 7)

3.1 Summary

Table 3.1-1: Information on Arvalin Forte *

Product name and code	Stutox-II / Arvalin Forte (DET-12345-R-0-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 Arvalin Forte 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):	101-102-264-270-280-301+312+330-501
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 Arvalin Forte

	Result	PPE / Risk mitigation measures
Operators	Acceptable	- 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. [NT660] - Place bait out of reach for children, domestic animals and animals living in the wild. [NT667] - 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. [NT668] - Avoid any unnecessary contact with the product. Misuse can lead to health damage. [SB001] - Keep away from children. [SB011] - 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. [SB111] - Wear standard protective gloves (plant protection) when handling the product. [SS1201] - Protective gloves (plant protection) must be worn when collecting remaining baits and when cleaning bait stations. [SF531] - 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. [SS206]
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	2	3	4	5	6	7	8			
Crops [1] and situation (e.g. growth stage of crop)	**F/G or I [2]**	**Application**		**Application rate**		**Remarks:** (e.g. surfactant (L /ha))	**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**	**critical gap for operator, worker, bystander or resident exposure based on [*Exposure model*]**	**Operator**	**Worker**	**Bystander**	**Residents**
Field crops, vegetable, fruit crops, vine, ornamentals, grassland, forest plants	F	Placing baits in vole holes or bait stations	a) 3 b) 3	a) 0.05 b) 0.15						

	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

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 diphospide**	
With regard to toxicological enpoints (according to the criteria in Dir. 67/548/EEC)	Table 3.2 of Annex VI to CLP 00 / ATP 01 T+ - Very toxic R15/29 - Contact with water liberates toxic, extremely flammable gas R28 - Very toxic if swallowed R32 - Contact with acids liberates very toxic gas Proposal Germany*: T+ - Very toxic R21 - Harmful in contact with skin R28 - Very toxic if swallowed R32 - Contact with acids liberates very toxic gas
With regard to toxicological enpoints (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, R15/29, H260 and EUH029 are not supported.	
Classification and proposed labelling **Phosphine**	
With regard to toxicological enpoints (according to the criteria in Dir. 67/548/EEC)	Table 3.2 of Annex VI to CLP 00 T+ - Very toxic R26 - Very toxic by inhalation R34 - Causes burns

With regard to toxicological enpoints (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 conern with regard to toxicology	
Review Report for active substance	None

3.3 Toxicological Evaluation of Plant Protection Product

The product contains the active substance zinc phosphide and more than 90% non-toxic bait formulants (foodstuff). In contrast to other metal phosphides, zinc phosphide is practically insoluble in water or organic solvents. It is degraded hydrolytically to phosphine only in acidic medium (e.g. in the stomach following ingestion). Given the inert nature of the co-formulants in Arvalin Forte, no studies on the toxicity of the product were conducted. Instead, study results for zinc phosphide were used for the evaluation of product toxicity. The justifications for waiving the studies are given in Appendix 2. MSDS on Arvalin Forte 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 Arvalin Forte

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 Arvalin Forte

	Substance (Concentration in product, % w/w)	**Classification of the substance (acc. to the criteria in Dir. 67/548/EEC and/or in Reg. 1272/2008)**	**Reference**	**Classification of product (acc. to the criteria in Dir. 67/548/EEC, in Dir. 1999/45/EC and/or in Reg. 1272/2008)**
Toxicological properties of active substance(s) (relevant for classification of product)	Zinc phosphide (2.5 % (w/w))	R28; R22 (principle of additivity) R29 [1)] R32 H300; H302 (principle of additivity) EUH029 [1)] EUH032	Reg. (EC) No 1272/2008	R22 R32 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 Arvalin Forte 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 Arvalin Forte

	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	Stutox-II / Arvalin Forte (DET-12345-R-0-RB)

Formulation type	RB
Category	Rodenticide
Container size(s), short description	2 x 5 kg polyethylene bags stored in 10 kg buckets
Active substance(s) (incl. content)	**Zinc phosphide** 25 g/kg
AOEL systemic	0.042 mg/kg bw/d *
Inhalative absorption	100 %
Oral absorption	100 %
Dermal absorption	Default value of 10 % for zinc phosphide and phosphine

* based on a maximum liberation of gas of 0.26 g PH_3/g zinc phosphide in acidic medium

3.5.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is 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:

$A_{der} = Q_{prod} \times Fc_{prod} / V_{prod} / D \times TH_{der} \times Area_{der}$

A_{der}	amount of active substance (mg) on the skin
D	dilution factor = 1
Q_{prod}	amount of undiluted product (mg) used = 10000000 mg
Fc_{prod}	weight fraction of active substance in the product = 2.5 %
V_{prod}	volume of undiluted product (cm^3) = 10000 g / 0.712 g/cm^3 = 14045 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; 25th percentile, US EPA)

Assuming that 10 kg product (area: 5 ha) with a density of 0.712 g/cm^3 are applied per day by a professional operator and that the hands of the operator get into contact with the product then:

A_{der} = 10000000 mg x 2.5 % / 14045 cm^3 / 1 x 0.01 cm x 820 cm^2 = 146.0 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_{der} = A_{der} (appl.) + A_{der} (disp.) = 146.0 mg a.s. + 146.0 mg a.s. x 20 % = 175 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 potential of dust exposure is considered low with respect to the formulation as ready-to-use grain bait. Therefore, the overall exposure is only based on dermal contact and was calculated as follows:

% AOEL-S = A_{der} x Abs_{der} / BW /AOEL-S x 100

AOEL-S	systemic AOEL (mg/kg bw/d) = 0.042 mg/kg bw/d
Abs_{der}	dermal absorption (%) = 10 %
BW	body weight (kg) = 60 kg

% AOEL-S = 175 mg a.s. x 10 % / 60 kg / 0.042 mg/kg bw/d x 100 = 694.4 %

The estimated worst case exposure for a professional operator exceeds the systemic AOEL. Hence, gloves should be taken into account for handling the product as well as for disposal and cleaning. Assuming a protection factor of 99 % for wearing protective gloves the operator exposure will be below the AOEL-S with 6.9 %.

3.5.2.2 Measurement of operator exposure

Not required since worker exposure is considered to be negligible.

3.5.3 Worker exposure (IIIA 7.5)

3.5.3.1 Estimation of worker exposure

Worker exposure is considered to be negligible. The application of the product into holes/burrows will prevent any potential for direct exposure with the product. In contrast to other phosphide active substances, the release of phosphine will only occur in acidic environments (i.e. in the stomach of the target organism) and therefore there is little or no potential for worker exposure to evolved phosphine.

3.5.3.2 Measurement of worker exposure

Not required since worker exposure is considered to be negligible.

3.5.4 Bystander and resident exposure (IIIA 7.4)

3.5.4.1 Estimation of bystander and resident exposure

Bystander and resident exposure is considered to be negligible. The application of the product into holes/burrows will prevent any potential for direct exposure with the product. In contrast to other phosphide active substances, the release of phosphine will only occur in acidic environments (i.e. in the stomach of the target organism) and therefore there is little or no potential for bystander/resident exposure to evolved phosphine. The potential for dust exposure is considered low with respect to the formulation as ready-to-use grain bait. 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

Not required since bystander and/or resident exposure is considered to be negligible.

3.5.5 Statement on combined exposure

Not relevant. 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 only consisting of foodstuff and the physical properties of the formulated product.

Comments of zRMS:	Acceptable.

A 2.2 Acute oral toxicity (IIIA1 7.1.1)

Comments of zRMS:	Waiving of the study acceptable.

Justification for non-submission as given by the applicant

No particular justification for non-submission was given.

Conclusion

The acute oral toxicity LD_{50} 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 Arvalin Forte containing 2.5 % zinc phopshide (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 Arvalin Forte 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 (in line with study results for similar zinc phosphide formulations).

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

Comments of zRMS:	Justification for waiving of the study acceptable.

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

1. Zinc phosphide is practically water insoluble (<1.4 g/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.

2. 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 this circumstance, nor would the substance be mobile even if it had penetrated through skin.

3. In the 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.

4. The plant protection product represents a ready-to-use rodenticide pressed pellet bait, where zinc phosphide in a low concentration is combined to foodstuff materials. 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 therefore negligible.

Conclusion

The dermal (intact skin) LD_{50} for zinc phosphide in rats was calculated to be 2000 mg/kg bw (1750-2300) over 24 hours and 1000 mg/kg bw (909-1100) over 14 days for both sexes. According to Directive 67/548/EEC, classification as 'Harmful in contact with skin' (R21) is required for zinc phosphide. However, given the low concentration of zinc phosphide in Arvalin Forte it is proposed that no classification for dermal toxicity is required for this product according to Directive 1999/45/EEC or 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.

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

1. There is no potential for any inhalation exposure due to the extremely low pressure of the Active Substance zinc phosphide (6.5×10^{-9}hPa at 20 °C, IIA 2.3.1/01).

2. The GAP for Arvalin Forte does not involve either spraying or any dust exposure, as the product is formulated as pressed pellet bait the potential for dust exposure is negligible. This is confirmed experimentally under GLP by a dry sieve analysis, which yielded 0.13% of particles are in the range 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 Arvalin Forte does not contain any measurable content of particles of an inhalable particle size.

3. Therefore, release of the Active Substance or the metabolite phosphine is not expected to any relevant extent during normal handling and use of the product, and the potential for any inhalation exposure is therefore negligible.

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.

Justification for non-submission as given by the applicant

The submission of data or the performance of a test on the skin irritation potential of the product Arvalin Forte is not considered to be required, for the following reasons:

1. The plant protection product represents ready-to-use rodenticide bait, in which zinc phosphide in a low concentration is combined to raw foodstuff material in pressed pellet format. The toxicity of the product can be addressed based on extrapolation from the Active Substance and is not predicted to be influenced by the presence of toxicologically inert co-formulants.

2. Due to the proposed GAP, no relevant extent of dermal contact of the user or other persons with the product is to be expected.

3. Further, it is noted that in a test for acute skin irritation of zinc phosphide in the rabbit (KIIIA1 7.1.4/01), no skin irritation was observed. Considering the composition of the formulated product, which consists largely of raw food-grade materials, Arvalin Forte does not require classification for skin irritation according to the requirements specified by Directive 1999/45/EC or Regulation (EC) No. 1272/2008.

Conclusion

None of the substances in Arvalin Forte 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.

Justification for non-submission as given by the applicant

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

1. The plant protection product is formulated as a ready-to-use rodenticide bait, in which zinc phosphide in a low concentration is combined to raw foodstuff material in pressed pellet format. The toxicity of the product can be addressed based on extrapolation from the Active Substance and is not predicted to be influenced by the presence of toxicologically inert co-formulants.

2. Due to the proposed GAP, no exposure of the eyes or mucous membranes with the product is expected.

3. Further, it is noted that in a test for acute eye irritation of zinc phosphide in the rabbit (KIIIA1 7.1.5/01), no eye irritation was observed. Considering the composition of the formulated product, which consists largely of food-grade materials, Arvalin Forte does not require classification for eye irritation according to the requirements specified by Directive 1999/45/EC or Regulation (EC) No. 1272/2008.

Conclusion

None of the substances in Arvalin Forte 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.

Justification for non-submission as given by the applicant

No particular justification for non-submission was given by the applicant.

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: Arvalin Forte

Active Substance: zinc phosphide 25 g/kg

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Detia Freyberg GmbH

Date: February 2014

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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_3P_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.

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

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

	Ruminant:	**Poultry:**	**Pig:**
	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 central zone are presented in Table 8.2-1. They have 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
					Application			**Application rate**				
Use-No.	**Member state(s)**	**Crop** **(crop codes according to Annex I of Reg. (EC) No 396/2005)** **(a)**	**F G or I** **(b)**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)** **(c)**	**Method / Kind** **(d-f)**	**Timing / Growth stage of crop & season** **(g)**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season** **(h)**	**kg product / ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**	**PHI (days) (i)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures** **(j)**
001, 003, 005, 007, 009, 011, 013	DE	**field crops** (0211000, 0213110, 0300020, 0300030, 0401010, 0401030, 0401050, 0401060, 0401070, 0401080, 0401100, 0401130, 0401140, 0500010, 0500020, 0500030, 0500040, 0500050, 0500060, 0500070, 0500080, 0500090, 0500990, 0900010), **vegetables** (0210000, 0220000, 0230000, 0240000, 0250000, 0260000, 0270000, 0280000), **fruit crops** (0110000, 0120000, 0130000, 0140000, 0150000, 042010), **table and wine grapes** (0151000, 0151010, 0151020) **grassland, pasture, meadow ornamentals, forest plants**	F	common vole (*Microtus arvalis*)	lay out poisoned pellets in vole holes	if required	a) 3 b) 3	a) 2 (4 pellets per hole) b) 6	a) 0.05 b) 0.15		F/N	The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha.

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop** **(crop codes according to Annex I of Reg. (EC) No 396/2005)** **(a)**	**F G or I** **(b)**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)** **(c)**	**Application**			**Application rate**			**PHI (days) (i)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures** **(j)**
					Method / Kind **(d-f)**	**Timing / Growth stage of crop & season** **(g)**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season** **(h)**	**kg product / ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
002, 004, 006, 008, 010, 012, 014	DE	**field crops** (0211000, 0213110, 0300020, 0300030, 0401010, 0401030, 0401050, 0401060, 0401070, 0401080, 0401100, 0401130, 0401140, 0500010, 0500020, 0500030, 0500040, 0500050, 0500060, 0500070, 0500080, 0500090, 0500990, 0900010), **vegetables** (0210000, 0220000, 0230000, 0240000, 0250000, 0260000, 0270000, 0280000), **fruit crops** (0110000, 0120000, 0130000, 0140000, 0150000, 042010), **table and wine grapes** (0151000, 0151010, 0151020) **grassland, pasture, meadow** **ornamentals, forest plants**	F	common vole (*Microtus arvalis*)	lay out poisoned pellets in bait stations	if required	a) 3 b) 3	a) 2 (50 g per bait station) b) 6	a) 0.05 b) 0.15		F/N	The application rate of 2.00 kg/ha per use can be divided into 3 single applications of 0.66 kg/ha.

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop** **(crop codes according to Annex I of Reg. (EC) No 396/2005)** **(a)**	**F G or I** **(b)**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)** **(c)**	**Application**			**Application rate**			**PHI (days) (i)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures** **(j)**
					Method / Kind **(d-f)**	**Timing / Growth stage of crop & season** **(g)**	**Max. number (min. interval between applications) a) per use b) per crop/ season (h)**	**kg product / ha a) max. rate per appl. b) max. total rate per crop/season**	**kg as/ha** **a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha** **min / max**		
	AT, BE, CZ, PL, SL	agricultural areas	F	common vole (*Microtus arvalis*)	lay out poisoned pellets - in vole holes - in bait stations	not defined	a) 3 b) 9	a) 2 (2-4 pellets/hole or 20- 50 g pellets/bait station) b) 6	n.a.		F	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.
	AT, BE, CZ, PL, SL	agricultural crops, vegetable crops, fruit crops, vinicultural crops, grassland, lawns and meadows, ornamental crops, coniferous and deciduous trees	F	common vole (*Microtus arvalis*)	lay out poisoned pellets in vole holes	not defined	a) 3 b) 9	a) 2 (2-4 pellets/hole) b) 6	a) 0.05 b) 0.15		F	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.
	AT, BE, CZ, PL, SL	agricultural crops, vegetable crops, fruit crops, vinicultural crops, grassland, lawns and meadows, ornamental crops, coniferous and deciduous trees	F	common vole (*Microtus arvalis*)	lay out poisoned pellets in bait stations	not defined	a) 3 b) 9	a) 2 (20-50 g/bait station) b) 6	a) 0.05 b) 0.15		F	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.

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 suckling 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. Repeated application of baits will not alter this conclusion.

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

The envisaged uses are not relevant in terms of consumer health protection. Thus, 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 consumer intake and risk assessment is based on the appropriate input values given in Table 8.3-1 and the toxicological reference values stated in Table 8.3-2. For the detailed calculation results it is referred to Appendix 3.

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 are 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	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

* Y: Yes, relied on
N: No, not relied on
Add: Relied on, study not submitted by applicant but necessary 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.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,011**	ARfD (mg/kg bw):	**0,049**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

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	
3	23
No of diets exceeding ADI:	---

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	10,5	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	PRODUCTS OF ANIMAL ORIGIN	
17,2	IE adult	6,0	CEREALS	4,9	FRUIT (FRESH OR FROZEN)	1,6	Tropical root and tuber vegetables	
16,4	FR toddler	5,3	FRUIT (FRESH OR FROZEN)	3,9	PRODUCTS OF ANIMAL ORIGIN	2,7	CEREALS	
16,2	DK child	9,5	CEREALS	2,3	FRUIT (FRESH OR FROZEN)	2,0	PRODUCTS OF ANIMAL ORIGIN	
13,6	FR infant	6,9	FRUIT (FRESH OR FROZEN)	2,5	PRODUCTS OF ANIMAL ORIGIN	1,4	Other root and tuber vegetables	
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 kids/toddler	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)	0,7	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: Arvalin Forte

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

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: **Detia Freyberg GmbH**

Date: **October 2016, updated March 2018**

Table of Contents

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 Arvalin Forte 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 Arvalin Forte

Code	008023-00/00		
plant protection product	Arvalin Forte		
applicant	Detia Freyberg GmbH		
date of application	July 2013		
Formulation type (WP, EC, SC, …; density)	Ready for use - pressed pellet 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 Arvalin Forte. A list of all intended uses within the zone is given in Appendix 3 /Part B.

Table 5.2-1: Critical use pattern of Arvalin Forte

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	agricalure 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_3P_2
Molecular mass	258.1 g/mol
Structural formula	Zn_3P_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 × m^3 × 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 P_{OW}	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 relevanrt	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/cm³ (rate constant 1.6 x 10^{-11} cm³/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 Arvalin Forte 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. PECgw 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 Arvalin Forte in all crops the application rate of zinc phosphid is higher, so that the leaching potential of the soil metabolite phosphine 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”	Soil: relevant

		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.	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)

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 DT_{50} 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 Q_{10} 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 (PECgw) the following empirical estimation methods were applied for zinc phosphide (1) and phosphine (2) based on its water solubility:

(1) Log Koc = -0.55 log S +3.64 [mg/L] [Kenaga, E.E. & Goring, C.A.I. (1978)]

(2) Log Koc = -0.557 log S + 4.277 [µmol/L] [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)

PECsoil 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 Table 5.2-1 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 is presented in Table 5.5-1.

Table 5.5-1: Input parameters related to application for PEC_{Soil} calculations

Plant protection product	Arvalin Forte
Use No.:	00-01 to 00-015
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 Arvalin Forte in all crops (soil bulk density 1.5 g/cm^{-3}, 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 (PECsw/PECsed) (KIIIA1 9.7)

Justification for non-submission

The calculation of predicted environmental concentrations in surface waters (PECsw) and consequently in sediments for zinc phosphide and the metabolite phosphine following the GAP uses of Arvalin Forte 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 Arvalin Forte 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 cm) = 0.2 mg/kg soil).

(ii) Zinc phosphide is of extremely low water solubility (< 1.4 µg/L at 20 °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 Arvalin Forte 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 Arvalin Forte 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 Arvalin Forte do not pose an unacceptable risk to groundwater.

5.8 Potential of active substance for aerial transport

The vapour pressure at 20 °C of the active substance zinc phosphide is $<<10^{-5}$ 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 Arvalin Forte 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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
1	Central zone (Germany, Austria, Belgium, Czech Republic, Slovakia)	Agricultural areas	F	Common vole (*Microtus arvalis*)	1) in vole holes 2) in bait stations	Not defined	a) 3 b) 9	2-4 pellets / hole or 20-50 g pellets /bait station a) 2.00kg/ha b) 6.00kg/ha	n.a.	n.a.	Not required	Type/formulation: RB (pellet bait) 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 (Germany, Austria, Belgium, Czech Republic, Slovakia)	Agricultural crops	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / hole a) 2.00kg/ha b) 6.00kg/ha	a) 50g as/ha b) 150g as/ha	n.a.	Not required	Type/formulation: RB (pellet bait) 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 (Germany, Austria, Belgium, Czech Republic, Slovakia)	Agricultural crops	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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 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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
												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 (Germany, Austria, Belgium, Czech Republic, Slovakia)	Vegetable crops	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) 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 (Germany, Austria, Belgium, Czech Republic, Slovakia)	Vegetable crops	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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 (Germany, Austria, Belgium, Czech	Fruit crops	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3	2-4 pellets / hole	a) 50 g as/ha	n.a.	Not required	Type/formulation:

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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
	Republic, Slovakia)						b) 9	a) 2.00kg/ha b) 6.00kg/ha	b) 150 g as/ha			RB (pellet bait) 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.
7	Central zone (Germany, Austria, Belgium, Czech Republic, Slovakia)	Fruit crops	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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.

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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
8	Central zone (Germany, Austria, Belgium, Czech Republic, Slovakia)	Vinicultural crops	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) 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 (Germany, Austria, Belgium, Czech Republic, Slovakia)	Vinicultural crops	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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 (Germany, Austria, Belgium, Czech Republic, Slovakia)	Grassland, lawns and meadows	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) 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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
												A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
11	Central zone (Germany, Austria, Belgium, Czech Republic, Slovakia)	Grassland, lawns and meadows	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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 (Germany, Austria, Belgium, Czech Republic, Slovakia)	Ornamental crops	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) 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 (Germany, Austria, Belgium, Czech Republic, Slovakia)	Ornamental crops	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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 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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
												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 (Germany, Austria, Belgium, Czech Republic, Slovakia)	Coniferous and deciduous trees	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) 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 (Germany, Austria, Belgium, Czech Republic, Slovakia)	Coniferous and deciduous trees	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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: Arvalin Forte

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

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM – Germany

Applicant: **Detia Freyberg GmbH**

Date: **October 2016**

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

The exposure assessment of the plant protection product Arvalin Forte in its intended uses in agriculture, orchard, vegetables, ornamentals, grassland, forestry and vinyards is documented in detail in the core assessment of the plant protection product Arvalin Forte dated from December 2013 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 Arvalin Forte in Germany according to uses listed in Appendix 3.

A risk assessment for PECgw and PECsw is not considered to be required. Justification for non-submission see core assessment, Part B, section 5, chapter 5.6 and 5.7.
PECsoil 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 Arvalin Forte

Code	008023-00/00		
plant protection product	Arvalin Forte		
applicant	Detia Freyberg GmbH		
date of application	July 2013		
Formulation type (WP, EC, SC, …; density)	Ready for use - pressed pellet 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 Arvalin Forte

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)

A/ 00-001 to 00-024	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

* 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 (December 2013), 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 (December 2013), part B, section 5, point 5.4.1.

5.4.2 Adsorption/desorption

Zinc phosphide

Please refer to the core assessment (December 2013), part B, section 5, point 5.4.2.

5.4.3 Rate of degradation in water/sediment

Zinc posphide

Please refer to the core assessment (December 2013), part B, section 5, point 5.4.3.

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Results of PECsoil calculation for Arvalin Forte according to EU assessment considering 5 cm soil depth are given in the core assessment December 2013, 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 PECsw calculation of zinc phosphide for the intended for uses of Arvalin Forte in all crops using are given in the core assessment (December 2013), part B, section 5, chapter 5.6.

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Justification for non-submission of PECgw calculation of zinc phosphode for the intended uses of Arvalin Forte in all crops are given in the core assessment (December 2013), 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 26.09.2013)

PPP (product name/code) **Arvalin Forte** **Formulation type:** **type**
active substance 1 **Zinkphosphid** **Conc. of as 1:** **25 g/kg**

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

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)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					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		
001	DE	Field crops (NNNAC)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
002	DE	Field crops (NNNAC)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.

003	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
004	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
005	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
006	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
007	DE	Grape vine (VITVI)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
008	DE	Grape vine (VITVI)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
009	DE	Grassland, pasture, meadow (NNNFW)	F	Common vole (MICRAR)	lay out poisoned	if required	a) 3	a) 2 kg/ha	a) 50 g as/ha			The dose corresponds to 4 pellets per hole

					pellets		b) 3	b) 6 kg/ha	b) 150 g as/ha			The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
010	DE	Grassland, pasture, meadow (NNNFW)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
011	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
012	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
013	DE	Forest plants (NNNWW)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
014	DE	Forest plants (NNNWW)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/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.

REGISTRATION REPORT
Part B

Section 6: Ecotoxicological studies
Detailed summary of the risk assessment

Product code: **Arvalin Forte**
Active Substance: **Zinc phosphide 25 g/kg**

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: **Detia Freyberg GmbH**
Date: **October 2016, updated March 2018**

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Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

This document reviews the ecotoxicological studies for the product Arvalin Forte 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.

Arvalin Forte 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 Arvalin Forte and for the active substance zinc phosphide or its major metabolites.

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 areas	F	n.d.	n.d.	0.05	0.15	X1		X1				
2, Agricultural crops	F	n.d.	n.d.	0.05	0.15	X1		X1				
3, Agricultural crops	F	n.d.	n.d.	0.05	0.15	X1		X1				
4, Vegetable crops	F	n.d.	n.d.	0.05	0.15	X1		X1				
5, Vegetable crops	F	n.d.	n.d.	0.05	0.15	X1		X1				
6, Fruit crops	F	n.d.	n.d.	0.05	0.15	X1		X1				
7, Fruit crops	F	n.d.	n.d.	0.05	0.15	X1		X1				
8, Vinicultural crops	F	n.d.	n.d.	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, Vinicultural crops	F	n.d.	n.d.	0.05	0.15	X1		X1				
10, Grassland, lawns and meadows	F	n.d.	n.d.	0.05	0.15	X1		X1				
11, Grassland, lawns and meadows	F	n.d.	n.d.	0.05	0.15	X1		X1				
12, Ornamental crops	F	n.d.	n.d.	0.05	0.15	X1		X1				
13, Ornamental crops	F	n.d.	n.d.	0.05	0.15	X1		X1				
14, Coniferous and deciduous trees	F	n.d.	n.d.	0.05	0.15	X1		X1				
15, Coniferous and deciduous trees	F	n.d.	n.d.	0.05	0.15	X1		X1				

F: Field use; G: Glasshouse use

Remarks:
- Safe use identified
- 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”: There is an acute risk for non-target birds and mammals indicated from dietary exposure. 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). 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 Arvalin Forte

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 (subdivison into 3 x 3 x 16.6 possible)= max. 150
Grouping for overall environmentals 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	Outdoor use in: Agricultural areas / not defined	1) in vole holes, 2-4 pellets/hole 2) in bait stations, 20 -50 g pellets/bait station	3 x 3 appl. per season Zinc phosphide: max. 3 x 50 (subdivison into 3 x 3 x 16.6 possible)= max. 150
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 vole holes, 2-4 pellets/hole	3 x 3 appl. per season Zinc phosphide: max. 3 x 50 (subdivison into 3 x 3 x 16.6 possible)= max. 150
A 3 / 3, 5, 7, 9, 11, 13, 15	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	3 x 3 appl. per season Zinc phosphide: max. 3 x 50 (subdivison into 3 x 3 x 16.6 possible)= max. 150

Please note: the intended use no. 1 (agricultural areas) is not precisely defined and could potentially include non-cultivated areas. Members states will have to check, how the intended uses are exactly defined for their national authorization and check whether they fully comply with the regulation. For the authorization in Germany no use outside cultivated area has been applied for by the applicant.

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 (MIIIA 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
Colinus virginianus	Zinc phosphide	acute oral 1d Method EPA 850.2100, 71-1	LD50 = 12.9 mg/kg bw	[redacted] 27.01.1978 MRID 00006032	46052
Branta canadensis	Zinc phosphide	acute oral 1d	LD50 = 12 mg/kg	[redacted] 01.01.1983	57257

Colinus virginianus	Zinc phosphide	Short term Dietary with vehicle 5 d	LC50 468.5 mg/kg feed	[redacted] 11.03.1978 MRID 00006031	46057
Coturnix japonica	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	[redacted] 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 GAP uses of Arvalin Forte and in line with the EU DAR two pathways of exposure have to be considered for risk assessment as potential routes of critical exposure:

- Primary poisoning - Feeding on bait (i.e. Arvalin Forte)
- Secondary poisoning - Feeding on animals that have incorporated Arvalin Forte

The applicant concluded an acceptable risk in the overall conclusion. Citation from the applicant's core assessment is given in italics:

"Zinc phosphide is highly toxic to vertebrates, and even the consumption of one treated sunflower kernel results in a TER of 0.1 for birds. The representative use of zinc phosphide intends to eliminate the exposure to birds by application of pressed cereal pellet bait applied to targeted vole burrows and bait stations. However, in addition, appropriate mitigation measures should be considered to avoid the spread of the treated cereal, where only part of the content has been consumed.

Secondary poisoning of birds and non-target mammals was considered unlikely due to:

1) the rapid dissipation of phosphine in carcasses of zinc phosphide poisoned target rodents

2) predators tend not to take up the gastro-intestinal tract of prey, which contains the highest amount of residues

3) poisoned target organisms usually die in their burrows

Based on the insignificant exposure expected from the representative use, the risk to birds and non-target mammals was assessed as low.

The existing registered GAP use of Stutox - II as a rodenticide is restricted to the application of the baits into the voles' burrows or in bait stations. Since birds are known not to enter the burrows or bait stations a direct access to the bait and exposure can be excluded.

Based on the insignificant exposure expected from the intended mode of application, EFSA concluded for other zinc phosphide products applied using a similar technique, that the risk to birds via diet, drinking water and secondary poisoning was low. In case other modes of application of zinc phosphide are considered, appropriate risk mitigation measures should be considered at Member State level for the protection of birds."

6.2.2.1 Primary poisoning

The zRMS draws a different conclusion than the applicant. The zRMS considers the risk of spillage not negligible as in difference to the representative product assessed in the DAR (Arrex E Köder) Arvalin Forte is a ready-to-use bait that comes as lose kernels. The product evaluated in the DAR was provided in foliated bags as part of the formulation and in line with the specific provision for Annex I inclusion should additionally be laid out in "bait stations or target locations", i.e. hidden places not attractive for birds (i.e. non-target species). The study of [redacted] (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 Arvalin Forte is 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 4 kernels (the max. amount applied into one hole) would be available for birds at once. According to the applicant a portion of 4 kernels contains 5 mg zinc phoshide. In consideration of the lowest available LD_{50} of 12.9 mg/kg bw (and without consideration of a safety factor), this results in unacceptable lethal risk for small granivorous or omnivorous birds of less than 388 g bodyweight (e.g. linnet, partridge).

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 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, the intended uses of Arvalin Forte lack further complementary risk mitigation (i.e. provision in foliated bags).

For the intended uses with bait stations is 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 group A2 and group A1 (i.e. those intended uses of group A 1 that foresee loose provision in vole holes) 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 3 and A 1 (i.e. intended uses of group A1 that foresee the 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 on member state level. For German criteria please refer to the National Addendum.

In agreement with the DAR evaluation 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 (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 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 Arvalin Forte 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 = 4 grains = 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) 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 is not necessary to determine bioaccumulation in non-target organisms (please refer to the EU DAR and EFSA Journal (2010) 8(7):1671)).

6.2.4 Overall conclusions

Dietary risk assessment

On individual level, acute dietary risk cannot be excluded as in comparison to the representative use evaluated in the DAR, the intended uses of Arvalin Forte lack “intrinsic” risk mitigation (i.e. provision in foliated bags). As a worst-case, 4 kernels equivalent to 5 mg zinc phosphide (the amount applied into one hole) may be available for birds. In consideration of the lowest available LD_{50} (12.9 mg/kg bw), a lethal risk cannot be excluded for any granivorous or omnivorous birds of less than 388 g bodyweight (e.g. linnet, partridge, pigeon). It is acknowledged, that this scenario may be restricted to very rare cases as baits should ideally be rapidly consumed by target organisms and the applications in vole holes reduce the risk of exposure to birds.

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

For intended use group A2 and A1 (intended use loose provision in vole holes) 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 3 and A 1 (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 on member state level. For German criteria please refer to the National Addendum.

Due to the lack of systematic continuous ingestion, 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 Arvalin Forte.

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 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 Journal 2010; 8(7):1671)	[redacted] (2000), TOX2006-19 [redacted] (1979), 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 have not been submitted are not considered necessary.

6.3.2 Risk assessment (MIIIA 10.3.1) for baits, pellets, granules, prills or treated seeds

Referring to the GAP uses of Arvalin Forte and in line with the EU DAR two pathways of exposure have to be considered for risk assessment as potential routes of critical exposure:

- Primary poisoning - Feeding on bait (i.e. Arvalin Forte)
- Secondary poisoning - Feeding on animals that have incorporated Arvalin Forte

The applicant concluded an acceptable risk in the overall conclusion. Citation from the applicant's core assessment is given in italics:

"Zinc phosphide is highly toxic to vertebrates. The representative use of zinc phosphide intends to eliminate the exposure to non-target mammals by applicationofpressed pellet bait applied to targeted vole burrows and bait stations. However, in addition, appropriate mitigation measures should be considered to avoid the spread of the treated cereal where only part of the content has been consumed.

Secondary poisoning of non-target mammals was considered unlikely due to:

1) the rapid dissipation of phosphine in carcasses of zinc phosphide poisoned target rodents

2) predators tend not to take up the gastro-intestinal tract of prey, which contains the highest amount of residues

3) poisoned target organisms usually die in their burrows

Based on the insignificant exposure expected from the representative use, the risk to birds and non-target mammals was assessed as low

The existing registered GAP use of Stutox - II as a rodenticide is restricted to the application of the baits into the voles' burrowsor in bait stations. As a result of the targeted use of the product exposure of non-target mammals can be excluded.

Based on the localised and insignificant exposure expected from the intended mode of application, EFSA concluded for other zinc phosphide products applied using a similar technique, the risk to non-target mammals via diet, drinking water and secondary poisoning was assessed as low. In case other modes of application of zinc phosphide are considered, appropriate risk mitigation measures should be considered at Member State level for the protection of birds."

6.3.2.1 Primary poisoning

The zRMS draws a different conclusion than the applicant. The zRMS considers the risk of spillage not negligible as in difference to the representative product assessed in the DAR (Arrex E Köder) Arvalin Forte is a ready-to-use bait that comes as lose pellets. 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 Arvalin Forte is 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 (2-4 pellets per vole hole, per application 50 g a.s./ha).

When considering the intended uses as given in the GAP table, two scenarios for acute dietary risk assessment have to be considered:

For intended uses with envisaged application of portions of 4 kernels per vole hole, an amount of 5 mg zinc phosphide could be consumed at once as worst case assumption. Considering the EU-agreed LD_{50} of 37 mg/kg bw, the amount of zinc phosphide contained in one portion of bait results in TER values < 1 for mammal with a bodyweight of less than 135 g. 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 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 or they may be preyed. 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. Thus, there is an acute risk for non-target mammals indicated from dietary exposure that is only considered to be acceptable when risk mitigation that ensures hidden application is considered.

For the intended application in bait stations according to the GAP table, as second worst case scenario, it is assumed that a small non-target mammal would access a bait station filled with up to 50 g of bait, corresponding to 1.25 g of zinc phosphide. In this scenario, the consumption of more than 4 pellets is likely, when the bait is provided loosely in the bait station. Also, bait could be collected by non-target rodents and be brought to their food storage. Therefore, for the intended uses with provision of the bait loosely in bait stations, risk cannot be excluded and hence approval can only be supported when suitable bait stations are used that may reduce the risk due to their construction.

In conclusion, for intended use group A2 and A1 (for loose provision in vole holes) 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 3 and A 1 (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 on member state level. For German criteria please refer to the National Addendum.

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

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 (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 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 Arvalin Forte 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 (MIIIA 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 phosphide 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 [redacted] (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 mammals 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 Arvalin Forte 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 (4 pellets per vole hole, per application 50 g a.s./ha). Thus, on individual level, acute dietary risk cannot be excluded as in comparison to the representative use evaluated in the DAR, the intended uses of Arvalin Forte lack the combination of risk

mitigation measures (i.e. hidden placement plus inherent risk mitigation comparable to provision in foliated bags as part of the formulation)..

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

For intended use group A2 and A1 (for loose provision in vole holes) 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 3 and A 1 (for use in bait stations) 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.

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 Arvalin Forte.

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 assessement. 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 is 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. Update March 2018: No statement has been submitted. However, the authority acknowledges that to date clear guidance on this area of risk assessment is not yet implemented and that based on the current state of knowledge it is reasonable to assume that both amphibians and reptiles are not attracted by the type of bait and thus the risk from primary (dietary) poisoning is not in scope here. Also, dermal absorption (possibly relevant

pathway for amphibians) is not likely as the active substance is effectively bound to the bait matrix. With respect to secondary poisoning of reptiles similar arguments account as already presented for birds and mammals. It cannot be excluded that still living, yet already intoxicated voles may be preyed. However, based on available data there is no indication that the risk from Arvalin forte would be unacceptable for reptiles.

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
Leuciscus idus	Zinc phosphide technical	4 d Semi-static OECD 203	LC50 > 0.0217 mg/L	[redacted] 13.09.2001 20001426/01-AAli	46056
Daphnia magna	Zinc phosphide technical	2 d Static OECD 202	EC50 = 0.114 mg/L	Heintze, A. 13.09.2001 20001426/01-AADm	46067
Desmodesmus subspicatus	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 Arvalin Forte 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)

Registration Report Part B Section 6 (25 g/kg zincphosphid) is applied to discrete sites in form of baits with low concentration of active substance. Due to the mode of application, only rodents can obtain any relevant access to the pellets. No data from bee toxicity tests are required.

Overall conclusion:
It is concluded that Arvalin Forte will not adversely affect bees or bee colonies when used as recommended.

6.6.1 Hazard quotients for bees

Not required.

6.6.1.1 Oral exposure Q_{HO}

Not required.

6.6.1.2 Contact exposure Q_{HC}

Not required.

6.6.2 Acute toxicity of the formulation to bees

Not required.

6.6.2.1 Oral

Not required.

6.6.2.2 Contact

Not required.

6.6.3 Effects on bees of residues on crops

Not required.

6.6.4 Cage tests

Not required.

6.6.5 Field tests

Not required.

6.6.6 Investigation into special effects

Not required.

6.6.6.1 Larval toxicity

Not required.

6.6.6.2 Long residual effects

Not required.

6.6.6.3 Disorienting effects on bees

Not required.

6.6.7 Tunnel tests

Not 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 Arvalin Forte 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 Arvalin Forte 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
Eisenia foetida	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
Eisenia foetida	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 6 kg product/ha and treatment, i.e. 150 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 Arvalin Forte / 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 LC_{50} value to generate acute TER values. The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50}\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

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/ha

Species	Test item	Time scale	Endpoint [mg/kg soil dw]	Max. PEC_{SOIL} [mg/kg soil dw]	TER
Eisenia fetida	zinc phosphide	Acute	1000	0.1244 (5 cm)	8039
	zinc phosphide	Acute	1000	0.62 (1 cm)	1613

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 Arvalin Forte 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 Arvalin Forte 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 Arvalin Forte 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 Arvalin Forte.

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	0.1244 (5 cm)	Yes, MoS = 2.6
zinc phosphide	0.32	0.62 (1 cm)	*No (please refer to the argumentation below)*

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 Arvalin Forte 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 Arvalin Forte 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 / Arvalin Forte according to the GAP of the formulation Arvalin Forte 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, in agreement with the argumentation of the applicant 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 Arvalin Forte 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

None submitted.

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 assesment 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

n.a.

Appendix 3 Table of Intended Uses in the central zone (GAP table)

GAP rev. , date: year-month-day

PPP (product name/code)	**Stutox - II**	**Formulation type:**	**RB Ready to use bait**
Active Substance 1	**Zinc phosphide**	**Conc. of as 1:**	**2.5%**
Active Substance 2	**Not applicable**	**Conc. of as 2:**	**Not applicable**
Active Substance	**Not applicable**	**Conc. of as:**	**Not applicable**
safener	**Not applicable**	**Conc. of safener:**	**Not applicable**
synergist	**Not applicable**	**Conc. of synergist:**	**Not applicable**
Applicant:	**Detia Freyberg GmbH**	**professional use**	☒
Zone(s):	**Central/EU**	**non professional use**	☐
Verified by MS: j/n			

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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
1	Central zone (Austria, Belgium, Czech Republic, Poland, Slovakia)	Agricultural areas	F	Common vole (*Microtus arvalis*)	1) in vole holes 2) in bait stations	Not defined	a) 3 b) 9	2-4 pellets / hole or 20-50 g pellets /bait station a) 2.00kg/ha b) 6.00kg/ha	n.a.	n.a.	Not required	Type/formulation: RB (pellet bait) 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, Poland, Slovakia)	Agricultural crops	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait)

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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
												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, Poland, Slovakia)	Agricultural crops	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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, Poland, Slovakia)	Vegetable crops	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) 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.

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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
5	Central zone (Austria, Belgium, Czech Republic, Poland, Slovakia)	Vegetable crops	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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, Poland, Slovakia)	Fruit crops	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) 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.
7	Central zone (Austria, Belgium, Czech Republic, Poland, Slovakia)	Fruit crops	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
												A maximum of 3 uses per season (resulting in 6.00 kg/ha) must not be exceeded.
8	Central zone (Austria, Belgium, Czech Republic, Poland, Slovakia)	Vinicultural crops	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) 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, Poland, Slovakia)	Vinicultural crops	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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, Poland, Slovakia)	Grassland, lawns and meadows	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.

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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
												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, Poland, Slovakia)	Grassland, lawns and meadows	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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, Poland, Slovakia)	Ornamental crops	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) 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, Poland, Slovakia)	Ornamental crops	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait)

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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
												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, Poland, Slovakia)	Coniferous and deciduous trees	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) 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, Poland, Slovakia)	Coniferous and deciduous trees	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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: **Arvalin Forte**

Active Substance: **Zinc phosphide 25 g/kg**

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM

Applicant: **Detia Freyberg GmbH**

Date: **October 2016, updated March 2018**

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Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

A full risk assessment according to Uniform Principles for the plant protection product Arvalin Forte in its intended uses is documented in detail in the core assessment of the plant protection product Arvalin Forte dated from February 2014 performed by zRMS DE.

This document comprises specific risk assessment for some annex points for authorization of the plant protection product Arvalin Forte in Germany according to the uses listed in Appendix 2.

General information on the formulation Arvalin Forte can be found in Table 5.1-1of Section 5 of the National addendum Germany (February 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 Arvalin Forte 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 Arvalin Forte

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/ 00-001 to 00-014	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 = max. 150
Grouping for overall environmentals 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 / 00-001, 00-003, 00-005, 00-007,00-009, 00-011, 00-013	Outdoor use in: Field crops; vegetables; fruit crops; grape vine; grassland, pasture and meadows; ornamentals; forest plants / if required	Lay out poisoned pellets, the dose corresponds to 4 pellets per hole	3 x per season Zinc phosphide: max. 3 x 50 (subdivison into 3 x 3 x 16.6 possible) = max. 150
A 2 / 00-002, 00-004, 00-006, 00-008, 00-010, 00-012, 00-014	Outdoor use in: Field crops; vegetables; fruit crops; grape vine; grassland, pasture and meadows; ornamentals; forest plants / if required	Lay out poisoned pellets, the dose corresponds to 50 g pellets per bait station	3 x 3 appl. per season Zinc phosphide: max. 3 x 50 (subdivison into 3 x 3 x 16.6 possible)= max. 150

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 further 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 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.

Due to the lack of systematic continuous ingestion, the risk of short- and long-term exposure was not calculated (see core assessment).

Consequences for authorization:

For intended use group A 1 (intended use loose provision 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 further 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 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.

Due to the lack of systematic continuous ingestion, the risk of short- and long-term exposure was not calculated (see core assessment).

.

Consequences for authorization:

For intended use group A 1 (intended use loose provision 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)

Please refer to the core assessment.

Consequences for authorization:

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

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 Arvalin Forte 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 (*Desmodesmus subspicatus*) Acute M-factor = 100 NOE_rC 0.00140 mg/L (*Desmodesmus subspicatus)* Chronic M-factor:10
Classification and labelling according to Directive 67/548/EC, 78/631/EC and 1999/45/EC	
Hazard symbol	N, dangerours for the environment
Risk phrases	R 50-53
Classification and labelling according to Regulation 1272/2008	
Hazard sysmbol	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: *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

Table 6.11-2 Mandatory conditions of use according to § 36 (1) PflSchG for use no. 00-001, 00-002, 00-003, 00-004, 00-005, 00-006, 00-007, 00-008, 00-009, 00-010, 00-011, 00-012, 00-013 and 00-0014

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 6.11-3 Additional mandatory conditions of use according to § 36 (1) PflSchG for uses no. 00-001, 00-003, 00-005, 00-007, 00-009, 00-011, 00-013

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.

Table 6.11-4 Additional mandatory conditions of use according to § 36 (1) PflSchG for uses no. 00-002, 00-004, 00-006, 00-008, 00-010, 00-012, 00-014

NTneu(5)	Proposal: Bait stations must be used that fulfill the following criteria: - bait stations have to be mechanically stable, resistent to wheathering 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“

Appendix 1 Table of Intended Uses in Germany (according to BVL dd.mm.yyyy)

GAP-Table of intended uses for Germany

GAP rev. (No), date: 2013-09-26

PPP (product name/code)	**Arvalin Forte**	**Formulation type:**	**type**
active substance 1	**Zinkphosphid**	**Conc. of as 1:**	**25 g/kg**
Applicant:	**Detia Freyberg GmbH**	**professional use**	**x**
Zone(s):	**central**	**non professional use**	

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)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					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		
001	DE	Field crops (NNNAC)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
002	DE	Field crops (NNNAC)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.

003	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
004	DE	Vegetables (NNNVV)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
005	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
006	DE	Fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
007	DE	Grape vine (VITVI)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
008	DE	Grape vine (VITVI)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
009	DE	Grassland, pasture, meadow (NNNFW)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 4 pellets per hole

												The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
010	DE	Grassland, pasture, meadow (NNNFW)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
011	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
012	DE	Ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
013	DE	Forest plants (NNNWW)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 4 pellets per hole The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.
014	DE	Forest plants (NNNWW)	F	Common vole (MICRAR)	lay out poisoned pellets	if required	a) 3 b) 3	a) 2 kg/ha b) 6 kg/ha	a) 50 g as/ha b) 150 g as/ha			The dose corresponds to 50 g per bait station The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/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.

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product Code: Arvalin Forte

Reg. No.: 008023-00/00

Active Substance: 25 g/kg zinc phosphide

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Detia Freyberg GmbH

Date: July 2013

Evaluator: Julius Kühn-Institut

Date: 2018-01-29

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IIIA1 6 Efficacy Data and Information on the Plant Protection Product

General information

This document summarises the information related to the efficacy of the plant protection product Arvalin Forte (pressed ready to use bait) containing the active substance zinc phosphide, which was included into Annex I of Directive 91/414 under EU Directive 2010/85/EU. The SANCO report for zinc phosphide (SANCO/12548/2010 final) is considered to provide the relevant review information or a reference to where such information can be found.

The Annex I Inclusion Directive for zinc phosphide (2010/85/EU) provides specific provisions under Part A and 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:

Only uses as rodenticides in the form of ready-to-use baits placed in bait stations or target locations may be authorised.

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.

These concerns have been addressed within the current submission.

Information and data will be submitted for zonal registration to support the use of Arvalin Forte. An overview about zonal rapporteur member state and concerned member states is given in Table 1~~Table 1~~. Arvalin Forte is currently not registered in any member state of the Central regulatory zone, but representative products containing the same active substance as Arvalin Forte are given in Table 2~~Table 2~~.

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Table 1: Zonal rapporteur member state (zRMS) and concerned member states (cMS)

zRMS	Germany	DE
cMS	Austria	AT
	Belgium	BE
	Czech Republic	CZ
	Slovakia	SK

Table 2: Representative products containing zinc phosphide in Europe

Country	Product name	Formulation	Authorisation no.	Registration rate	Use(s)
		Type/ Concentration			
Austria	Detia Mäuse Giftkörner	Grain bait (30.4 g/kg zinc phosphide)	900998	5 grains per hole	Agricultural crops, vegetable crops, fruit crops, vinicultural crops, grassland, lawns and meadows, ornamental crops, coniferous and deciduous trees
Belgium	Not yet registered in Belgium	-	-	-	-
Czech Republic	Stutox I	Granulat bait (GB) (5% zinc phosphide)	1220-2	5 kg/ha	Agricultural areas
Germany	Detia Mäuse Giftkörner	Grain bait (30.4 g/kg zinc phosphide)	040902-00	5 grains per hole	Agricultural crops, vegetable crops, fruit crops, vinicultural crops, grassland, lawns and meadows, ornamental crops, coniferous and deciduous trees
Poland	Not yet registered in Poland	-	-	-	-
Slovakia	Currently not registered, but formerly registered as Stutox I with same indications as given in CZ	-	-	-	-

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

Appendix 2 of this document is the table of intended uses for Arvalin Forte.

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

Recent registration situation/history of the PPP

The active substance is registered in Germany and in countries of zone B in different rodenticidal products. The test product Arvalin Forte is not registered in any country of the EU yet. The applicant presented attempts which were executed under a divergent trade name.

Information on the active ingredients (Uptake and mode of action)

Arvalin Forte is a pressed ready to use bait. It contains 2.5% w/w zinc phosphide, which develops the toxic gas phosphine (PH_3) in an acidic environment. Zinc phosphide is a quick-acting acute poison and soluble in acids (such as gastric acid) or alkalizes well. After the consumption the decomposition is carried out in the stomach to phosphine. Zinc phosphide has an unpleasant garlic-like smell. After the ingestion the decomposition is carried out in the stomach to phosphine. 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.

Information on crops and pests

Arvalin Forte is a pressed 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 coniferous and deciduous trees.

Grassland, lawns and meadows and areas with coniferous and deciduous trees, agricultural crops, fruit crops, ornamental crops, vegetable crops and vinicultural crops may be infested with common voles (*M. arvalis*).

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 10-12 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.

Common voles can have three to ten litters per year with four to eight cubs each. Gestation lasts for three 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.

Common voles can be found in most parts of Europe, North America and northern Asia. There are irregular outbreaks of common voles about every two to five years in Germany (Frank, 1957) and other parts of Europe (Mackin-Rogalska and Nabaglo, 1990). Vole densities can reach several thousand individuals per hectare and huge crop damage can be caused (Truszkowski, 1982). Common voles are strict vegetarian feeders. Their diet consists of seeds, grass, leaves, tubers, conifer needles and nuts.

For the classification of the pest organism *M. arvalis* and different agricultural uses see Table 3~~Table 3~~.

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Table 3: Classification of agricultural uses and pest organism M. arvalis in the rapporteur and concerned member states

	EPPO code	Classification	
		major	**minor**
Agricultural use [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
Pest organism 2)			
Microtus arvalis	MICRAR	AT, BE, CZ, DE, PL, SK	-

[1)] http://www.eppo.int/PPPRODUCTS/zonal_efficacy/12-18159_Distribution_of_crops_in_Europe.doc (2013-06-17);
[2)] Briner et al., 2005

Proposed uses for this product are supplied in Appendix 2. For the spectrum of activity of Arvalin Forte see Table 4~~Table 4~~. Arvalin Forte 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.

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Table 4: Spectrum of activity of Arvalin Forte

Crops	Agricultural areas (Agricultural crops, vegetable crops, fruit crops, vinicultural crops, grassland, lawns and meadows, ornamental crops and coniferous and deciduous trees)
Pest	Common vole (*Microtus arvalis*)
Method of application	Spreading in vole holes or bait stations
Timing of application	Not defined
Application doses	2 - 4 pellets/hole or 20 - 50 g pellets/bait station
Spray volume	Not applicable
PHI	Not required

Information on the intended uses

Arvalin Forte, as a bait rodenticide degassing phosphine after ingestion of the bait, is intended to be used in agricultural areas, either underground in holes or as surface application in bait stations.

Appendix 2 of this document is the table of intended uses for Arvalin Forte.

IIIA1 6.1 Efficacy data

Efficacy trials were carried out by different contractor companies and official research institutes. The efficacy trials presented in section IIIA 6.1.3 were done by contractor companies which follow the EPPO standards and are officially recognised by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).
The Central regulatory zone covers countries in the EPPO Maritime, the EPPO South-east and the EPPO North-east zone, as described in EPPO standard PP 1/241. This submission includes data from Germany and the Czech Republic which are representative for the proposed GAP.

IIIA1 6.1.1 Preliminary range-finding tests

No preliminary range finding tests were conducted for Arvalin Forte, because the rodenticidal action of the active substance and formulations based thereon has been established for more than 40 years.

IIIA1 6.1.2 Minimum effective dose tests

A laboratory trial was performed in Germany in 2009 to determine the minimum effective dose of zinc phosphide against common vole (Jacob et al., 2009). The study was published in the scientific journal Pest Management Science.

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 2.5% zinc phosphide seemed to balance bait uptake and bait efficacy best.

Conclusions
Jacob et al. examination points, that a more or less clear dose response to the respective target organism. The minimum effective dose appears to be justified.

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, Zn_3P_2 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; Hygnstrom, et al., 1998) and others.

Zinc phosphide-treated pellets have been used extensively for example for the control of rat (*Rattus spp.*) populations (Hygnstrom et al., 1998). The Zn_3P_2 in pellets is considered to be less susceptible to physical weathering than in cereal formulations (Koehler et al., 1995). Laboratory studies indicated that pellets were equally or more effective than cereal formulations on rats (Tobin et al., 1990; Sugihara et al., 1995). Jacob et al. (2009) could show in bait choice tests that wheat kernels were preferred initially, but within 12 hours similar amounts of wheat-based pellets and wheat kernels were eaten.

For the preparation of this submission, two trials were carried out to evaluate the efficacy of Arvalin Forte for the control of common vole in agricultural areas. Furthermore, one trial conducted with Detia Mäuse Giftkörner is presented to support the efficacy data package for Arvalin Forte. Detia Mäuse Giftkörner has the same active substance content and is used similarly but is based on a different formulation, as it is a non-pressed cereal. 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 5~~Table 5~~ and Table **6**~~Table 6~~.

As shown in Table **6**~~Table 6~~, 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, bait pellets 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 Arvalin Forte is applied into vole holes can be extrapolated to an application in bait stations.

For information on the trial locations and testing facilities see

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Table 7~~Table 7~~.

Table 5: Number of efficacy trials included in the BAD

Year / Country	2012	2013	Total
Czech Republic	1	1	**2**
Germany	1	-	**1**
Total	2	1	**3**

Table 6: Location of the trials in the EPPO climatic zones

EPPO zone / Country	Maritime	South-east	North-east
Czech Republic	2	-	-
Germany	1	-	-

Table 7: Summary of trial locations, testing facilities and effect tested in each trial

Regulatory zone/ EPPO zone/ Country	Affiliation/ testing facility	Trial No.	Year	Evaluated effects/trial type			
				Minimum effective dose	Efficacy	Yield	Phyto-toxicity
C-EU/ MA/ Germany	Federal research centre for cultivated plants, Germany	DOI 10.1002/ps.1841	2009	X	-	-	-
C-EU/ MA/ Czech Republic	Testing station Rýmařov s.r.o.	DELIRYMI12/0709	2012	-	X	-	-
C-EU/ MA/ Germany	Ingenieurbüro für landwirtschaftliche Feldversuche Andreas Hetterich	Detia2012Het01	2012	-	X	-	-
C-EU/ MA/ Czech Republic	Testing station Rýmařov s.r.o.	DELIRYMI13/0709	2013	-	X	-	-

Conclusions – Efficacy tests

The number of efficacy tests submitted by the applicant does not comply with EPPO Standard PP 1/226 'Number of efficacy trials'. The applicant submitted a total of only 3 experiments from more recent times. The investigations were carried out in fruit trees and agricultural crops (stubble fields). The application was placed directly inside the holes openings. In these 3 efficacy tests, the average efficiency was 85 (span: 82-90%) 14 days after application.

An extrapolation for comparability of ´Arvalin Forte` with other authorized plant protection products according to the EPPO standard PP 1/257 ´Efficacy and crop safety extrapolations for minor uses` was not submitted.

The applicant also did not carry out any separate investigations for the application technology bait stations, nor did they carry out any extrapolation according to the EPPO standard PP 1/257. There is thus no reliable information about the acceptance behavior of common vole (*Microtus arvalis*) from bait stations, the distance between the bait stations, and also the delay in effect after application.

IIIA1 6.1.3.1 Efficacy of Arvalin Forte in agricultural crops

In total, two field trials were carried out in the Czech Republic in 2012 and 2013 to assess the efficacy of the rodenticide Arvalin Forte in agricultural crops. Both trials were carried out accord-

ing to GEP by officially recognised testing organisations and the guideline EPPO PP 1/169(2) was used. Results from the efficacy trials conducted with Arvalin Forte in agricultural crops are presented in **Fehler! Verweisquelle konnte nicht gefunden werden.**~~Table 8~~.

In most cases, a good to very good control efficacy of common vole could be achieved in agricultural crops by using Arvalin Forte. Data demonstrated that Arvalin Forte at the proposed rate of 2-4 pellets/hole was equivalent to the efficacy of Detia Mäuse Giftkörner and Ratron Giftweizen (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. Results from this trial are presented in section IIIA 6.1.3.3 and can be used to support the efficacy data package for Arvalin Forte, as both products differ only in their formulations, but are otherwise identical.

Table 8: Efficacy of Arvalin Forte against common vole in agricultural crops

DA-A	Product	Rate (baits/hole)	No. of trials	Mean (%)	Min (%)	Max (%)
3	Untreated (reopened holes in %)		2	**137.5**	112.0	163.0
	Arvalin Forte	2-4	2	**95.0**	94.0	96.0
	Detia Mäuse Giftkörner	5	1	**98.0**	-	-
	Ratron Giftweizen	5	2	**92.5**	90.0	95.0
7	Untreated (reopened holes in %)		2	**126.0**	114.0	138.0
	Arvalin Forte	2-4	2	**93.5**	92.0	95.0
	Detia Mäuse Giftkörner	5	1	**98.0**	-	-
	Ratron Giftweizen	5	2	**93.0**	93.0	93.0
14	Untreated (reopened holes in %)		2	**80.5**	45.0	116.0
	Arvalin Forte	2-4	2	**86.0**	82.0	90.0
	Detia Mäuse Giftkörner	5	1	**94.0**	-	-
	Ratron Giftweizen	5	2	**83.5**	76.0	91.0
21	Untreated (reopened holes in %)		2	**86.0**	36.0	136.0
	Arvalin Forte	2-4	2	**79.5**	73.0	86.0
	Detia Mäuse Giftkörner	5	1	**72.0**	-	-
	Ratron Giftweizen	5	2	**77.5**	65.0	90.0

IIIA1 6.1.3.2 Efficacy of Arvalin Forte in vegetable crops

Two field trials were carried out in the Czech Republic in 2012 and 2013 to assess the efficacy of the rodenticide Arvalin Forte in agricultural crops. The results presented in section IIIA 6.1.3.1 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. The results of this trial are presented in section IIIA 6.1.3.3 and can be extrapolated to support the use in vegetable crops, because the agricultural situations are supposed to be comparable in this context. In addition, the results can be used to support the effi-

cacy data package for Arvalin Forte, as both products differ only in their formulations, but are otherwise identical.

IIIA1 6.1.3.3 Efficacy of Arvalin Forte 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. Results from this trial can be used to support the efficacy data package for Arvalin Forte, as both products differ only in their formulations, but are otherwise identical. The trial was carried out according to GEP by an officially recognised testing organisation and the guideline EPPO PP 1/169(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 Ratron Giftweizen (5 grains/hole) against common vole.

Furthermore, two field trials were carried out in the Czech Republic in 2012 and 2013 to assess the efficacy of the rodenticide Arvalin Forte in agricultural crops. The results presented in section IIIA 6.1.3.1 can be extrapolated to support the use in fruit crops, because the agricultural situations are supposed to be comparable in this context.

Results from the efficacy trial conducted with Detia Mäuse Giftkörner in a former fruit orchard are presented in **Table 9**~~Table 9~~. It is important to note that the number of re-opened holes was comparable for all different treatments before application of baits (36.3-42.8 re-opened holes per plot). Six days after application, 31.5 vole holes were re-opened per plot in the untreated control indicating a good constitution of the present voles. Detia Mäuse Giftkörner offered a very good pest control of 90.6%, which was superior to the efficacy of reference product Ratron Giftweizen (79.7%).
15 days after application, 33.3 vole holes were re-opened per plot in the untreated control indicating a still good constitution of the present voles. Detia Mäuse Giftkörner offered a good pest control of 83.3%, which was superior to the efficacy of reference product Ratron Giftweizen (75.2%).

Table 9: Efficacy of Detia Mäuse Giftkörner against common vole in fruit orchards

DA-A [1)]	Product	Rate (baits/hole)	No. of trials	Mean (%)
6	Untreated (no of reopened holes/plot)		1	**31.5**
	Detia Mäuse Giftkörner	5	1	**90.6**
	Ratron Giftweizen	5	1	**79.7**
15	Untreated (no of reopened holes/plot)		1	**33.3**
	Detia Mäuse Giftkörner	5	1	**83.3**
	Ratron Giftweizen	5	1	**75.2**

[1)] *DA-A = Days after application A*

IIIA1 6.1.3.4 Efficacy of Arvalin Forte in vinicultural crops

Two field trials were carried out in the Czech Republic in 2012 and 2013 to assess the efficacy of the rodenticide Arvalin Forte in agricultural crops. The results are presented in section IIIA 6.1.3.1 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. The results are presented in section IIIA 6.1.3.3 and can be extrapolated to support the use in vinicultural crops, because the agricultural situations are supposed to be comparable in this context. In addition, the results can be used to support the efficacy data package for Arvalin Forte, as both products differ only in their formulations, but are otherwise identical.

IIIA1 6.1.3.5 Efficacy of Arvalin Forte in grassland, lawns and meadows

Two field trials were carried out in the Czech Republic in 2012 and 2013 to assess the efficacy of the rodenticide Arvalin Forte in agricultural crops. The results are presented in section IIIA 6.1.3.1 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 IIIA 6.1.3.3 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. In addition, the results can be used to support the efficacy data package for Arvalin Forte, as both products differ only in their formulations, but are otherwise identical.

IIIA1 6.1.3.6 Efficacy of Arvalin Forte in ornamental crops

Two field trials were carried out in the Czech Republic in 2012 and 2013 to assess the efficacy of the rodenticide Arvalin Forte in agricultural crops. The results are presented in section IIIA 6.1.3.1 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. The results are presented in section IIIA 6.1.3.3 and can be extrapolated to support the use in ornamental crops, because the agricultural situations are supposed to be

comparable in this context. In addition, the results can be used to support the efficacy data package for Arvalin Forte, as both products differ only in their formulations, but are otherwise identical.

IIIA1 6.1.3.7 Efficacy of Arvalin Forte in coniferous and deciduous trees

Two field trials were carried out in the Czech Republic in 2012 and 2013 to assess the efficacy of the rodenticide Arvalin Forte in agricultural crops. The results are presented in section IIIA 6.1.3.1 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. The results are presented in section IIIA 6.1.3.3 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. In addition, the results can be used to support the efficacy data package for Arvalin Forte, as both products differ only in their formulations, but are otherwise identical.

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 Arvalin Forte. This is intended for the following countries: Austria, Belgium, the Czech Republic, Slovakia, Germany and Poland. They might use the core dossier either to support or to supplement the registration package within their own countries.

IIIA1 6.1.3.9 Effects of climate

None of the test results obtained or observations made so far have indicated that there is any negative impact on the performance of Arvalin Forte under normal climatic conditions. Arvalin Forte, when applied according to 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

The investigation of potential effects on the yield and quality following the use of the product Arvalin Forte 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, Arvalin Forte will not affect the 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 Arvalin Forte 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, Arvalin Forte will not affect the quality of plants. See also section IIIA 6.1.4.3.

IIIA1 6.1.4.2 Effects on the processing procedure

The investigation of effects on processing procedure for the product Arvalin Forte is not considered to be required for the following reasons: Besides for the reasons given in section IIIA 6.1.4.3, no influence on the 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 Arvalin Forte is not considered to be required for the following reasons: Arvalin Forte 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 Arvalin Forte are predominantly applied to discrete sites in the form of baits directly in the holes or in bait stations. Due to the non-solubility of the active substance 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 cations and phosphine. Zinc cations are normal constituents of the soil. Phosphine is a gas which can be subjected to rapid atmospheric degradation upon volatilisation. Alternatively, it may be re-adsorbed into soil and subsequently be degraded to phosphate. Therefore, soil accumulation is not expected to occur. In the soil, zinc and phosphate are taken up and metabolised 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 Arvalin Forte is not considered to be required for the reasons given above (please refer to section IIIA 6.1.4.3).

IIIA1 6.2.2 Adverse effects on health of host animals

This is not an EC data requirement.

IIIA1 6.2.3 Adverse effects on site of application

This is not an EC data requirement.

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

The rodenticide Arvalin Forte (25 g/kg zinc phosphide) has been proposed for three applications per crop and season each at a rate of 2 kg/ha in field crops, vegetable and fruit growing, grape vine, grassland, forestry and ornamentals. The pellets are to be applied hidden.

In the Biological Assessment Dossier (Stutox – II), IIIA 6.2.4 (July 2013), the applicant stated that non-target organisms are affected to a very limited extend by accidental consumption and that secondary poisoning is not expected to any relevant degree, however, this referred to vertebrates only.

According to draft Registration Report Part B, Section 6 (Effects on Arthropods Other Than Bees), Core Assessment (July 2013 and October 2016), the submission of data or the perfor-

mance of tests on the effects of Arvalin Forte on arthropods other than bees is not considered to be required, since the test product is predominantly applied to discrete hidden sites in form of baits with low concentration of active substance. It has been concluded that there is no unacceptable risk from the proposed use to arthropod populations.

Beneficial arthropods may have access to the application sites but are not expected to feed on the baits containing vegetable and dairy ingredients.
Nevertheless, there may be a limited exposure and thus a potential risk. According to the directions for use, Arvalin Forte develops toxic gases at contact with water and very toxic gases at contact with acids. This exposure cannot be excluded when the test product is applied in burrow systems or holes in moist soil. The gases formed are probably toxic to arthropods. The risk is not quantifiable but should be limited to soil-dwelling or ground active beneficial organisms.

Proposal for classification:

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 IIIA 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 Arvalin Forte is not considered to be required, since there is no danger 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 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 approximately one month after contact with soil.

IIIA1 6.2.7 Impact on other plants including adjacent crops

Not required for reasons given above (please refer to section IIIA 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 substance. However, it was considered relevant to briefly summarise 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 phe-

nomenon 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.

IIIA1 6.4 Benefits

The following list describes the main perceived benefits in using Arvalin Forte for the control of common vole:

1. Higher yield as a result of crop protection
2. Timing flexibility
3. Excellent safety for beneficial arthropods and wildlife found within target crops. No risk of secondary poisoning on vertebrates
4. Good degradability in soil and air
5. No formation of persistent metabolites, no potential for water and air contamination
6. Acceptable operator and dietary risk

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 other studies available.

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 Arvalin Forte in the Central administrative zone (laboratory and field trials in Germany and the Czech Republic).

The applicant states: The Central zone has been defined on the basis of comparable climates in the form of a 'Climatic Justification' paper as approved by EPPO and found within the standard PP 1/241(1), thus the issue of climatic differences does not need to be addressed within this dossier.

The applicant does not submit any tests from the three climatic zones according to the EPPO standard PP 1/241 ´Guidance on comparable climates´.

Arvalin Forte is a pressed 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 coniferous and deciduous trees.

A total of three trials were conducted between 2012 and 2013 in order to assess the efficacy of Arvalin Forte against common vole. Arvalin forte reduced the number of re-opened holes by 85 (span: 82-90%) 14 days after application. In a further experiment, the marginal effort was determined according to EPPO Standard PP 1/225 'Minimum effective dose'.

The applicant states: Arvalin Forte showed very good or good effectiveness against common vole. It is recommended to use Arvalin Forte 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. No adverse effects of any kind are expected from an application of Arvalin Forte. In addition, there is no risk of resistance development due to the mode of action of zinc phosphide.
The results of the presented trials demonstrate the effectiveness of the recommended dose and safe use of Arvalin Forte in the Central administrative zone.

Due to the proposed use pattern of the test product, populations of plant dwelling beneficial organisms will not be at risk.

The applicant neither submitted an extrapolation in accordance with EPPO Standard PP 1/257 „Efficacy and crop safety extrapolations for minor uses" nor a letter of access regarding the acceptance behavior of its agent, taking into account various application methods such as: As an open application, laying out in mouse hole or bait stations. Likewise, the applicant did not submit any comparative studies with analogously formulated rodenticides which are suitable for bait stations.

IIIA1 6.7 List of test facilities including the corresponding certificates

Country	Affiliation/ testing facility	Trial no.	Year	Address
Germany	Federal research centre for cultivated plants, Germany	DOI 10.1002/ps.1841	2009	Toppheideweg 88 48161 Münster, Germany
	Ingenieurbüro für landwirtschaftliche Feldversuche Andreas Hetterich	Detia2012Het01	2012	Bamberger Straße 50 97359 Schwarzach, Germany
Czech Republic	Testing station Rýmařov s.r.o.	DELIRYMI12/0709	2012	8. května 61 79501 Rýmařov, Czech Republic

LfL

Bescheinigung

Die Anerkennung der Versuchseinrichtung Ingenieurbüro für landwirtschaftliche Feldversuche **Andreas Hetterich**
Bamberger Str. 50, OT Düllstadt

mit dem Hauptsitz in 97359 Schwarzach

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

STÁTNÍ 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

právnická osoba: **Zkušební stanice Rýmařov s.r.o.**

sídlo 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 Minář, 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	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6	Anonym ous	20 13	Biological Assessment Dossier TSGE-2013-Stutox-II N/N N 2495233/326994	N	J		
KIIIA1 6	Anonym ous	20 13	Biological Assessment Dossier (word) TSGE-2013-Stutox-II k.A. N/N N 2495234/326995	N	J		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6	Briner, T.; Netwig, W.; Airoldi, J.-P.	20 05	Habitat quality of wildflower strips for common voles (Microtus arvalis) and its relevance for agriculture Ecosystems & Environment, N/N J 2495235/326996	N	N		
KIIIA1 6	Frank, F.	19 57	The causality of microtine cycles in Germany (Second Preliminary Research Report) The Journal of Wildlife Management, N/N J 2495237/326997	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6	Hucorne , P.	20 12	The actual distribution of crops in Europe 12-18159 http://www.eppo.int/PPPRODUCTS/zonal_efficacy/12-18159_Distribution_of_crops_in_Europe.doc N/N J 2495239/326998	N	N		
KIIIA1 6	Mackin-Rogalska, R.; Nabaglo, L.	19 90	Geographical variation in cyclic periodicity and synchrony in common vole, Microtus arvalis Oikos, N/N J 2495241/326999	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6	Truszko wski, J.	19 82	The Impact of the common vole on the vegetation of agroecosystems ACTA THERIOLOGICA; N/N J 2495243/327000	N	N		
KIIIA1 6.1.2	Jacob, J.; Budde, M.; Leukers, A.	20 09	Efficacy and attrativeness of zinc phosphide bait in common voles (Microtus arvalis) Pest Management Science 2010; N/N J 2495245/327001	J	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6.1.2	Tkadlec, E.; Rychnov sky, B.	20 13	Residues of Zn3P2 in the common vole (Microtus arvalis) and secondary poisoning hazards to predators Folia Zoologica, N/N J 2495247/327002	N	N		
KIIIA1 6.1.3	Ruzicka, A	20 12	An evaluation of the efficacy of STUTOX II for the control of common voles (Microtus arvalis) in the Czech Republic. DELIRYMI12/0709 k.A. N/J N 2495249/327003	N	J		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6.1.3	Hetterich , A.	20 12	Efficacy of rodenticides Detia Mäuse Giftkörner against Microtus arvalis Detia2012Het01 k.A. N/J N 2495251/327004	N	J		
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 (Microtus arvalis) in the Czech Republic. DELIRYMI13/0709 k.A. N/J N 2495253/327005	N	J		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6.1.3	Advani, R.	19 95	Mouse populations and their control in New York City International Biodeterioration & Biodegradation N/N J 2495255/327006	N	N		
KIIIA1 6.1.3	Bell, H.B.; Dimmick , R.W.	19 75	Hazards to predators feeding on prairie voles killed with zinc phosphide The Journal of Wildlife Management N/N J 2495257/327007	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6.1.3	Bhat, S.K.; Mathew, D.N.	20 13	Comparative toxicity of two acute rodenticides to the Western ghats squirrel (Funambulus tristriatus Waterhouse) International Pest Control, N/N J 2495259/327008	N	N		
KIIIA1 6.1.3	Bradfield , A.A.G.; Gill, J.E.	19 84	Laboratory trials of 5 rodenticides for the control of Mesocricetus auratus Journal of Hygiene (Cambridge) N/N J 2495261/327009	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6.1.3	Hegdal, P.L.; Gatz, T.A.; Fite, E.C.	19 81	Secondary effects of rodenticides on mammalian predators The worldwide Furbearer Conference Proceedings, N/N J 2495263/327010	N	N		
KIIIA1 6.1.3	Hygnstro m, S.E.; McDonal d, P.M.; Virchow, D.R.	19 98	Efficacy of three formulations of zinc phosphide for managing black tailed prairie dogs International Biodeterioration & Biodegradation, N/N J 2495265/327011	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6.1.3	Khan, A.A.; Ahmad, M.F	19 91	Field efficacy of the 2nd generation anticoagulants, zinc phosphide and bromethalin against Meriones hurrianae Jerdon Indian Journal of Plant Protection, N/N J 2495267/327012	N	N		
KIIIA1 6.1.3	Koehler, A.E.; Tobin; M.E.; Goodall, M.J.; Sugihara , R.T.	19 95	Weatherability and acceptance of selected commercial zinc phosphide rodent baits International Biodeterioration & Biodegradation, N/N J 2495269/327013	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6.1.3	Lefebvre , L.W.; Holler, N.R.; Decker, D.G.	19 85	Efficacy of aerial application of a 2 % zinc phosphide bait on roof rats in sugarcane Wildlife Society Bulletin, N/N J 2495271/327014	N	N		
KIIIA1 6.1.3	Matschk e, G.H.; Marsh, M.P. and Otis, D.L.	19 83	Efficacy of zinc phosphide broadcast baiting for controlling Richardson's ground squirrels on rangeland Journal of Range Management, N/N J 2495273/327015	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6.1.3	Rudd, R.L.; Genelly, R.E.	19 56	Pesticides: their use and toxicity in relation to wildlife Game Bulletin No. 7 N/N J 2495275/327016	N	N		
KIIIA1 6.1.3	Schitosk ey, F.	19 75	Primary and secondary hazards of three rodenticides to kit fox The Journal of Wildlife Management N/N J 2495277/327017	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6.1.3	Sheikher , C.; Jain, S.D.	19 91	Damage and hoarding by rodents and their control in standing wheat in Himachal Pradesh Tropical Pest Management, N/N J 2495279/327018	N	N		
KIIIA1 6.1.3	Sterner, R.T.; Ramey, C.A.; Edge, W.D.; Manning , T.; Wolff, J.O.; Fagersto ne, K.A.	19 96	Efficacy of zinc phosphide baits to control voles in alfalfa - an enclosure study Crop Protection, N/N J 2495281/327019	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6.1.3	Sugihara , R.T.; Tobin, M.E; Koehler, A.E.	19 95	Zinc phosphide baits and prebaiting for controlling rats in Hawaiian sugarcane The Journal of Wildlife Management, N/N J 2495283/327020	N	N		
KIIIA1 6.1.3	Tietjen, H.P.	19 76	Zinc phosphide - Its development as a control agent for black-tailed prairie dogs U.S. Dept. of the Interior, Fish and Wildlife Service- Special Scientific report - Wildlife No. 195 N/N J 2495285/327021	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6.1.3	Tobin, M.E.; Sugihara , R.T.; Ota, A.K.	19 90	Rodent damage to Hawaiian sugarcane Proceeding of the Fourteenth Vertebrate Pest Conference. Paper N/N J 2495287/327022	N	N		
KIIIA1 6.1.3	Uresk, D.W.; King, R.M.; Apa, A.D.; Linder, R.L.	19 86	Efficacy of zinc phosphide and strychnine for black tailed prairie dog control Journal of Range Management N/N J 2495289/327023	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6.1.3	Wood, J.E.	19 65	Response of rodent populations to controls The Journal of Wildlife Management, N/N J 2495291/327024	N	N		
KIIIA1 6.2.8	Bäumler, W.	19 92	Köderscheu bei Wühlmäusen Anzeiger für Schädlingskunde, Pflanzenschutz, Umweltschutz, N/N J 2495293/327025	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIIA1 6.2.8	Bhardwa j, D., Prakash, I.	19 82	Mitigation of poison aversion in the house rat Rattus Rattus rufescens (gray) through acclimatization Indian Journal of Experimmental Biology N/N J 2495295/327026	N	N		
KIIIA1 6.2.8	Bhardwa j, D.; Siddiqui, J.A.; Ahmad Khan, J.	19 84	Mitigating poison and bait-shyness developed by wild rats (Rattus rattus L.), II. Use of boiled foods and oily cereal mixtures Zeitschrift für Angewandte Zoologie, N/N J 2495297/327027	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
MIIIA1 Sec 1	Detia	20 13	dRR - B1 - core assess. - DE - 008023-00/00 - Arvalin Forte N/N N 2495301/327030	N	N		
MIIIA1 Sec 1	Detia	20 13	dRR - B1 - core assess. - DE - 008023-00/00 - Arvalin Forte (word) N/N N 2495302/327031	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
MIIIA1 Sec 6	Detia	20 13	dRR - B6 - core assess. - DE - 008023-00/00 - Arvalin Forte N/N N 2495310/327033	N	N		
MIIIA1 Sec 6	Detia	20 13	dRR - B6 - core assess. - DE - 008023-00/00 - Arvalin Forte (word) N/N N 2495311/327034	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
MIIIA1 Sec 7	Detia	20 13	dRR - B7 - core assess. - DE - 008023-00/00 - Arvalin Forte N/N N 2495312/327035	N	N		
MIIIA1 Sec 7	Detia	20 13	dRR - B7 - core assess. - DE - 008023-00/00 - Arvalin Forte (word) N/N N 2495313/327036	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
Docu ment N	Detia	20 13	dRR - A - DE - 008023-00/00 - Arvalin Forte N/N N 2495314/327037	N	N		
Docu ment N	Detia	20 13	dRR - A - DE - 008023-00/00 - Arvalin Forte (word) N/N N 2495315/327038	N	N		
KIIIA1 3.9	Anonym ous	20 13	Gebrauchsanleitung - Arvalin Forte N/N N 2504544/327040	N	J		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIA 8.12	Boawn, L.C., Rasmus sen, P.E.	19 71	Crop response to excessive zinc fertilization of alkaline soil #35 Agr. J. 63, 874-876 N/N J 2525960/327041	N	N		
KIIA 8.14.1	Paul, W.	19 80	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 ! #1025 (#227) k.A. N/N N 2525963/327042	J	J		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIA 8.14.1	Ramey, C.A., Sterner, R.T.	19 95	Mortality of gallinaceous birds associated with 2 percent zinc phosphide baits for control of voles in alfalfa #113 Int. Biodet. Biodegr. 36, 51-64 N/N J 2525965/327043	J	N		
KIIA 8.14.1	Bell, H.B., Dimmick , R. W.	19 75	Hazards to predators feeding on prairie voles killed with zinc phoshide J. Wildl. Manage. 39, 816-819 N/N J 2525969/327044	J	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIA 8.14.1	Schitosk ey, F.	19 75	Primary and secondary hazards of three rodenticides to kit fox J. Wildl. Manage. 39, 416-418 N/N J 2525970/327045	J	N		
KIIA 8.14.1	Tkadlec, E., Rychnov sky, B.	19 90	Residues of Zn3P2 in the common vole (Microtus arvalis) and secondary poisoning hazards to predators Folia Zoologica 39, 147-156 N/N J 2525972/327046	J	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIA 8.14.1	Hill, E.F., Carpent er, J.W.	19 82	Responses of siberian ferrets to secondary zinc phosphide poisoning #79 J. Wildl. Manage. 46, 678-685 N/N J 2525973/327047	J	N		
KIIA 8.14.1	Oehme, F.W.	19 70	Species differences: The basis for and importance of comparative toxicology #60 Clin. Toxicol. 3 (1), 5-10 N/N J 2525987/327048	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIA 8.14.1	Wangen heim, M., et al.	19 71	Rodenticide poisonings of animals in Switzerland #102 Schweiz. Arch. Tierheilk. 113, 350-360 N/N J 2525992/327049	N	N		
KIIA 8.14.1	Clarke, M.L., et al.	19 81	Zinc phosphide #92 Veterinary Toxicology, 2nd Ed., 77-78 N/N J 2526011/327050	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIA 8.14.1	Sample, B.E., Arenal, C.A.	19 99	Allometric models for interspecies extrapolation of wildlife toxicity data #1 Bull. Environ. Contam. Toxicol. 62, 653-663 N/N J 2526019/327051	N	N		
KIIA 8.14.1	Drolet, R., et al.	19 96	Zinc phosphide poisoning in a horse Equine Vet. J. 28, 161-162 N/N J 2526020/327052	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIA 8.14.1	Casteel, S.W., Bailey, E.M.	19 85	A review of zinc phosphide poisoning #97 Vet. Hum. Toxicol. 28, 151-154 N/N J 2526021/327053	N	N		
KIIA 8.14.1	Sterner, R.T., Mauldin, R.E.	19 95	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 2526022/327054	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIA 8.14.1	Joerman n, G.	19 98	Reported pesticide poisonings in vertebrates (1994-1997) - Engl. transl. of German doc.: Meldungen über Pflanzenschutzmittelvergiftungen von Wirbeltieren #1027 (#920) Nachrichtenbl. Deut. Pflanzenschutzd., 50, 187 N/N J 2526025/327055	N	N		
KIIA 8.14.1	Joerman n, G., Gemme ke, H.	19 94	Reported pesticide poisonings of wildlife - Engl. transl. of German doc.: Meldungen über Pflanzenschutzmittelvergiftungen von Wirbeltieren (Reported pesticide poisonings of wildlife) #1026 (#919) Nachrichtenbl. Deut. Pflanzenschutzd., 46, 295-297 N/N J 2526063/327056	N	N		

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Verte-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=No)	Justifi-cation if data protec-tion is claime d	Own er
KIIA 8.14.1	Anonym ous	20 04	Reported pesticide poisonings in vertebrates (1998-2003) - Engl. transl. of German doc.: Meldungen über Pflanzenschutzmittelvergiftungen von Wirbeltieren (1998-2003) #1028 (#922) BVL, Germany, online: www.bvl.bund.de/pflanzenschutz/ Monitoring N/N J 2526064/327057	N	N		
KIIA 8.14.1	Shivapra sad, H.L., Galey, F.	20 01	Diphacinone and zinc phosphide toxicity in a flock of peafowl #903 Avian Pathology 30, 599-603 N/N J 2526065/327058	N	N		

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KIIA 8.14.1	Bayer, U.	19 82	Acceptance test in pheasants (Phasianus colchicus) in aviaries, with 3 different types of "Arrex" mouse baits - Engl. transl. of German doc. 1-9-345-82 ! #1029 (#251) k.A. N/N N 2526272/327063	J	J		
MIIIA1 Sec 1	Detia Freyberg GmbH	20 15	dRR - B1 - core assess. - DE - 008023-00-00 - Arvalin Forte Supplement, September 2015 Detia Freyberg GmbH N/N N 2936139/413580	N	J		Detia Freyb erg Gmb H

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KIIIA1 6	Anonym ous	20 13	Biological Assessment Dossier - Annex III, Section 7: Stutox - II; Central Regulatory zone N/N N 2938215/413581	N	J		Detia Freyb erg Gmb H
KIIIA1 6.1.3	Ruzika, A.	20 12	An evaluation of the efficacy of Stutox II for the control of common voles (Microtus arvalis) in the Czech Republic DELIRYMI12/0709 N/J N 2938216/413582	N	J		Detia Freyb erg Gmb H

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KIIIA1 6.1.3	Hetterich , A.	20 12	Efficacy of rodenticides "Detia Mäuse Giftkörner" against Microtus arvalis Detia2012Het01 N/J N 2938217/413583	N	J		Detia Freyb erg Gmb H
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 (Microtus arvalis) in the Czech Republic DELIRYMI13/0709 N/J N 2938218/413584	N	J		Detia Freyb erg Gmb H

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Ver-te-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=N o)	Justifi-cation if data pro-tection is claime d	Owner
KCA 3.7	Wilde, T.	20 13	Statement - Information on the occurrence or possible occurrence of the development of resistance of the plant protection product Equip for use in maize (for submission in Europe) M-466655-01-1 BCS N/N N 2889846/481159	N	N		Bayer CropSc ience Langen feld
KCA 8.6.2	Roux, F., Matejic ek, A., Reboud , X.	20 05	Response of Arabidopsis thaliana to 22 ALS inhibitors: Baseline toxicity and cross-resistance of csr1-1 and csr1-2 resistant mutants. M-458576-01-1 Weed Res., Volume 45, Issue 3, Page 220-227, Publication Year 2005 N/N J 2889933/481177	N	N		Bayer CropSc ience Langen feld

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Docu ment C	Anon.	20 11	Monsoon - Austria M-456135-01-1 BCS N/N N 2889981/481193	N	N		Bayer CropSc ience Langen feld
Docu ment C	Anon.	20 12	Equip OD - Bulgaria M-456146-01-1 BCS N/N N 2889982/481194	N	N		Bayer CropSc ience Langen feld
Docu ment C	Anon.	20 12	Equip - Belgium / Luxembourg M-464023-01-1 BCS N/N N 2889983/481195	N	N		Bayer CropSc ience Langen feld

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Ver-te-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=N o)	Justifi-cation if data pro-tection is claime d	Owner
Docu ment C	Anon.	20 13	Equip OD - Cyprus M-456168-01-1 BCS N/N N 2889984/481196	N	N		Bayer CropSc ience Langen feld
Docu ment C	Anon.	20 12	Equip OD - Czech Republic M-456172-01-1 BCS N/N N 2889985/481197	N	N		Bayer CropSc ience Langen feld
Docu ment C	Anon.	20 12	Monsoon - Czech Republic M-456174-01-1 BCS N/N N 2889986/481198	N	N		Bayer CropSc ience Langen feld

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Docu ment C	Anon.	20 13	Cubix - France M-456185-01-1 BCS N/N N 2889987/481199	N	N		Bayer CropSc ience Langen feld
Docu ment C	Anon.	20 13	Equip - France M-456176-01-1 BCS N/N N 2889988/481200	N	N		Bayer CropSc ience Langen feld
Docu ment C	Anon.	20 04	Equip OD - Greece M-456165-01-1 BCS N/N N 2889989/481201	N	N		Bayer CropSc ience Langen feld

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Docu ment C	Gottsch ild, D.	20 09	Monsoon - Germany M-456223-01-1 BCS N/N N 2889990/481202	N	N		Bayer CropSc ience Langen feld
Docu ment C	Anon.	20 11	Monsoon - Hungary M-456234-01-1 BCS N/N N 2889991/481203	N	N		Bayer CropSc ience Langen feld
Docu ment C	Anon.	20 13	Equip - Italy M-456244-01-1 BCS N/N N 2889992/481204	N	N		Bayer CropSc ience Langen feld

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Docu ment C	Anon.	20 13	Option - Portugal M-456261-01-1 BCS N/N N 2889993/481205	N	N		Bayer CropSc ience Langen feld
Docu ment C	Anon.	20 13	Equip - Romania M-456276-01-1 BCS N/N N 2889994/481206	N	N		Bayer CropSc ience Langen feld
Docu ment C	Anon.	20 13	Equip - Slovakia M-456283-01-1 BCS N/N N 2889995/481207	N	N		Bayer CropSc ience Langen feld

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Ver-te-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=N o)	Justifi-cation if data pro-tection is claime d	Owner
Docu ment C	Anon.	20 13	Monsoon - Slovakia M-472276-01-1 BCS N/N N 2889996/481208	N	N		Bayer CropSc ience Langen feld
Docu ment C	Anon.	20 13	Cubix - Spain M-456290-01-1 BCS N/N N 2889997/481209	N	N		Bayer CropSc ience Langen feld

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Ver-te-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=N o)	Justifi-cation if data pro-tection is claime d	Owner
Docu ment C	Brownjo hn, I.	20 13	Document C - Copies of existing or proposed labels for the plant protection product foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) for which the product dossier is submitted M-471664-01-1 BCS N/N N 2889998/481210	N	N		Bayer CropSc ience Langen feld
Docu ment C	Brownjo hn, I.	20 13	Attachment: FSN_Doc C_Labels.docx M-471664-01-1 BCS N/N N 2889999/481211	N	N		Bayer CropSc ience Langen feld

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Ver-te-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=N o)	Justifi-cation if data pro-tection is claime d	Owner
KCP 4.2	Friessle ben, R.	20 08	Summary and conclusive report of studies on spray tank cleaning realized in the years 2000 - 2008 M-357166-01-1 N/N N 2890044/481225	N	N		Bayer CropSc ience Langen feld
KCP 4.2	Anony mous	20 13	Safety data sheet - FSN+IDF OD 22,5+22,5A G - U-EU M-443049-02-1 N/N N 2890045/481226	N	J		Bayer CropSc ience Langen feld

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Ver-te-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=N o)	Justifi-cation if data pro-tection is claime d	Owner
MCP Secti on 1	Le Gren, I.	20 13	Summary of the identity of the plant protection product foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) M-471936-01-1 BCS N/N N 2890078/481231	N	N		Bayer CropSc ience Langen feld
MCP Secti on 1	Le Gren, I.	20 13	Attachment: Rep form_MCP_Section 1 Identity of the PPP.doc M-471936-01-1 BCS N/N N 2890079/481232	N	N		Bayer CropSc ience Langen feld

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Ver-te-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=N o)	Justifi-cation if data pro-tection is claime d	Owner
MCP Secti on 3	Young, K.	20 13	Summary of the data on application foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) M-471937-01-1 BCS N/N N 2890082/481233	N	N		Bayer CropSc ience Langen feld
MCP Secti on 3	Young, K.	20 13	Attachment: Rep_Form_MCP_Section_3_Data_o n_application.doc M-471937-01-1 BCS N/N N 2890083/481234	N	N		Bayer CropSc ience Langen feld

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Ver-te-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=N o)	Justifi-cation if data pro-tection is claime d	Owner
MCP Secti on 6	Young, K.	20 13	Summary of the efficacy data foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) M-471945-01-1 BCS N/N N 2890088/481237	N	N		Bayer CropSc ience Langen feld
MCP Secti on 6	Young, K.	20 13	Attachment: Rep_Form_MCP_Section_06_Efficacy_data_for_the_PPP.docx M-471945-01-1 BCS N/N N 2890089/481238	N	N		Bayer CropSc ience Langen feld

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Ver-te-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=N o)	Justifi-cation if data pro-tection is claime d	Owner
MCP Secti on 10	Fliege, S. H. ; Sowig, P.; Nikolaki s, A.; Vocken huber, E.	20 13	Summary of the ecotoxicological studies foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) M-472197-01-1 BCS N/N N 2890096/481241	N	N		Bayer CropSc ience Langen feld
MCP Secti on 10	Fliege, S. H. ; Sowig, P.; Nikolaki s, A.; Vocken huber, E.	20 13	Attachment: Rep_Form_MCP_Section_10_Ecoto xicological_studies.doc M-472197-01-1 BCS N/N N 2890097/481242	N	N		Bayer CropSc ience Langen feld

Data Point	Au-thor(s)	Ye ar	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Ver-te-brate study (J=Ye s O=Op en N=No)	Data pro-tec-tion claim ed (J=Y es O=O pen N=N o)	Justifi-cation if data pro-tection is claime d	Owner
MCP Secti on 1	Le Gren, I.	20 15	Summary of the identity of the plant protection product foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) - Amendment M-471936-02-1 BCS N/N N 2890108/481251	N	N		Bayer CropSc ience Langen feld
MCP Secti on 1	Le Gren, I.	20 15	Attachment: foramsulfuron_AIR_MCP_Section 1 Identity of the PPP_revised042015_final.doc M-471936-02-1 BCS N/N N 2890109/481252	N	N		Bayer CropSc ience Langen feld

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

GAP-Table of intended uses for Germany

Reg.-No.	008023-00/00		GAP rev.1, date: 2018-01-15
PPP (product name/code):	Arvalin Forte	Formulation type:	RB (a, b)
Active substance 1:	Zinkphosphid	Conc. of as 1:	25.00 g/kg (c)
Active substance 2:		Conc. of as 2:	0 (c)
Active substance 3:		Conc. of as 3:	0 (c)
Active substance 4:		Conc. of as 4:	0 (c)
Active substance 5:		Conc. of as 5:	0 (c)
Applicant:	Detia Freyberg GmbH	Professional use:	Yes
Zone(s):	central/interzonal (d)	Non professional use:	No
Verified by MS:	Yes	Field of use:	Rodenticide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application** Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	**Application rate** kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	**Conclusion (efficacy)**
001	DE	field crops (NNNAC)	F	Common vole (MICRAR)	lay out hide / from poisononous pellets / in burrow systems or per hole / 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 4 pellets per hole	A
002	DE	field crops (NNNAC)	F	Common vole (MICRAR)	lay out hide / from poi-	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-	N

					sononous pellets / in suitable bait stations / until uptake stops								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	
003	DE	vegetables (NNNVV)	F	Common vole (MICRAR)	lay out hide / from poisononous pellets / in burrow systems or per hole / 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 4 pellets per hole	A
004	DE	vegetables (NNNVV)	F	Common vole (MICRAR)	lay out hide / from poisononous pellets / in suitable bait stations / 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 50 g per bait station	N
005	DE	fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out hide / from poisononous pellets / in burrow systems or per hole / until up-	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	A

					take stops								corresponds to 4 pellets per hole	
006	DE	fruit crops (NNNOO)	F	Common vole (MICRAR)	lay out hide / from poisononous pellets / in suitable bait stations / 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 50 g per bait station	N
007	DE	grape vine (VITVI)	F	Common vole (MICRAR)	lay out hide / from poisononous pellets / in burrow systems or per hole / 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 4 pellets per hole	A
008	DE	grape vine (VITVI)	F	Common vole (MICRAR)	lay out hide / from poisononous pellets / in suitable bait stations / 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 50 g per bait station	N
009	DE	grassland, pasture, meadow (NNNFW)	F	Common vole (MICRAR)	lay out hide / from poisononous pellets / in burrow	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	A

					systems or per hole / until uptake stops								partial treatments at 0.66 kg/ha each Notes on dose rate: The dose corresponds to 4 pellets per hole	
010	DE	grassland, pasture, meadow (NNNFW)	F	Common vole (MICRAR)	lay out hide / from poisononous pellets / in suitable bait stations / 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 50 g per bait station	N
011	DE	ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out hide / from poisononous pellets / in burrow systems or per hole / 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 4 pellets per hole	A
012	DE	ornamentals (NNNZZ)	F	Common vole (MICRAR)	lay out hide / from poisononous pellets / in suitable bait stations / 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 50 g per bait station	N

013	DE	forest plants (NNNWW)	F	Common vole (MICRAR)	lay out hide / from poisononous pellets / in burrow systems or per hole / 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 4 pellets per hole	A
014	DE	forest plants (NNNWW)	F	Common vole (MICRAR)	lay out hide / from poisononous pellets / in suitable bait stations / 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 50 g per bait station	N

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:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 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)
4 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
8 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).

5 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.
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 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
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

Critical Uses – justification and GAP tables

GAP rev. , date: 2013-July

PPP (product name/code)	**Stutox - II**	**Formulation type:**	**RB Ready to use bait**
Active Substance 1	**Zinc phosphide**	**Conc. of as 1:**	**2.5%**
Active Substance 2	**Not applicable**	**Conc. of as 2:**	**Not applicable**
Active Substance	**Not applicable**	**Conc. of as:**	**Not applicable**
safener	**Not applicable**	**Conc. of safener:**	**Not applicable**
synergist	**Not applicable**	**Conc. of synergist:**	**Not applicable**
Applicant:	**Detia Freyberg GmbH**	**professional use**	☒
Zone(s):	**Central/EU**	**non professional use**	☐
Verified by MS:	**j/n**		

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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		

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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
1	Central zone (Austria, Belgium, Czech Republic, Poland, Slovakia)	Agricultural areas	F	Common vole (*Microtus arvalis*)	1) in vole holes 2) in bait stations	Not defined	a) 3 b) 9	2-4 pellets / hole or 20-50 g pellets /bait station a) 2.00kg/ha b) 6.00kg/ha	n.a.	n.a.	Not required	Type/formulation: RB (pellet bait) 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, Poland, Slovakia)	Agricultural crops	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) 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, Poland, Slovakia)	Agricultural crops	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.

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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
												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, Poland, Slovakia)	Vegetable crops	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) 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, Poland, Slovakia)	Vegetable crops	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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.

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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
6	Central zone (Austria, Belgium, Czech Republic, Poland, Slovakia)	Fruit crops	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) 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.
7	Central zone (Austria, Belgium, Czech Republic, Poland, Slovakia)	Fruit crops	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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, Poland, Slovakia)	Vinicultural crops	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.

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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
												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, Poland, Slovakia)	Vinicultural crops	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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, Poland, Slovakia)	Grassland, lawns and meadows	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) 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.

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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
11	Central zone (Austria, Belgium, Czech Republic, Poland, Slovakia)	Grassland, lawns and meadows	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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, Poland, Slovakia)	Ornamental crops	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) 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, Poland, Slovakia)	Ornamental crops	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) The application rate of 2.00kg/ha per use can be divided into 3 single applications of 0.66kg/ha.

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**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					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		
												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, Poland, Slovakia)	Coniferous and deciduous trees	F	Common vole (*Microtus arvalis*)	in vole holes	Not defined	a) 3 b) 9	2-4 pellets / 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 (pellet bait) 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, Poland, Slovakia)	Coniferous and deciduous trees	F	Common vole (*Microtus arvalis*)	in bait stations	Not defined	a) 3 b) 9	20-50 g pellets /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 (pellet bait) 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
(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
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, 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