

**REGISTRATION REPORT
Part A**

Risk Management

Product name(code): Beetix WG (HBT 05)

Active Substance: metamitron 700 g/kg

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: UK

NATIONAL ASSESSMENT

Applicant: United Phosphorus GmbH

Date: 25/03/2015

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of Beetix WG containing metamitron in Germany. This evaluation is required subsequent to the approval of metamitron.

The risk assessment conclusions are based on the information, data and assessments provided in “Beetix WG (HBT05)” Registration Report, Part B Sections 1-7 and Part C from United Kingdom and where appropriate the addendum for Germany. The information, data and assessments provided in Registration Report, Part B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to Beetix WG where that data has not been considered in the EU review. Otherwise assessments for the safe use of Beetix WG have been made using endpoints agreed in the EU review of metamitron.

This document describes the specific conditions of use and labelling required for Germany for the registration of Beetix WG.

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

Appendix 2: The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 16 of Directive 91/414/EEC.

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 United Phosphorus on 7 May 2012.

The application was for authorisation of Beetix WG (HBT05), water dispersible granules containing 700 g/kg of metamitron for use as a herbicide. HBT05 is used for pre- and post-emergence applications to control annual grasses and broad-leaved weeds in sugar and fodder beets, up to growth stage of BBCH 18.

1.2 Annex I inclusion

Metamitron was included on Annex I of Directive 91/414/EEC on 6 January 2009 under Commission Directive 2008/125/EC (SANCO/208/08 final, 6 January 2009).

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on metamitron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008, shall be taken into account.

The Annex I Inclusion Directive for metamitron (Inclusion Directive 2008/125/EC, SANCO/208/08 final, 6 January 2009) 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.

Member States should/must/may pay particular attention to the:

- operator safety and ensure that conditions of use prescribe the application of personal protective equipment, where appropriate.
- protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;
- risk to birds and mammals, and non target terrestrial plants.

Further data were identified which were considered necessary in relation to the inclusion of metamitron in Annex I under the current inclusion conditions, in particular:

- information as regards the impact of soil metabolite M3 on groundwater;
- information as regards residues in rotational crops;
- information to further address the long term risk to insectivorous birds, and the specific risk to birds and mammals that may be contaminated by the intake of water in field.

1.3 Regulatory approach

To obtain approval the product Beetix WG 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.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of Beetix WG, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B, sections 1 - 7 and Part C.

1.5 Letters of Access

Data access has been proven. United Phosphorus Ltd. provided own data, because it is the owner of the active ingredient. A letter of access isn't necessary.

2 Details of the authorisation

2.1 Product identity

Product Name	Beetix WG (HBT 05)
Authorization Number	007671-00/00
Function	herbicide
Applicant	United Phosphorus GmbH
Composition	700 g/kg metamitron

Formulation type	Water dispersible granules [Code: WG]
Packaging	5 kg bag-in-box

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

The following labelling is proposed in accordance with Directive 1999/45/EC:

<i>Symbol(s)/Indication(s) of danger:</i>	
Xn	Harmful
N	Dangerous for the environment
<i>Risk phrases:</i>	
R 50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R20	Harmful by inhalation
R22	Harmful if swallowed
<i>Safety phrases:</i>	
S2	Keep out of the reach of children
S13	Keep away from food, drink and animal feeding stuffs
S35	This material and its container must be disposed of in a safe way.
S46	If swallowed, seek medical advice immediately and show this container or label
S57	Use appropriate container to avoid environmental contamination.
<i>Specific labelling requirement:</i>	
To avoid risks to man and the environment, comply with the instructions for use.	

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

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

<i>Hazard classes and categories:</i>	
Acute Tox. 4, Eye Irrit. 2,	
<i>Hazard pictograms:</i>	
GHS07	exclamation mark
GHS09	environment
<i>Signal word:</i>	
Warning	
<i>Hazard statements:</i>	
H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
<i>Precautionary statements:</i>	
P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P501	Dispose of contents/container to ...
<i>Special rule for labelling of PPP:</i>	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
<i>Further labelling statements under Regulation (EC) No 1272/2008:</i>	
11.8 percent of the mixture consists of ingredients of unknown oral toxicity.	
27.8 percent or 70 percent of the mixture consists of ingredients of inhalation toxicity.	

2.2.3 Standard phrases under Regulation (EC) No 547/2011

None

2.3 Other phrases notified under Regulation (EC) No 547/2011

2.3.1 Restrictions linked to the PPP

The authorization 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.
SF245-01	Treated areas/crops may not be entered until the spray coating has dried.
Integrated pest management (IPM)/sustainable use	
WMC1	Mode of action (HRAC-group): C1
WH951	The risk of resistance has to be indicated on the package and in the instructions for use. Particularly measures for an appropriate risk management have to be declared.
NB6641	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)
Ecosystem protection	
NW 262	The product is toxic for algae.
NW 263	The product is toxic for aquatic invertebrates.
NW 265	The product is toxic for higher aquatic plants.
NW 642-1	The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed. Violations may be punished by fines of up to 50 000 EUR.

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use	
NN1001	The product is classified as non-harmful for populations of relevant beneficial insects.
NN1002	The product is classified as non-harmful for populations of relevant beneficial predatory mites and spiders.

2.3.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions (mandatory labelling):
See 2.4 (Product uses)

Integrated pest management (IPM)/sustainable use	
WH9161	The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not
Ecosystem protection	
NG404	Between treated areas with an incline of more than 2% and surface water - except only occasionally but including periodically water-bearing surface water - there must be a border under complete plant cover. The border's protective function must not be impaired by the use of implements. It must be at least 20 m wide. This border is not necessary if: - sufficient catching systems are available for the water and soil transported by run-off, which do not flow into surface water or are not connected with the urban drainage system or - the product is used for mulch or direct drilling methods.
NT103	In a strip at least 20 m wide which is adjacent to other areas, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 90 % (except agriculturally or horticulturally used areas, roads, paths and public places). Loss reducing equipment is not required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide or the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures.

2.4 Product uses

BVL-Reg.-No. 007671-00/00 **GAP rev. 2, date: 2015-01-28**

PPP (product name/code): Beetix WG **Formulation Type:** WG
Active substance: Metamitron **Conc. of a.s.:** 700 g/kg

Applicant: United Phosphorus GmbH **Professional use:** Yes
Zone(s): central/EU **Non-professional use:** No

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:
					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	fodder beet (BEAVC), sugar beet (BEAVA)	F	<i>Poa annua</i> (POAAN), annual dicotyledonous weeds (TTTDS) (excluded: <i>Galium aparine</i> (GALAP), <i>Polygonum spec.</i> (POLSS))	spraying (splitting, 3 applications)	Spring, before emergence (1 st treatment), after emergence (2 nd treatment and 3 rd treatment), BBCH 00-18	a) 3 (6 to 14 days) b) 3	a) timing 1: 3 kg/ha a) timing 2: 1 kg/ha a) timing 3: 1 kg/ha b) 5.00 kg/ha	a) timing 1: 2.100 kg/ha a) timing 2: 0.700 kg/ha a) timing 3: 0.700 kg/ha b) 3.50 kg/ha	timing 1: 200 - 300 timing 2: 200 - 300 timing 3: 200 - 300		No authorization: The crop safety of a pre-emergence application of 2100 g/ha metamitron is not verified by the data submitted.

002	DE	fodder beet (BEAVC), sugar beet (BEAVA)	F	<i>Poa annua</i> (POAAN), annual dicotyledonous weeds (TTTDS) (excluded: <i>Galium aparine</i> (GALAP), <i>Polygonum spec.</i> (POLSS))	spraying (splitting, 3 applications)	Spring, after emergence, BBCH 10-18	a) 3 (6 to 14 days) b) 3	a) timing 1: 1 kg/ha a) timing 2: 2 kg/ha a) timing 3: 2 kg/ha b) 5.00 kg/ha	a) a.s. 1: 0.700 kg/ha a) timing 2: 1.400 kg/ha a) timing 3: 1.400 kg/ha b) 3.50 kg/ha	timing 1: 200 - 300 timing 2: 200 - 300 timing 3: 200 - 300		WH9161 NG404 NT103
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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 'HBT05' is a water dispersible granule (WG) formulation containing 700 g/kg metamitron. All studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable. The appearance of the product is that of greyish-yellow sprinkles. It is not explosive and has no oxidising properties. 'HBT05' does not contain any components which are flammable or oxidising. In aqueous suspension, it has a pH close to neutral. It is concluded that the product complies with the basic requirements defined by FAO, WHO and EC for water dispersible granules for the investigated physical, chemical and technical characteristics.

After the accelerated storage stability tests (54°C for 14 days) most product characteristics under test were maintained and all properties still comply with FAO/WHO specifications. The appearance of the product did not change significantly after the applied storage test. The content of active ingredient increased slightly but is still within the FAO/WHO limits. This increase can be related to the decrease of the water content to 0.1%. The suspensibility and dispersibility stayed the same.

The product is stable for two years at ambient temperature.

Implications for labelling: none

Compliance with FAO specifications:

The product Beetix WG complies with FAO specification 381/WG/S/F (1992) with exception of foam volume after one minute. Nevertheless, the observed value is below the general limit of 60 mL according to 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 Beetix WG has been provided and is considered to be acceptable.

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

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

The method of analysis consists of using a HPLC method (Varian Chrompack Chromsep SS 150 x 4.6 mm Inertsil 5 ODS-2 column) with UV detection and an internal standard (methyl 4-hydroxybenzoate in acetonitrile) to determine the metamitron active substance and desamino-metamitron impurity content

within the WG formulation. Validation data has been submitted and checks have been made to ensure that the method is applicable.

As part of the EU review CIPAC method 381/TC/M/3 was assessed and found to be acceptable. This method uses GC-FID to determine the metamitron content within the formulation.

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

Adequate analytical methods are available to monitor all compounds given in the respective residue definition, i.e. metamitron in food of plant and animal origin, soil, water and air. New studies on residue analytics were submitted by the applicant and were found to be acceptably validated.

Metamitron residues can be monitored in food of plant and animal origin, soil, water and air by LC-MS/MS. Additionally, adequate validation data for the QuEChERS method (European Standard EN 15662:2008) are published in EURL Data Pool (<http://www.crl-pesticides-datapool.eu/>) for food of plant origin.

Methods for body fluids and tissues are not required since metamitron is not classified as toxic or highly toxic.

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

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

For further details please refer to the registration report of the zonal RMS UK.

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

The evaluation of the zRMS UK is contradictory in Part A and Part B Section 3 concerning R36. In Part B3 R36 is proposed whereas it is not mentioned in Part A.

HBT05 won't be labelled with R36 in Germany. Neither the study with the preparation according to OECD Guideline 405 nor the amount of components that are irritating to the eye in the preparation classify HBT05 with R36. The outcome of the the study with the preparation according to OECD Guideline 405 leads to a classification of HBT05 with H319 (Eye irrit. 2) according to Regulation (EU) No 1272/2008 (but not to a classification with R36 according to Directive 67/548/EEC).

Furthermore Germany classifies the product with R20/H332. No acute inhalation study was performed. The classification with R20/H332 is according to Directive 1999/45/EC or the acute toxicity estimates according to Regulation (EU) No 1272/2008.

In addition to UK's labelling with R22 and Acute Tox.4 Germany also labels the product with H302.

For further details please refer to the registration report of the zonal RMS UK.

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

Please refer to the registration report of the zonal RMS UK.

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

Please refer to the registration report of the zonal RMS UK.

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

Please refer to the registration report of the zonal RMS UK.

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

See 2.2

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

The intended uses in fodder beet and sugar beet will not result in residues above the MRLs (LOQ) for metamidron set in Regulation (EC) No 396/2005. A risk for consumers through the consumption of food possibly containing residues of these active substances is not expected.

For further details please refer to the registration report of the zonal RMS UK.

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

Please refer to the registration report of the zonal RMS UK.

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

Please refer to the registration report of the zonal RMS UK.

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

A full exposure assessment for the plant protection product Beetix WG (HBT05) in its intended uses in sugar and fodder beet is documented in detail in the core assessment of the plant protection product HBT05 dated from 29.02.2012 performed by applicant United Phosphorus Ltd. and zRMS UK.

The following chapters summarise specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of HBT05 in Germany according to its intended use in sugar and fodder beet (use no. 00-001 – 00-002).

Metabolites

No new study on the fate and behaviour of metamitron or Beetix WG (HBT05) has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

The risk assessment for the metabolites of metamitron has already been performed for EU approval (see SANCO/208/08 final – 06/01/2009). 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.

However, in the specific groundwater risk assessment for Germany considering the entry path surface run-off and drainage with subsequent bank filtration the soil metabolites of Metamitron are included. For details see Part B, core assessment, section and National Addendum respectively.

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 Beetix WG (HBT05) in sugar and fodder beet according to use No 00-001 and 00-002 PEC_{soil} was calculated for the active substance metamitron considering a soil depth of 2.5 cm. Due to the fast degradation of the active substance metamitron in soil the accumulation potential was not considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} considering the relevant soil depth of 2.5 cm or 1.0 cm, respectively.

The soil effective application rate is 2100/560/560 g as/ha for use 001 and 700/1120/1120 g as/ha for use 002.

Details are given in Part B National Addendum-Germany, Section 5, chapter 5.5.

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

3.1.5.2 Predicted Environmental Concentration in Ground Water (PEC_{GW}) (Part B, Section 5, Point 9.6)

1. Direct leaching into groundwater

Results of modelling with FOCUSPelmo4.4.3 show that the active substance metamitron is not expected to penetrate into groundwater at concentrations of $\geq 0.1\mu\text{g/L}$ in the intended uses of formulation HBT05 according to use no. 00-001 and 00-002.

For the metabolite desamino-metamitron concentrations of $\geq 0.1\mu\text{g/L}$ in groundwater can be excluded.

Additionally because in core assessment concentrations of $\geq 0.1\mu\text{g/L}$ are calculated the metabolite

desamino-metamitron is classified as not relevant for groundwater according to the guidance document on the relevance of metabolites (EU, 2003) (see core assessment, part B, section 5, IIIA 9.6.

For details see Part B, National Addendum-Germany, Section 5, chapter 5.7.1.

Consequences for authorization:

None

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

According to modelling with EXPOSIT 3.01, groundwater contamination at concentrations $\geq 0.1 \mu\text{g/L}$ by the active substance metamitron due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded when risk mitigation measures (vegetated buffer strip of 20 m) are applied.

According to modelling with EXPOSIT 3, groundwater contamination at concentrations $\geq 0.1 \mu\text{g/L}$ by the soil metabolite desamino-metamitron due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

For details see Part B, National Addendum-Germany, Section 5, chapter 5.7.2.

Consequences for authorization:

The authorization of the plant protection product Beetix WG (HBT05) is linked with following labelling:

Use No. 00-001 and NG 404
00-002

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

For the intended use of the plant protection product Beetix WG (HBT05) in sugar and fodder beet according to use No 001 and 002 PEC_{sw} was calculated for the active substance metamitron considering the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately.

The calculation of concentrations in surface water was based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance metamitron is $< 10^{-5}$ Pa. Hence the active substance metamitron is regarded as non-volatile. Therefore, exposure of surface water by the active substance metamitron due to deposition following volatilization was not considered.

The concentration of the active substance metamitron in adjacent ditch due to surface run-off and drainage was calculated using the model EXPOSIT 3.01.

Details are given in Part B, National Addendum-Germany, Section 5, chapter 5.6.

The results for PEC surface water for the active substance and its metabolites were used for the ecotoxicological risk assessment.

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

No losses due to volatilization are expected.

For details see Part B 5 core IIIA 9.9

Implications for labelling resulting from environmental fate assessment

For the authorization of the plant protection product HBT05 following labelling and conditions of use are mandatory:

Classification and labelling

Based on the data on the active substance metamitron the plant protection product Beetix WG (HBT05) is considered to be not readily degradable in the sense of the CLP regulation.

Metamitron is regarded as a candidate for R 53.

Further data requirements:

none

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

Parts of risk assessment according to Uniform Principles for the plant protection product Beetix WG (HBT05) in its intended uses in sugar and fodder beet are documented in the core assessment of the plant protection product HBT05 dated from April 2014 performed by UK. The intended use of Beetix WG (HBT05) in Germany is partially covered by the uses evaluated in the course of the core assessment by UK.

The following chapters summarise specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of Beetix WG (HBT05) in Germany according to its intended use in sugar and fodder beet (use no. 00-001 and 00-002).

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).

The acute and long-term risks of Beetix WG (HBT05) to birds and mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with metamitron.

The TER values for birds, calculated for recommended scenarios, all exceeded the trigger value of 10 for acute risk at Tier I. For long-term risk a higher tier risk assessment was necessary.

The TER values for mammals, calculated for recommended scenarios, all exceeded the trigger values in Tier I, except for the scenario of large herbivorous mammals for the pre-and post-emergence scenario. For this scenario, a higher tier risk assessment showed acceptable risk for large herbivorous mammals. For long-term risk a higher tier risk assessment was necessary.

Risk of secondary poisoning has not been assessed, as metamitron and its metabolite desamino-metamitron have logPOW <3.0.

Based on the presumptions of the Tier 1 and higher tier, the calculated TER values for the acute and long-term risk resulting from an exposure of birds to the active substance metamitron according to the intended use of the formulation Beetix WG (HBT05) in sugar and fodder beet achieve the acceptability criteria $TER \geq 10$ and $TER \geq 5$, respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for terrestrial vertebrates.

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

Consequences for authorization:

None

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

Results of aquatic risk assessment for the intended for uses of Beetix WG (HBT05) in sugar and fodder beet based on FOCUS Surface Water PEC values is presented in the core assessment, Part B, Section 6, chapter 6.4.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

Exposure by spraydrift and deposition following volatilization

For details see Part B, National Addendum-Germany, Section 6, chapters 6.4.3.

Exposure by surface run-off and drainage

The concentration of the active substance metamitron in adjacent ditch due to surface runoff and drainage was calculated using the model EXPOSIT 3.01.

The calculated TER values for the risk to aquatic organisms resulting from an exposure of surface water by the active substance metamitron due to run-off and drainage according to the use no 00-001 and 00-002 achieve the acceptability criteria of $TER \geq 100$ or 10 respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. Risk mitigation measures do not need to be applied.

For details see Part B, National Addendum-Germany, Section 6, chapters 6.4.4.

Consequences for authorization:

For the authorization of the plant protection product Beetix WG (HBT 05) the following labelling and conditions of use are mandatory:

Required Labelling

NW262	metamitron: <i>Pseudokirchneriella subcapitata</i> NOEC < 0.12 mg/L Beetix WG: <i>Pseudokirchneriella subcapitata</i> NOEC = 0.03
NW263	metamitron: <i>Daphnia magna</i> EC ₅₀ = 5.7 mg/L
NW265	metamitron: <i>Lemna minor</i> NOEC = 0.04 mg/L

Safety precautions / Conditions of use

All uses NW468

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

Bees

Toxicity

Table 3.1.6.3-1 presents the results of bee toxicity studies with HBT01. According to the zRMS HBT01 (Metamitron 700 SC) has identical content of metamitron as HBT05 (Metamitron 700 WG) but differs only in small amounts of inert co-formulants.

Table 3.1.6.3-1: Toxicity to bees of HBT01

Substance	Endpoint	Value	Reference
HBT01	24 h contact LD ₅₀	>112 µg formulation/bee (= 65.7 µg a.s./bee) ^a	Wilkins, 2001 (HT4100)
	24 h oral LD ₅₀	>108 µg formulation/bee (= 63.3 µg a.s./bee) ^a	

^aBased on 71%w/v a.s. content and formulation specific gravity of 1.211 kg/L

Exposure

Applications of pesticides can potentially result in exposure of honeybees either through direct overspray, or by contact with residues on plants whilst bees are foraging for food. However, these sources of exposure are considered highly unlikely in the case of application of HBT05, as the likelihood of bees foraging in sugar beet fields is extremely low. Sugar beet fields are not attractive to bees, since they do not offer any food sources. Despite this, in order to consider an worst-case scenario which also covers off-field exposure caused by spray drift, the maximum application rates for of 2100 g a.s./ha is used for risk assessment purposes.

Hazard quotients for bees

The acute risk to honeybees from use of HBT05 was assessed using the maximum single application rate and the LD₅₀ values to calculate hazard quotients (*EPPO 2003*)¹ as follows:

$$\text{Hazard Quotient} = \frac{\text{Maximum application rate (g formulation/ha)}}{\text{Acute LD}_{50} (\mu\text{g formulation/bee})}$$

Hazard quotients were calculated for oral exposure (Q_{HO}) and contact exposure (Q_{HC}) to HBT05 with the highest individually applied dose of 2100 g a.s./ha and the toxicity endpoint of the formulation. A hazard quotient of less than 50 indicates a low risk to bees in the field. The results are shown in Table 3.1.6.3-2.

Table 3.1.6.3-2: Risk to bees from exposure to HBT05

Substance	Application rate [g a.s./ha]	LD ₅₀ [µg a.s./bee]	Hazard quotient
HBT05	2100	Contact > 65.7	< 32
		Oral > 63.3	< 33

Overall conclusion

The risks of HBT05 to honey-bees was assessed from hazard quotients between toxicity endpoints, estimated from acute oral and contact studies with active ingredient and formulated product, and the maximum single application rate of 2100 g formulation/ha. All the hazard quotients are considerably less than 50, indicating that the active ingredient poses a low risk to bees. Therefore, a low risk to bees is expected from the application of HBT05 according to the recommended use pattern.

Label NB6641 is assigned to the product

Other non-target arthropods

For details please refer to the National Addendum Germany Part B, section 6, chapter 6.6.

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

In the German national assessment, the calculation of the PEC_{soil} values differs from the core assessment approach. For the calculation of PEC_{soil}, a soil depth of 1 or 2.5 cm is applied, depending on the K_{foc} of the active substance.

¹ EPPO/OEPP (2003) Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145.

The risk assessment for earthworms based on the recommendations of the Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (SANCO/10329/2002) indicated an acceptable risk for earthworms.

For details please refer to the National Addendum Germany Part B, section 6, chapter 6.7.

Consequences for authorization:

None

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

Please refer to the core assessment performed by UK Part B, section 6, chapter 6.7.

Consequences for authorization:

None

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

Studies on the toxicity of metamitron on non-target micro-organisms were submitted and evaluated by the zRMS UK. The effects on carbon mineralization and nitrogen transformation from exposure to the formulation Beetix WG (HBT05) indicated an acceptable risk to non-target micro-organisms following the use of the product according to the proposed use pattern.

Please refer to the core assessment performed by UK Part B, section 6, chapter 6.8.

Consequences for authorization:

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

The effects of Beetix WG (HBT05) on non-target plants were evaluated and described in the core assessment performed by zRMS UK and in the National Addendum Germany. The use of the product according to the proposed use pattern poses no unacceptable risk to non-target terrestrial plants in off-crop areas according to the proposed use pattern. Risk mitigation measures need to be applied.

For details please refer to the National Addendum Germany Part B, section 6, chapter 6.9.

Consequences for authorization:

For the authorization of the plant protection product Beetix WG (HBT05) following labelling and conditions of use are mandatory:

Safety precautions / Conditions of use

use no. 00-001	NT103
use no 00-002	NT103

Implications for labelling resulting from ecotoxicological assessment:

For the authorization of the plant protection product Beetix WG (HBT05) the following labelling and conditions of use are mandatory:

Classification and labelling

Relevant toxicity	Active substance: metamitron EbC50 = 0.38 mg/L (<i>Lemna minor</i>) M-factor = 1 Product Beetix WG NOEC = 0.03 mg/L (<i>Pseudokirchneriella subcapitata</i>) M-factor = 1
Classification and labelling according to Directive 67/548/EC, 78/631/EC and 1999/45/EC	
Hazard symbol	N, dangerous for the environment
Risk phrases	R 50 – 53
Classification and labelling according to Regulation 1272/2008	
Hazard symbol	GHS09
Signal word	No signal word used
Hazard statement	H400, H411

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

All uses:

NW 468

Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing 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.

NT103

In a strip at least 20 m wide which is adjacent to other areas, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 90 % (except agriculturally or horticulturally used areas, roads, paths and public places). Loss reducing equipment is not required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide or the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures.

Other labels

NW262

The product is toxic for algae.

NW263

The product is toxic for aquatic invertebrates.

NW265

The product is toxic for higher aquatic plants.

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

Information on the active substance

Metamitron is a triazinone herbicide (HRAC group C1) which also includes the triazines (eg atrazine and simazine) and phenyl-carbamates (eg phenmedipham and desmedipham). Herbicides in group C1 act by inhibition of photosynthesis at photosystem II. Metamitron is both an effective soil-acting herbicide with residual activity and a contact, foliar herbicide. The active substance metamitron is rapidly taken up in solution by the roots and leaves of weeds and transported to the chloroplasts. HBT01 has a systemic action; therefore it is affected by soil type. Soil moisture is necessary for good residual activity.

Label WMC1 is defined to the product.

Efficacy data

Preliminary range finding tests with weed species are not reported, since according to the zRMS the effect of the active substance metamitron is well known.

Metamitron is a well-known active substance, and according to the zRMS experience showed that for broad-leaved weeds of sugar beet fields, the intended doses of the current application are the minimum required to obtain a good control.

A total of 23 efficacy trials were conducted in the European Central zone to prove and support the proposed label claims for HBT05. The trials were conducted in Austria (3), Germany (3) Belgium (1), Czech Republic (1), Hungary (3), Netherlands (3), Poland (5) and United Kingdom (3).

For use 007671-00/00-001 no data were submitted to specifically support this pattern of use. Consequently this use was rated negative by the JKI.

For use 007671-00/00-002 for some weeds which are described in the label as being controlled well, only a few or no efficacy results were reported. The requirement WH9161 is defined for this particular use.

Effects on yield and quality

The Registration Report includes data of 1 crop safety trial for the pre-emergence application of HBT05. The recommended and even the double rate applied on sugar beet didn't influence adversely beet quality parameters, such as sugar content.

The post-emergence applications of HBT05 with the recommended and even with the double rate does not influence adversely and significantly beet quality parameters, such as sugar content, K content, Na content and N content.

However, EPPO guideline PP1/226 (1) indicates that typically, at least 8 specific crop safety trials per major crop are required, to cover the range of conditions of use, including soil types, weather conditions that are likely to be encountered.

Adverse effects

Phytotoxicity to host crop

According to the zRMS use 001 of Beetix WG HBT05 at the recommended rate and application pattern is considered as safe for a wide selection of commercially available sugar beet varieties. Unintended light transient phytotoxic effects may be observed early after application, but the phytotoxicity symptoms disappear during growing period and have no adverse impact on yield or its quality, according to the zRMS. However, according to the JKI the selectivity of a pre-emergence application of 2100 g/ha metamitron is not sufficiently verified by the provided data for the following reasons: The Registration Report includes data of 4 selectivity trials of which only 1 is reasonably valid according to the EPPO standards (this trial was conducted in the maritime zone and also the double dosage was tested). All selectivity trials were done in just one year (2011). Only 1 trial (from Hungary) has been harvested. Due to different dosages a bridging of use 002 is not possible. Considering also that crop damages occurred in some selectivity and efficacy trials a registration of use 001 is not possible for Germany.

For use 002 the zRMS states that HBT05 at the recommended rate and application pattern is considered as safe for a wide selection of commercially available sugar beet varieties. Unintended transient phytotoxic effects may be observed early after application, however, the phytotoxicity symptoms disappeared during growing period and didn't show adverse impact on both yield and quality parameters.

Adverse effects on beneficial organisms (other than bees)

Studies using the test product were not made available. On the basis of laboratory studies with SC-formulations with the same content of metamitron as Beetix WG, the proposed application rate of the test product can be considered as not harmful for the parasitoid wasp *Aphidius rhopalosiphi*, the ladybird *Coccinella septempunctata* and for spiders of the genus *Pardosa* and as (at most) slightly harmful for the predatory mite *Typhlodromus pyri*. According to the results on these indicator species the product is classified not harmful for beneficial insects and relevant predatory mites and spiders.

Labels NN1001 and NN1002 are assigned to the product.

Impact on succeeding crops

The applicant did not specifically consider the risk to succeeding crops. According to the zRMS HBT05 is not expected to have adverse effects on succeeding crops when used correctly. However, other MS should consider the risk to succeeding crops based on their local conditions. No such recommendation was made by JKI.

Impact on other plants including adjacent crops

The toxicity exposure ratio (TER) was calculated between the lowest ER₅₀ values from pre- and post-emergence studies, with the maximum off-field PER, according to the following equation:

$$TER_{LT} = \frac{\text{Corrected ER}_{50}[\text{g/ha}]}{\text{Off-field PER} [\text{g/ha}]}$$

The TER values exceeded the recommended trigger of 10 indicating that the use of HBT01 at 1 m distance from the treated field poses acceptable risk to non-target plants.

Possible development of resistance or cross-resistance

As resistance in *Chenopodium album* to metamitron has been detected in Belgium, France, Netherlands, Sweden and Germany and because the number of resistance cases in Germany has increased in the last years, the resistance risk of Beetix WG has to be rated as high. This is also due to the high number of resistance cases reported for Germany in the HRAC group C1.

In addition, many target species especially *Amaranthus* spp., *Chenopodium album*, *Senecio vulgaris*, *Solanum nigrum* and *Poa annua* can be regarded as high risk species. The general resistance risk of Beetix WG under German conditions is therefore assessed as being high.

The label warning WH951 is therefore defined for the product.

3.2 Conclusions

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

Concerning analytical methods (formulation) an authorisation can be granted.

With respect to analytical methods for residues an authorisation can be granted.

Regarding efficacy (IPM)/sustainable use incl. effects on honeybees an authorisation can be granted for use 002. Use 001 cannot be authorized due to lack of data and particularly evidence for insufficient crop safety.

Concerning toxicology, residues and consumer protection an authorisation can be granted.

With respect to environmental fate and behaviour and ecotoxicology an authorisation can be granted.

An authorisation can be granted for use 002 only.

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 has to fulfil the requirements according to Article 16 of Directive 91/414/EEC.

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
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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.007671-00/00.69315
(bitte bei Antwort angeben)

DATUM 7. Mai 2015

ZV3 007671-00/00

Beetix WG

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit dem Wirkstoff: 700 g/kg Metamitron

Zulassungsnummer: 007671-00

Versuchsbezeichnungen: UPL-07671-H-0-WG

Antrag vom: 7. Mai 2012

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

Zulassungsende

Die Zulassung endet am 31. August 2020.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

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

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
007671-00/00-002	Einjähriges Rispen- gras, Einjährige zweikeimblättrige Unkräuter (ausge- nommen: Klet- ten-Labkraut, Knöte- rich-Arten)	Futterrübe, Zuckerrübe	

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 des Gesetzes vom 2. Dezember 2014 (BGBl. I S. 1928), festgesetzt:

(NW468)

Anwendungsflüssigkeiten und deren Reste, Mittel und dessen Reste, entleerte Behältnisse oder Packungen sowie Reinigungs- und 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 Metamitron weist aufgrund seiner Toxizität ein hohes Gefährdungspotenzial für aquatische Organismen auf. Jeder Eintrag von Rückständen in Oberflächengewässer, der den Eintrag als Folge der bestimmungsgemäßen und sachgerechten Anwendung des Mittels entsprechend der guten fachlichen Praxis übersteigt, würde daher zu einer Gefährdung des Naturhaushaltes aufgrund von nicht akzeptablen Auswirkungen auf Gewässerorganismen führen. Da ein erheblicher Anteil der in Oberflächengewässern nachzuweisenden Pflanzenschutzmittelfrachten auf Einträge aus kommunalen Kläranlagen zurückzuführen ist, muss dieser Gefährdung durch die bußgeldbewehrte Anwendungsbestimmung durchsetzbar begegnet werden.

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
Faltschachtel mit Innenbeutel	PE	1		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:

Kennzeichnungsaufgaben:

(NW262)

Das Mittel ist giftig für Algen.

(NW263)

Das Mittel ist giftig für Fischnährtiere.

(NW265)

Das Mittel ist giftig für höhere Wasserpflanzen.

(SB001)

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

(SF245-01)

Behandelte Flächen/Kulturen erst nach dem Abtrocknen des Spritzbelages wieder betreten.

(WMC1)

Wirkungsmechanismus (HRAC-Gruppe): C1

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

Sonstige Auflagen:

(WH951)

Auf der Verpackung und in der Gebrauchsanleitung ist auf das Resistenzrisiko hinzuweisen. Insbesondere sind Maßnahmen für ein geeignetes Resistenzmanagement anzugeben.

Vorbehalt

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

Angaben zur Einstufung und Kennzeichnung gemäß § 4 Gefahrstoffverordnung

Gefahrensymbole: N, Xn

Gefahrenbezeichnungen: Umweltgefährlich, Gesundheitsschädlich

Gefahrenhinweise (R-Sätze):

R 50/53: Sehr giftig für Wasserorganismen, kann in Gewässern längerfristig schädliche Wirkungen haben.

R 20 : Gesundheitsschädlich beim Einatmen

R 22 : Gesundheitsschädlich beim Verschlucken

Sicherheitshinweise (S-Sätze):

S 2 : Darf nicht in die Hände von Kindern gelangen

S 13 : Von Nahrungsmitteln, Getränken und Futtermitteln fernhalten

S 35 : Abfälle und Behälter müssen in gesicherter Weise beseitigt werden

S 46 : Bei Verschlucken sofort ärztlichen Rat einholen und Verpackung oder Etikett vorzeigen

S 57 : Zur Vermeidung einer Kontamination der Umwelt geeigneten Behälter verwenden

Zur Vermeidung von Risiken für Mensch und Umwelt ist die Gebrauchsanleitung einzuhalten.

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

Signalwort:

(S1) Achtung

Gefahrenpiktogramme:

(GHS07) Ausrufezeichen

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(EUH 401)

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

(H302)

Gesundheitsschädlich bei Verschlucken.

(H319)

Verursacht schwere Augenreizung.

(H332)

Gesundheitsschädlich bei Einatmen.

(H400)

Sehr giftig für Wasserorganismen.

(H411)

Giftig für Wasserorganismen, mit langfristiger Wirkung.

Sicherheitshinweise (P-Sätze):

(P101)

Ist ärztlicher Rat erforderlich, Verpackung oder Etikett bereithalten.

(P102)

Darf nicht in die Hände von Kindern gelangen.

(P261)

Einatmen von Staub/Rauch/Gas/Nebel/Dampf/Aerosol vermeiden.

(P271)

Nur im Freien oder in gut belüfteten Räumen verwenden.

(P280)

Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.

(P305+P351+P338)

BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen.

(P308+P313)

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

(P312)

Bei Unwohlsein GIFTINFORMATIONSZENTRUM oder Arzt anrufen.

(P501)

Inhalt/Behälter ... zuführen.

Abgelehnte Anwendungsgebiete bzw. Anwendungen

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

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
007671-00/00-001	Einjähriges Rispen- gras, Einjährige zweikeimblättrige Unkräuter (ausge- nommen: Klet- ten-Labkraut, Knöte- rich-Arten)	Futtermübe, Zuckerrübe	

Hinweise

Auf dem Etikett und in der Gebrauchsanleitung kann angegeben werden:

(NB6641)

Das Mittel wird bis zu der höchsten durch die Zulassung festgelegten Aufwandmenge oder Anwendungskonzentration, falls eine Aufwandmenge nicht vorgesehen ist, als nicht bienengefährlich eingestuft (B4).

(NN1001)

Das Mittel wird als nicht schädigend für Populationen relevanter Nutzinsekten eingestuft.

(NN1002)

Das Mittel wird als nicht schädigend für Populationen relevanter Raubmilben und Spinnen eingestuft.

Weitere Hinweise und Bemerkungen

Zum Etikett:

Auf dem Etikett ist zusätzlich zum Wirkstoffgehalt anzugeben:

"Enthält ca. 110 g /kg Kaolin (Al.-silikat) als Füllstoff."

Zu KIIIA1 6.2.8:

Hinweis und Begründung für die Kennzeichnungsaufgabe zum Wirkungsmechanismus (WMC1: Metamitron):

Die HRAC-Klassifizierung ist als neutrale Information direkt dem Wirkstoff zuzuordnen. Die Kennzeichnung erleichtert der Praxis die Bestimmung des Wirkungsmechanismus von Herbiziden und ermöglicht so ein gezieltes Wirkstoffmanagement.

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

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

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

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

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Martin Streloke
Abteilungsleiter

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

Anlage

Anlage 1 zugelassene Anwendung: 007671-00/00-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Einjähriges Rispengras, Einjährige zweikeimblättrige Unkräuter (ausgenommen: Kletten-Labkraut, Knöterich-Arten)

Pflanzen/-erzeugnisse/Objekte: Futterrübe, Zuckerrübe

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	10 bis 18
Anwendungszeitpunkt:	Frühjahr, nach dem Auflaufen
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	3
- für die Kultur bzw. je Jahr:	3
- Abstand:	6 bis 14 Tage
Anwendungstechnik:	spritzen
- Erläuterungen:	im Splittingverfahren (3 Behandlungen)
Aufwand:	
- Zeitpunkt 1:	1 kg/ha in 200 bis 300 l Wasser/ha
- Zeitpunkt 2:	2 kg/ha in 200 bis 300 l Wasser/ha
- Zeitpunkt 3:	2 kg/ha in 200 bis 300 l Wasser/ha
- Erläuterungen:	Maximaler Mittelaufwand in der Kultur je Vegetationsperiode: 5 kg/ha

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

(WH9161)

In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden,

sowie eine Arten- und/oder Sortenliste der Kulturpflanzen, für die der vorgesehene Mittelaufwand verträglich oder unverträglich ist.

2.3 Wartezeiten

- (F) Freiland: Futterrübe
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.
- (F) Freiland: Zuckerrübe
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

(NG404)

Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss eine Mindestbreite von 20 m haben. Dieser Randstreifen ist nicht erforderlich, wenn: - ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden bzw. mit der Kanalisation verbunden sind, oder - die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.

Begründung:

Der im o.g. Pflanzenschutzmittel enthaltene Wirkstoff Metamitron weist ein hohes Potenzial für Einträge in das Grundwasser über den Pfad Oberflächenabfluss mit anschließender inverser Uferfiltration auf. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 399,9 mg/L; DT50 Boden = 30,5 d; KOC = 102) und einer Berechnung der zu erwartenden Einträge mit dem Modell Exposit 3.0 sind nach dem Stand der wissenschaftlichen Erkenntnisse die Vorgaben der o.g. Anwendungsbestimmung einzuhalten, um einen ausreichenden Schutz des Grundwassers vor Rückständen des Wirkstoffs Metamitron (Konzentration im Grundwasser < 0,1 µg/L) zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen.

(NT103)

Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungskategorie 90 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.

Begründung:

Das o.g. Pflanzenschutzmittel bzw. der darin enthaltene Wirkstoff Metamitron weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 54,9 g a.s./ha (*Lactuca sativa*) im Keimungstest. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die o.g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen.

Anlage 2 nicht zugelassene Anwendung: 007671-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Einjähriges Rispengras, Einjährige zweikeimblättrige Unkräuter (ausgenommen: Kletten-Labkraut, Knöterich-Arten)

Pflanzen/-erzeugnisse/Objekte: Futterrübe, Zuckerrübe

Verwendungszweck:

2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Ackerbau

Anwendungsbereich: Freiland

Anwendung im Haus- und Kleingartenbereich: Nein

Stadium der Kultur: 00 bis 18

Anwendungszeitpunkt: Frühjahr, vor dem Auflaufen (1. Behandlung), nach dem Auflaufen (2. Behandlung) und nach dem Auflaufen (3. Behandlung)

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Abstand: 6 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Zeitpunkt 1: 3 kg/ha in 200 bis 300 l Wasser/ha

- Zeitpunkt 2: 1 kg/ha in 200 bis 300 l Wasser/ha

- Zeitpunkt 3: 1 kg/ha in 200 bis 300 l Wasser/ha

- Erläuterungen: Maximaler Mittelaufwand in der Kultur je Vegetationsperiode: 5 kg/ha

3 Begründung

Wirksamkeit

Die Prüfung hat ergeben, dass die Kulturpflanzenverträglichkeit mit einer Aufwandmenge von 2100 g/ha Metamitron nicht ausreichend belegt ist.

Begründung:

In Anbetracht der Tatsache, dass in einigen Verträglichkeits- und Wirkungsversuchen Schäden nach der beantragten Voraufaufanwendung auftraten, kann eine Zulassung für Deutschland nicht vorgesehen werden.

Zu KIIIA1 6.2.1

Die Verträglichkeit dieser Anwendung mit einer Aufwandmenge von 2100 g/ha Metamitron im Voraufbau ist nicht ausreichend belegt.

Begründung:

Gemäß EPPO Richtlinie PP1/226 sind 8 Versuche aus zwei Jahren aus der maritimen Zone erforderlich, die die Kulturpflanzenverträglichkeit belegen. Die Versuche sind gemäß EPPO Richtlinie PP1/135 mit der doppelten Aufwandmenge unter unkrautfreien Bedingungen durchzuführen. Im Registration Report sind hierzu Ergebnisse aus 4 Verträglichkeitsversuchen dargestellt, von denen jedoch nach EPPO-Richtlinien nur ein einziger verwertbar ist, weil er sowohl in der maritimen Zone als auch mit der doppelten Dosis durchgeführt worden ist. Nur ein Versuch (aus Ungarn) ist beerntet worden. Sämtliche Verträglichkeitsdaten stammen zudem nur aus einem Versuchsjahr (2011). Wegen abweichender Aufwandmengen sind die Ergebnisse aus Anwendung Nr. 002 nicht übertragbar. Eine vergleichbare Anwendung ist bislang in Deutschland nicht zugelassen, so dass entsprechende Daten und Erfahrungen folglich nicht vorliegen.

**REGISTRATION REPORT
Part B**

**Section 5 Environmental Fate
Detailed summary of the risk assessment**

Product code: HBT05= Beetix WG
Active Substance: Metamitron 700 g/kg

Central Zone
Zonal Rapporteur Member State: United Kingdom

NATIONAL ADDENDUM – Germany

Applicant: United Phosphorus Ltd
Date: September/2014

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

The exposure assessment of the plant protection product HBT05 in its intended uses in fodder beet and sugar beet is documented in detail in the core assessment of the plant protection product HBT05 dated from 29.02.2012 performed by applicant United Phosphorus Ltd. and member state UK.

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for authorization of the plant protection product HBT05 in Germany according to intended uses listed in Appendix 3.

Regarding PEC_{gw} relevant risk mitigation measures, if necessary, are documented in this document. PEC_{soil}, PEC_{sw} are used for risk assessment to derive specific risk mitigation measures if necessary (see National Addendum Germany, part B, section 6 and part A).

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation HBT05

Code	First registration name: Beetix WG (M11154) New name: HBT05		
plant protection product	HBT05 (UK) = Beetix WG (DE)		
applicant	United Phosphorus Ltd.		
date of application	29.02.2102		
Formulation type (WP, EC, SC, ...; density)	WG		
active substances (as)	Metamitron		
Concentration of as	700g/kg		
Data pool/task force	-		
letter of access/cross reference	-		

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 HBT05

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)
00-001	Fodder beet and sugar beet	Spraying (arable crops)	Up to 3 applications in spring 1 pre-emergence or 1 after weed appearance application in spring from 1.4. Up to 3 post-emergence applications in spring (crop BBCH 10-18) from 16.4. Interception: 0% pre emergence 20% post-emergence Minimum application interval: 6 days	3/1/1 kg/ha HBT05 Metamitron: max. 3 applications Max. 3.5kg/ha /year 1.) 2100 g/ha 2.) 700 g/ha 3.) 700 g/ha	1.) 2100g 2.) 560 3.) 560
00-002	Fodder beet and sugar beet	Spraying (arable crops)	Up to 3 applications in spring Up to 3 post-emergence applications in spring (crop BBCH 10-18) from 16.4. Interception: 20% post-emergence Minimum application interval: 6 days	1/2/2 kg/ha HBT05 Metamitron: max. 3 applications Max. 3.5kg/ha /year 1.) 700 g/ha 2.) 1400 g/ha 3.) 1400 g/ha	1.) 560 2.) 1120 3.) 1120

* 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 Metamitron

Please refer to the core assessment (29.02.2012), part B, section 5.

Metabolites of Metamitron

Metabolit Desamino-metamitron

The environmental occurring metabolite Desamino-metamitron requiring further assessment according to the results of the assessment of Metamitron for EU approval are summarized in Table 5.3-1 of the national addendum.

The risk assessment for this metabolite has already been performed for EU approval (see Sanco/208/08 final – 06/01/2009) as well as in the core assessment by UK, Part B, section 5 and section 6.

Metabolit M3

There are further information on the metabolit M3 in the Addendum to DAR from 2014 required as a condition of inclusion in Annex 1.

Regarding this information on soil metabolite M3 in relation to impact on groundwater the RMS agrees with the applicant assessment that M3 is a likely artefact of the reaction of metamitron with acetone as an extraction solvent, especially under higher temperature conditions. M3 is not present in a confirmatory study (Gärtner, C., 2011) or in other existing studies reviewed in the DAR which were conducted where acetone is not a primary extraction solvent. (In the confirmatory study there is co-chromatography with a reference standard of “Schiff’s base” metamitron, and no metabolites form to the same levels as M3 from the original study of Fischer (1994). The reaction between metamitron and its “Schiff’s base is a reversible reaction, so may be formed during extraction but not present during chromatography.)

It is concluded that the metabolite M3 is likely an artefact of the reaction of metamitron with acetone as an extraction solvent and the metabolit M3 is classified as not relevant. Hence an national assessment of this metabolite is not required.

Table 5.3-1: Metabolites of Metamitron 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 (Max. at day/	Status of Relevance according to the core assessment by zRMS UK
Desamino-Metamitron	<p>Mm = 187.2 g/mol</p>	<p>Soil, aerob: max. 7.5 - 17.1 % after 28 - 30 d</p> <p>Water: max. 54 % after 58 d</p> <p>Sediment: max. 27.5 % after 58 d</p>	<p>Aquatic organisms: Water: not relevant? * Sediment: not relevant? *</p> <p>Terrestrial organisms: not relevant? *</p> <p>Groundwater: not relevant (Step 2)¹⁾ not relevant (Step 3 and 4)¹⁾ **</p>

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)

*) There are no comment in the core assessment.

***) The following comment is in the core assessment: “An assessment of the relevance of desamino-metamitron in groundwater has been carried out according to the respective EU guidance document (2003). This assessment showed that desamino-metamitron is not relevant. Therefore, it can be concluded that the use of metamitron is not likely to pose an unacceptable risk to shallow groundwater if the active substance is used in compliance with label recommendations.”

5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Metamitron

The DT₅₀ values of Metamitron used in the core assessment, part B, (refer to Annex Point IIIA 9.6.) were analysed according to Holdt et al. 2011 ¹.

The statistical results for Metamitron according to the program INPUT DECISION 3.3 are listed in Table 5.4-1.

Table 5.4-1: Statistic values according to INPUT DECISION 3.3 for Metamitron for PEC_{GW} modelling

Does the active substance dissociate ?	no	
correlation DT ₅₀ and pH	Kendall-τ: 0.059 p-value: 0.915	not significant correlation
coefficient of variation	66	Sufficiently low
DT ₅₀ for PEC _{GW} (d)	12.5	Geomean (according to Holdt et al. 2011) n=9 (without consideration study of Allen and Walker, 1987)
	19	Geomean (according to Holdt et al. 2011 and LoEP /under consideration of study of Allen and Walker, 1987) n= 27 UK accepted the more conservative values in core assessment 2014, hence it is mentioned here in national addendum of Germany too.

¹ (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

The DT₅₀ values of the metabolite Desamino-metamitron of Metamitron used in the core assessment (refer to Annex Point IIIA 9.6.) were analysed according to Holdt et al. 2011.

The statistical results for the metabolite Desamino-metramitron according to the program INPUT DECISION 3.3 are listed in Table 5.4-2.

Table 5.4-2: Statistic values according to INPUT DECISION 3.3 for the metabolite Desamino-metamitron for PEC_{GW} modelling

Does the active substance dissociate ?	no	
correlation DT ₅₀ and pH	Kendall-τ: 0.222 p-value: 0.466	correlation not significant
coefficient of variation	23%	sufficiently low
DT ₅₀ for PEC _{GW} (d)	30.4	geomean according to Holdt et al. 2011 and LoEP n=7

In the core assessment performed by UK DT₅₀ values from the EU assessment were considered.

As laboratory studies on degradation in soil belong to the basic data set of an active substance DT₅₀ values from all available studies are considered for exposure assessment. (see Table 5.4-3 below).

Table 5.4-3: Summary of aerobic degradation rates for Metamitron - laboratory studies

Soil type	pH (H ₂ O)	T (°C)	moisture	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20 °C pF2/10kPa	Fit r ²	Kinetic	Reference
Sandy loam	6.3	20	40% MWHC	15.7	52.6	12.5	0.977	SFO	Gilges, 2002
Silt	6.7	20	40% MWHC	26.7	88.7	25.5	0.919	SFO	Sneikus, 2002
Loamy sand	6.2	20	40% MWHC	21.1	70.1	21.1	0.988	SFO	Sneikus & Brumhard, 2002
Silt loam	7.3	20	40% MWHC	3.4	11.3	2.2	0.982	SFO	Sneikus & Brumhard, 2002
Sand (UK)	5.5	23	40% MWHC	7.1	23.6	9.4	0.995	SFO	Schneider, E., 1992
Sandy loam (UK)	5.5	23	40% MWHC	8.4	27.9	9	0.955	SFO	Schneider, E., 1992
Loamy sand (UK)	5.54	23	40% MWHC	11.0	36.5	14.6	0.989	SFO	Schneider, E., 1992
Silt loam (UK)	6.2	23	40% MWHC	7.4	24.6	9.2	0.915	SFO	Schneider, E., 1992

Clay loam		20		6.8		44.5			Allen and Walker 1987 **
Clay		20		7.2		22.6			Allen and Walker 1987 **
Sandy clay loam		20		7.4		15.4			Allen and Walker 1987 **
Clay loam		20		7.3		20.8			Allen and Walker 1987 **
Sandy clay loam		20		6.5		27.7			Allen and Walker 1987 **
Sandy clay loam		20		6.6		21.5			Allen and Walker 1987 **
clay loam		20		6.8		44.4			Allen and Walker 1987 **
silty clay loam		20		5		36.9			Allen and Walker 1987 **
Sandy loam		20		6.4		20.4			Allen and Walker 1987 **
Sandy clay loam		20		6.4		23.9			Allen and Walker 1987 **
clay loam		20		6.4		33			Allen and Walker 1987 **
clay		20		6.8		28.7			Allen and Walker 1987 **

Sandy clay loam		20		6.6		28.9			Allen and Walker 1987 **
Sandy loam		20		6.3		16.4			Allen and Walker 1987 **
Aggregated DT50 (n=9)*	Coefficient of variation (%)						* Geomean of studies accepted by Germany		
	Geometric mean (d)				12* (n= 9)		** Geomean of all studies (EU agreed geomean with studies of Allen and Walker) = 19.12 d = worst case according to LoEP (n=27) **		
	90th Percentil				27.2		Laboratory normalised to 20°C, pF2		

Formatiert: Englisch (USA)

*remark: The study of Allen and Walker, 1987 was not accepted by Germany because there are no pH and moisture data available.

Formatiert: Englisch (USA)

Metabolites of Metamitron

Formatiert: Englisch (USA)

The data on the degradation in soil of the metabolite of Metamitron are summarized in the Table 5.4-4 below.

Table 5.4-4: Summary of aerobic degradation rates for metabolite Desamino-metamitron - laboratory studies

Soil type	pH (H ₂ O)	T (°C)	moisture	DT ₅₀ (d)	ff ³⁾	DT ₅₀ (d) 20 °C pF2/10 kPa	Fit	Kinetic	Reference
Sandy loam I (Laacher Hof A XXa, Monheim, Germany)	6.3	20	40% MWHC (100%= 34,42g/100g)	37.2	0.2	29.7	0.986	SFO	Gilges, 2002
Silt I (Hoefchen, Burscheid, Germany)	6.7	20	40% MWHC (100%= 63,1g/100g)	39.3	0.5	37.5	0.955	SFO	Sneikus., 2002
Loamy sand I (BBA 2.2, Hanhofen, Germany)	6.2	20	40% MWHC (100%= 56,18g/100g)	30.7	0.2	30.7	0.992	SFO	Sneikus. and Brumhard, 2002
Silt loam I (Laacher Hof AII, Monheim, Germany)	7.3	20	40% MWHC (100%= 35,1g/100g)	51.3	0.1	33.3	0.981	SFO	Sneikus and Brumhard, 2002
Loamy sand I	5.8	20	40% MWHC	24.7	0.4	24.7	0.951	SFO	Fischer,

(BBA 2.2, Germany)			(100%= 44g/100g)						1994, amendmen t 1994
Sand2 (Speyer 2.1, Germany)	6.0	20	40% MWHC (100%= 29g/100g)	46.27	-- ⁴⁾	45.2	0.9699	SFO	Schneider, 1997
Loamy sand2 (Speyer 2.2, Germany)	6.1	20	40% MWHC (100%= 48g/100g)	22.81	-- ⁴⁾	22.8	0.8515	SFO	Schneider, 1997
Sandy loam2 (Speyer 2.3, Germany)	6.6	20	40% MWHC (100%= 37g/100g)	28.37	-- ⁴⁾	23.8	0.9567	SFO	Schneider, 1997
Sandy loam1 (Laacher Hof A XXa, germany)	6.4	20	40% MWHC (100%= 34,4g/100g)	40.9	-- ⁴⁾	32.6	0.952	SFO	Schneider, 1997

Formatiert: Englisch (USA)

¹ USDA classification
² UK classification
³ f.f. = formation fraction (modelled Maximum) calculated by RMS (see DAR)
⁴ Metabolite as parent

Aggregated DT₅₀ (n=7)	Coefficient of variation (%)	23	According to Input Decision (3.3): No pH-dependence, use geometric mean for PEC _{gw}
	Geometric mean (d)	30.4	
	90th Percentil	39	
Formation fraction a.s.→ metabolite Desamino-metamitron (n = 1)		0.5 maximum	arithmetic mean: 0.28

5.4.1.2 Field studies

The field studies available in DAR/EU assessment for Metamitron were not checked concerning ctgbcriteria. For national addendum only the not normalized maximal DT₅₀ of 22 days can be used as input parameter for PEC soil. (reference: Maierhofer, 1996 (4 studies), Fuchsbichler, 1995, and Seiterle-Winn, 2008.)

5.4.2 Adsorption/desorption

Metamitron and metabolite Desamino-metamitron

In the core assessment K_{foc} values from the EU assessment were considered. The K_{foc} values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011). See table 5.4-5 to 5.4-8.

Table 5.4-5: K_r , K_{foc} and $1/n$ (Freundlich exponent) values for Metamitron

Soil Type	OC (%)	pH (-)	K_r (mL g ⁻¹)	K_{foc} (mL g ⁻¹)	$1/n$ (-)	Reference
Borstel, Loamy sand	1.08	5.1	0.933	86.4	0.8048	Müller, 2003
LUFA 3A, Sandy silt loam	2.60	7.1	1.413	54.4	0.7019	Müller, 2003
LUFA 2.2, Sandy loam	2.30	6.2	1.292	56.2	0.8204	Müller, 2003
Parabraunerde Soest, Silt loam	1.86	6.0	1.190	64.0	0.8305	Müller, 2003
Lufa 2.1, sand	0.6	5.8	1.82	303	0.67	Brumhard and Führ, 1992
Lufa, clay	0.9	7.4	1.04	116	0.85	Brumhard and Führ, 1992
Parabraunerde Ap, silt loam	1.1	7.1	1.54	140	0.75	Brumhard and Führ, 1992
Parabraunerde Bt, silty clay loam	0.3	6.7	0.36	120	0.95	Brumhard and Führ, 1992
Braunerde, sandy silt loam	0.8	5.5	1.49	186	0.75	Brumhard and Führ, 1992
Greenhouse, sandy silt loam	1.5	6.3	5.88	392	0.67	Brumhard and Führ, 1992
Borstel, Sandy loam	1.15	6.3	1.43	124	0.80	Scholz, 1992
Laacher Hof, Sandy loam	1.35	6.9	1.07	79	0.79	Scholz, 1992
BBA 2.2; Loamy sand	1.56	5.6	0.384	24.6	0.767	Balluff, 1995
Hetendorf; Loamy sand	2.25	5.0	1.511	67.2	0.779	Balluff, 1995
Dossenheim; Clay loam	1.68	7.5	0.376	22.4	0.656	Balluff, 1995

Table 5.4-6: Statistic values according to INPUT DECISION 3.3 for Metamitron for PEC_{GW} modeling

Does the active substance dissociate ?	no
--	----

correlation K_f and oc	Kendall- τ : 0.667 p-value: 0.308	not significant (p-Wert > significance level)
coefficient of variation K_{foc}	84	too high (> 60%)
Correlation K_f and pH	Kendall- τ : 0.840 p-value: 0.001	positive significant (p-Wert < significance level)
Correlation K_f and other soil parameters (clay, CEC)	-	not relevant
K_{foc}/K_f for PEC _{GW} _FOCUSPelmo	$K_f = 1.45$ für 1. -3. Horizon $K_f = 0$ für 4.- 6- horizon	arithmetic mean all soils / k_f -values specific for soil horizons (scenario hamburg) n= 15
1/n PEC _{GW}	0.773	arithmetic mean all soils / n= 15
K_{foc} for PEC _{sw} EXPOSIT Runoff	122	arithmetic mean all soils / n= 15
K_{foc} for PEC _{sw} EXPOSIT hazard group	37	10.perzentil / n= 15

Table 5.4-7: K_f , K_{foc} and 1/n (Freundlich exponent) values for the metabolite Desamino-metamitron

Soil Type	OC (%)	pH (-)	K_f (mL g ⁻¹)	K_{foc} (mL g ⁻¹)	1/n (-)	Reference
BBA 2.1, sand	0.59	5.8	0.802	136	0.808	Burhenne, 1998
BBA 2.2, loamy sand	2.48	6.3	1.703	69	0.777	Burhenne, 1998
Laacherhof, sandy loam	1.80	6.4	2.507	139	0.7899	Burhenne, 1998
Höfchen, silt	2.62	7.2	1.729	66	0.755	Burhenne, 1998

Table 5.4-8: Statistic values according to INPUT DECISION 3.2 for the metabolite Desamino-metamitron for PEC_{GW} modeling

Does the metabolite Desamino-metamitron dissociate ?	no	
correlation K_f and oc	Kendall- τ : 0.333 p-value: 0.367	not significant (p-Wert > significance level)
coefficient of variation K_{foc}	40%	sufficiently low (≤ 60)
Correlation K_f and pH	Kendall- τ : 0.667 p-value: 0.308	not significant (p-Wert < significance level)
Correlation K_f and other soil parameters (clay, CEC)	-	not relevant

K_{foc}/K_f for PEC _{GW} _FOCUSPelmo	102	arithmetic mean all soils / n= 4
1/n PEC _{GW}	0.782	arithmetic mean all soils / n= 4
K_{foc} for PEC _{sw} EXPOSIT Runoff	102	arithmetic mean all soils / n= 4
K_{foc} for PEC _{sw} EXPOSIT hazard group	102	arithmetic mean all soils / n= 4

5.4.3 Rate of degradation in water/sediment

Metamitron

Please refer to the core assessment

Table 5.4-9: Degradation in water/sediment of Metamitron

Water/sediment system	DegT ₅₀ / DegT ₉₀ whole system	Kinetic, Fit	DissT ₅₀ / DissT ₉₀ water	Kinetic, Fit	DissT ₅₀ / DissT ₉₀ sed.	Kinetic, Fit	Reference
Waldwinkel, Teich	10.8/35.9	SFO/ r ² =0.98	9.6 /31.9	SFO/ r ² =0.98	Not calculated	-	Fischer, 1993 (SANCO/208/08 final – 06/01/2009)
Rückhaltebecken	11.4/37.9	SFO/ r ² =0.98	11.6/38.4	SFO/ r ² =0.98	Not calculated	-	Fischer, 1993 (SANCO/208/08 final – 06/01/2009)
Max. DT50 (n=2)	11.4						

Accumulation of active substance and relevant metabolites in the sediment

active substance	Metamitron
accumulation potential in sediment	no (DT _{90,whole system} < 1 year, see core assessment)
accumulation factor (SFO) $f_{accu} = e^{-kt}/(1 - e^{-kt})$	-

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Results of PEC_{soil} calculation for HBT05 according to EU assessment considering 5 cm soil depth see in the core assessment.

For German exposure assessment the applied soil depth is based on experimental data (Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter

Pflanzenschutzmittelwirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999). Generally for active substances with a $K_{f,oc} < 500$ a soil depth of 2.5 cm is applied whereas for active substances with a $K_{f,oc} > 500$ a soil depth of 1 cm is applied. As soil bulk density 1.5 g cm^{-3} is assumed.

Due to the fast degradation of the active substance Metamitron in soil ($DT_{90} < 365$ d, Kinetic, laboratory/field data) the accumulation potential of Metamitron does not need to be considered.

The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters for Metamitron as presented in Table 5.5-1.

Table 5.5-1: Input parameters for HBT05 for PEC_{soil} calculation

Active substance	DT_{50}
Metamitron	22 d (SFO-Kinetik, Maximum, Field studies) Not required for PEC_{soil}
Desamino-metamitron	39.7 d

Additional $PEC_{soil,act}$ was calculated for the formulation HBT05 for a soil depth of 2.5 cm.

No short-term and long-term PEC_{soil} were calculated since $PEC_{soil,act}$ is considered sufficient for German risk assessment.

The calculated PEC_{soil} used for German risk assessment for Metamitron, for metabolite Desamino-metamitron and for the formulation HBT05 are summarized in Table 5.5-2.

Table 5.5-2: Results of PEC_{soil} calculation for the intended use in sugar beet/fodder beet used for German risk assessment

plant protection product:		HBT05				
use:		001/ Sugar and fodder beet				
Number of applications/intervall		3 applications /6 day interval				
application rate:		a.s.: 2100/700/700 HBT05: 3000/1000/1000				
crop interception:		0/20/20%				
active substance/ formulation	soil relevant application rate (g/ha)	soil depth _{act} (cm)	PEC_{act} (mg/kg)	tillage depth (cm)	PEC_{bkgd} (mg/kg)	$PEC_{accu} =$ $PEC_{act} +$ PEC_{bkgd} (mg/kg)
Metamitron	2100/560/560	2.5	6.56	-	-	-
Met Desamino- metamitron max . 17.1% MMfactor: 0.93	334/87/87	2.5	1.16	-	-	-
HBT05	3000/800/800	2.5	9.38	-	-	-
plant protection product:		HBT05				
use:		002/ Sugar and fodder beet				
Number of applications/intervall		3 applications /6 day interval				
application rate:		a.s. 700/1400/1400 g/ha				

		HBT05: 1000/2000/2000 g/ha				
crop interception:		20/20/20%				
active substance/ formulation	soil relevant application rate (g/ha)	soil depth_{act} (cm)	PEC_{act} (mg/kg)	tillage depth (cm)	PEC_{bkgd} (mg/kg)	PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)
Metamitron	560/1120/1120	2.5	6.48	-	-	-
Met Desamino- metamitron max . 17.1% MMfactor: 0.93	89/178/178	2.5	1.09	-	-	-
HBT05	800/1600/1600	2.5	11.21	-	-	-

5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

Results of PEC_{sw} calculation of Metamitron for the intended uses of HBT05 in sugar beet and fodder beet using FOCUS Surface Water are given in the core assessment from 29.02.2012.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

Surface water exposure via spray drift and volatilization with subsequent deposition is estimated with the models EVA 3.0. Surface water exposure via surface run-off and drainage is estimated using the model EXPOSIT 3.01.

The German surface water exposure assessment is outlined in the following chapters.

5.6.1 PEC_{sw} after exposure by spraydrift and volatilization with subsequent deposition

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance Metamitron is < 10⁻⁵ Pa. Hence the active substance Metamitron is regarded as non-volatile. Therefore exposure of surface water by the active substance Metamitron due to volatilization with subsequent deposition does not need to be considered.

The calculation of PEC_{sw} after exposure via spray drift is performed using the model EVA 3.0. For a single application, the exposure assessment via spray drift is based on the application rate in conjunction with the 90th percentile of the drift values. For multiple applications, lower percentiles of the drift values for each application are applied, resulting in an overall 90th percentile of drift probabilities. Only one volatilization event following the last use of pesticide is generally considered.

The endpoints used for modelling of surface water exposure via spray drift and volatilization with subsequent deposition with EVA 3.0 are summarized in Table 5.6-1.

Table 5.6-1: Endpoints of Metamitron used for the PEC_{sw} calculations with EVA 3.0

Parameter	Active substance Metamitron	Reference
vapour pressure at 20 °C (Pa)	3 x 10 ⁻⁷ (not necessary)	See core assessment, section 5
Solubility in water (mg/L)	1680 (not necessary)	See core assessment, section 5

DissT ₅₀ water (d)	11.6 d * (only for multiple application)	Maximum water-sediment study
DT ₅₀ water/sediment study, total system (d)	11.4 d ** (only for multiple application)	Maximum water-sediment study
DT ₅₀ hydrolysis/photolysis (d)	1000 (default)	

*SFO, worst case

**SFO, worst case

The calculated PEC_{sw} values after exposure via spray drift or the active substance Metamitron for the intended use of HBT05 in sugar and fodder beet according to use No. 001 and 002 are presented in the National addendum Germany, part B, section 6, chapter 6.5. considering the following input parameters related to the application.

Table 5.6-2: Input parameters for Metamitron used for PEC_{sw} calculations with EXPOSIT 3.01

Active substance	Metamitron
Use No.:	001
Number of application/ interval	3appl. / 6 d interval
Application rate (g a.s./ha)	2100/700/700
Drift scenario	Arable crops
Use No.:	002
Number of application/ interval	3 appl./ 6 d interval
Application rate (g a.s./ha)	700/1400/1400
Drift scenario	Arable crops

5.6.2 PEC_{sw} after exposure by surface run-off and drainage

The concentration of the active substance Metamitron in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01.

The parameters for Metamitron used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.01 are summarized in Table 5.6-3:

Table 5.6-3: Input parameters for Metamitron used for PEC_{sw} calculations with EXPOSIT 3.01

Parameter	Metamitron	Reference
K _{foc, Runoff}	122	arithm. Mean n=15
K _{foc, mobility class}	37	10.percentile n=15
DT ₅₀ soil (d)	22	Max. Field
Solubility in water (mg/L)	1680	see core assessment, section 5, point 5.3.1.1

Mobility class	3	
Reduction by bank filtration (only relevant for PEC _{gw} see 5.7.2)	90%	

The calculated PEC_{sw} in an adjacent ditch due to surface run-off and drainage for the active substance Metamitron for the intended use of HBT05 in sugar and fodder beet according to use No. 001 and 002 are presented in the National addendum Germany, part B, section 6, chapter 6.5. considering the following input parameters related to the application.

Table 5.6-4: Input parameters related to the application for PEC_{sw} calculations with Exposit 3.01

Active substance	Metamitron Metabolite Desaminometamitron
Use No.:	001
Application rate (g a.s./ha)	2100/700/700 Metabolite: 332/110/110 under consideration of molmass factor: 0.926 and max. formation rate of 17.1%
Number of application/ interval	3 applications / 6days
Crop interception:	0/20/20 %
Use No.:	002
Application rate (g a.s./ha)	700/1400/1400 Metabolite: 111/ 222/222 under consideration of molmass factor: 0.926 and max. formation rate of 17.1%
Number of application/ interval	3 applications / 6days
Crop interception:	20/20/20 %

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Results of PEC_{gw} calculation of Metamitron for the intended uses of HBT05 in sugar beet according to EU assessment using FOCUS PELMO/PEARL are given in the core assessment from 29.02.2012, part B, section 5.

For authorization in Germany, risk assessment for groundwater considers two pathways, (i) direct leaching of the active substance into the groundwater after soil passage and (ii) surface run-off and drainage of the active substance into an adjacent ditch with subsequent bank filtration into the groundwater.

Direct leaching after soil passage is assessed following the recommendations of the publication of Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011) for tier 1 and tier 2 risk assessment. According to Hold et al, 2011, endpoints for groundwater modelling are derived with the program INPUT DECISION 3.1 and subsequent simulations are

performed for the groundwater scenarios “Hamburg” or with the scenarios “Hamburg” and “Kremsmünster” of FOCUS PELMO 4.4.3.

In tier 3 risk assessment, results of experimental studies (lysimeter studies and/or field leaching studies) can also be considered in German groundwater risk assessment.

Surface run-off and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.

The German risk assessment for groundwater is given in the following chapters.

5.7.1 Direct leaching into groundwater

5.7.1.1 *PEC_{GW} modelling*

The worst case scenario used for PEC_{GW} modelling is summarized in Table 5.7-1:. It covers the intended uses of HBT05 in sugar beet according to Table 5.7-1(see also Appendix 3).

Table 5.7-1: Input parameters related to application for PEC_{GW} modelling with FOCUS PELMO 4.4.3

use evaluated	Beet sugar and fodder beet
application rate (kg as/ha)	001: 2100/ 700/ 700 002: 700 / 1400/ 1400
crop (crop rotation)	Sugar beet
date of application	001:9.4. / 15.4. / 21.4. (6-day-interval) 002: 16.4./ 22.4. / 28.4.
interception (%)	001:0%/20%/20% 002: 20%/20%/20% Soil effective application rate: 2100/560/560 and 560/1120/1120
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
plant uptake	0
simulation period (years)	26

Metamitron and metabolite

The endpoints used for groundwater modelling for Metamitron and its metabolite Desamino-metamitron according to INPUT DECISION 3.1 are summarized in Table 5.7-2:.

Table 5.7-2: Input parameters related to Metamitron and Desamino-metamitron for PEC_{GW} modelling

Parent	active substance Metamitron	Remarks/Reference to core assessment, part B, section 5
molecular weight (g/mol)	202.2	
DT₅₀ in soil (d) *	19	LoEP EFSA (2008) Geometric mean of laboratory studies (n=27 , SFO at 20°C and pF2)

		based on ff:0.5 → DT ₅₀ = 38 d for Met and CO ₂ (ff* k _{parent} =0.018241)
DT₅₀ in soil (d)	12	According to Holdt et al. ² : n=9 Based on ff:0.5 → DT ₅₀ = 24 d for Met and CO ₂ (ff* k _{parent} =0.289)
K_{foC}	86.4 adsorption is pH independent	LoEP EFSA (2008) median (n=15)
K_{foC} *	Kf: 1.45 for 1.-3. horizon and 0 for 4.-6.horizon and 0.773 for 1/n	According to Holdt et al. use of horizonspecific values 1/n= arith. mean
1/n	0.78	LoEP EFSA (2008) median (n=15)
metabolite	Desamino-metamitron	
Maximum observed level in soil (%)	17.1	LoEP EFSA (2008)
molecular weight (g/mol)	187.2	
Formation fraction	0.5	DAR Addendum (RMS, 2008)
DT₅₀ in soil (d)	30.4	Geometric mean of laboratory studies (n=9 , 20°C and pF2)
K_{foC}	102.5	LoEP EFSA (2008) Arithmetic mean (n=4)
1/n	0.78	LoEP EFSA (2008) Arithmetic mean (n=4)

The results of the groundwater simulation are presented in Table 5.7-3.

Table 5.7-3: PEC_{GW} at 1 m soil depth of Metamitron and its metabolite Desamino-metamitron considered relevant for German exposure assessment

Use No.	Scenario	80 th percentile PEC _{GW} at 1 m soil depth (µg L ⁻¹) modeled by FOCUS PELMO 4.4.3	
		Metamitron	Metabolite Desamino-metamitron
001	Hamburg	0.000 *	0.000 *
		0.001 **	(0.088) **
002	Hamburg	0.000 *	0.000
		0.001 **	0.056 **

² Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

* calculation according to Holdt et al.with DT₅₀ of 12 d and horizonspecific Kf values for Metamitron: Kf: 1.45 for 1.-3. horizon and 0 for 4.-6.horizon and 1/n:0.773

** calculation according to values LoEP

(Deviations in PEC calculations base upon the use of horizonspecific values for Metamitron according to national analyse in opposite to use of the median of k_{roc} used in EU what seems as more conservative.)

According to the results of the groundwater simulation with FOCUS-PELMO 4.4.3, a groundwater contamination of the active substance Metamitron in concentrations of $\geq 0.1 \mu\text{g/L}$ is not expected for the intended use in sugar beet.

For the metabolite Desamino-metamitron a groundwater concentration of $\geq 0.1 \mu\text{g/L}$ can be excluded for the application in sugar beet according to the results of the groundwater simulation with FOCUS-PELMO 4.4.3.

No additional experimental data from lysimeter studies/ field leaching studies are available to assess the leaching behaviour of the active substance Metamitron.

5.7.1.2 Summary on risk assessment for groundwater after direct leaching

Results of modelling with FOCUSPelmo4.4.3 show that the active substance Metamitron is not expected to penetrate into groundwater at concentrations of $\geq 0.1\mu\text{g/L}$ in the intended uses of formulation HBT05 according to use No. 001 and 002.

For the metabolite Desamino-metamitron concentrations of $\geq 0.1\mu\text{g/L}$ in groundwater can be excluded.

In core assessment concentrations of $\geq 0.1\mu\text{g/L}$ are calculated for the metabolite Desamino-metamitron but the metabolit are classified as not relevant for groundwater according to the guidance document on the relevance of metabolites (EU, 2003) (see core assessment, part B, section 5, IIIA 9.6 and study Pfister, 2011).

Consequences for authorization:

none

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

The input parameters for Metamitron used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.0 are summarized in Table 5.7-4.

Table 5.7-4: Input parameters for Metamitron used for PEC_{GW} calculations with EXPOSIT 3.01

Parameter	Metamitron	Reference
K _{foc, Runoff}	122	arithm. mean (see core assessment, section 5, chapter 5.4.2)
K _{foc, mobility class}	37	10.percentil (see core assessment,

		section 5, chapter 5.4.2)
DT ₅₀ soil (d)	22 d	Field maximum
Solubility in water (mg/L)	1680	
Mobility class	III	
Reduction by bank filtration	90%	

The calculated PEC_{gw} for Metamitron after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-5:.

Table 5.7-5: PEC_{gw} for Metamitron after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		Metamitron			
Use No.	application rate interception	PEC _{gw} due to bank filtration			
		run-off		drainage	
		vegetated buffer strip (m)	bank filtrate (µg/L)	Time of application	bank filtrate (µg/L)
001	2100/700/700 g/ha 0%/20%/20%	0	0.171	autumn/winter/ early spring	0.172 (use in autumn is not intended)
		5	0.148		
		10	0.127	spring/summer	0.056
		20	0.089		
required labelling		Yes: 20 meters buffer strip			
Active substance		Metamitron			
Use No.	application rate interception	PEC _{gw} due to bank filtration			
		run-off		drainage	
		vegetated buffer strip (m)	bank filtrate (µg/L)	Time of application	bank filtrate (µg/L)
002	700 / 1400/ 1400 20%/20%/20%	0	0.169	autumn/winter/ early spring	0.170 (use in autumn is not intended)
		5	0.146		
		10	0.125	spring/summer	0.055
		20	0.088		
required labelling		Yes: 20 meters buffer strip			

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations $\geq 0.1 \mu\text{g/L}$ by the active substance Metamitron due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded in case risk mitigation measures (vegetated buffer strip of 20 m) are applied.

Metabolites

The soil metabolites of Metamitron (see core assessment, part B, section 5, point 5.3.1.3) are formed > 10 % in soil. Therefore potential ground water contamination due to bank filtration via surface water exposure by run-off and drainage needs to be assessed using EXPOSIT 3.01.

The input parameter for the model EXPOSIT 3.01 are taken from the EU and core assessment respectively and summarized in Table 5.7-6 the results are given in Table 5.7-7.

Table 5.7-6: Input parameter for soil metabolites of Metamitron for EXPOSIT 3.01

Parameter	Metabolite Desamino-Metamitron
Molecular weight (g/mol)	187.2
Correction factor molecular weight	0.926 *
Maximum occurrence in soil (%)	17.1 % *
K _{foc, Runoff}	102
K _{foc, mobility class}	102
DT ₅₀ soil (d) ¹⁾	30.5 d
Solubility in water (mg/L)	399.9 mg/L(25°C)
Mobility class	2

¹⁾ only relevant for mobility class

Table 5.7-7: PEC_{gw} for soil metabolite of Metamitron after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Metabolit		Desamino-metamitron			
Use No.	application rate interception	PEC _{gw} due to			
		run-off		drainage	
		vegetated buffer strip (m)	bank filtrate (µg/L)	Time of application	bank filtrate (µg/L)
001	332/110/110 g/ha (calculated with *) 0%/20%/20%	0	0.074	autumn/winter/ early spring	0.075
		5	0.064		
		10	0.055	spring/summer	0.024
		20	0.039		
required labelling		none			
Metabolit		Desamino-metamitron			
Use No.	application rate interception	PEC _{gw} due to			
		run-off		drainage	
		vegetated buffer strip (m)	bank filtrate (µg/L)	Time of application	bank filtrate (µg/L)
002	110/221/221 g/ha	0	0.071	autumn/winter/ early spring	0.075
		5	0.061		

	(calculated with *) 20%/20%/20%	10	0.053	spring/summer	0.024
		20	0.037		
required labelling	none				

According to modelling with EXPOSIT 3, groundwater contamination at concentrations $\geq 0.1 \mu\text{g/L}$ by the soil metabolites Desamino-Metamitron due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization:

The authorization of the plant protection product HBT05 is linked with following labeling:

Use No. 001 and 002 NG404

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*
OECD: KIAA1 9.6.2	Pfister, K.	2011	assessment of relevance of groundwater metabolite desamino-metamitron Report-No. : none Authority registration No: 2365618	yes	United Phosphorus	3)

*

- 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

Report only studies, which have not previously been evaluated within a peer reviewed process at EU level (Annex I inclusion of active substance).

none

Appendix 3 Table of Intended Uses in Germany (according to BVL 09.07.2014)

PPP (product name/code) **HBT05** Formulation type: **WG**
 active substance 1 **Metamitron** Conc. of as 1: **700g/kg**
 active substance 2 **-** Conc. of as 2: **-**

For Germany modified to EU Central zone / national GAPs

Crop and/or situation (a)	Country	Product name	F G Or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	Method kind (f-h)	Growth stage & season (j)	Number min - max (k)	Interval between applications (min)	g a.s./hL min - max	Water L/ha min - max	g a.s./ha min - max		
Maximum total dose NOT to exceed 5 kg product/ha, i.e. 3500 g Metamitron/ha															
Sugar beet and fodder beet	Germany	HBT05 metamitron 700 g/kg	F	Annual dicotyledonous weeds (except GALAP, POLSS), POAAN	WG	70	Tractor mounted sprayer	1 pre-emergence or 1 after weed appearance application in spring Up to 2 post-emergence applications in spring (crop BBCH 10-18)	1 Up to 3	- 6-14 days		100 - 200 100 - 200	2100 (3 kg) 700 (1 kg)	Not applicable	Pre- and post emergence applications to be used in combination to control weeds, overall maximum dose must not exceed 5000 g as/ha/year

Sugar beet and fodder beet	Germany	HBT05 metamitron 700 g/kg	F	Annual dicotyledon ous weeds (except GALAP, POLSS), POAAN	WG	70	Tractor mounted sprayer	Up to 3 post- emergence applications in spring (crop BBCH 10-18)	1 Up to 3	- 6-14 days	100 - 200 100 - 200	700 (1 kg) 1400 (2 kg)	Not applic able	Pre- and post emergence applications to be used in combination to control weeds, overall maximum dose must not exceed 5000 g as/ha/year
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**DRAFT REGISTRATION REPORT
Part B**

**Section 6: Ecotoxicological studies
Detailed summary of the risk assessment**

Product code: Beetix WG (HBT05)
Active Substance: Metamitron 700g/kg

**Central Zone
Zonal Rapporteur Member State: United Kingdom**

**NATIONAL ADDENDUM
GERMANY**

Applicant: United Phosphorus Ltd., UK
Date: September 2014

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Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

A full risk assessment according to Uniform Principles for the plant protection product Beetix WG in its intended uses in sugar and fodder beet is documented in detail in the core assessment of the plant protection product Beetix WG dated from April 2014 performed by zRMS UK.

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

General information on the formulation Beetix WG can be found in Table 5.1-1 of Section 5 of the National addendum Germany (September 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 Beetix WG that will be assessed are summarized in the table below. The intended uses in Germany are partially covered by the core assessment performed by zRMS UK.

Table 6.1-1: Critical use pattern of Beetix WG

Group/use No.	Crop/growth stage/interception	Application method/drift scenario	Application rate, cumulative (g a.s./ha)
00-001	Sugar and fodder beet/ BBCH 00 – 18 / 0% pre-emergence, 20% post-emergence	Spraying Arable crops	max. 3 applications max. 3.5 kg/ha/year 1.) 2100 2.) 700 3.) 700 Soil effective application rate (g a.s./ha): 1.) 2100 2.) 560 3.) 560
00-002	Sugar and fodder beet/ BBCH 10 – 18 / 20%	Spraying Arable crops	max. 3 applications max. 3.5 kg/ha/year 1.) 700 2.) 1400 3.) 1400 Soil effective application rate (g a.s./ha): 1.) g 2.) 1120 3.) 1120

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)

The risk assessment for birds of the zRMS UK cannot be reproduced or assessed. In the dRR of UK reference has been made to a risk assessment of another plant protection product. In the respective dRR another reference to a further plant protection product is made. The relevant assessment was not provided and could not be found. Therefore DE has to perform its own risk assessment for birds.

Table 6.2-1: Endpoints used for risk assessment for birds

Species	Substance	Exposure System	Results	Reference	Internal code
<i>Coturnix japonica</i>	Technical metamitron	Acute toxicity	LD ₅₀ = 1358 mg/kg bw (male) LD ₅₀ = 1302 mg/kg bw (female) LD ₅₀ = 1325 mg/kg bw (combined)	Ebert, G. 1992 90 10 42 250	29712
<i>Colinus virginianus</i>	Technical metamitron	Reproductive toxicity	NOAEL = 81.5 mg/kg bw/d	Grau, R. 1992 VB-015	38429

6.2.1 Risk assessment (MIIIA 10.1.1, MIIIA 10.1.2) for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

Exposure to standard generic focal species was estimated according to the Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438)

$$\begin{aligned}
 \text{DDD} &= \sum_i \frac{\text{PD}_i \times \text{FIR}_{total}}{\text{bw}} \times \text{RUD} \times \text{AR} \times \text{PT} \\
 &= \sum_i \frac{\text{FIR}_i}{\text{bw}} \times \text{RUD} \times \text{AR} \times \text{PT}
 \end{aligned}$$

where:

- DDD = Daily dietary dose (mg/kg bw/day)
- PD_i = composition of diet obtained from treated area
- FIR_i = Food intake rate of indicator species i (g fresh weight/d)
- bw = Body weight (g)
- RUD = Residue per unit dose, bases on an application rate of 1 kg a.s./ha and assuming broadcast seedling
- AR = Application rate (kg/ha)
- PT = Proportion of diet obtained in the treated area (0...1)

In a first approach, it is assumed that birds do not avoid contaminated food items, that they feed exclusively in the treated area and on a single food type. Factors PT and PD are therefore equal to 1.

The risk assessment procedure follows a stepwise approach. A first screening step involves standard scenarios and default values for the exposure estimate, representing a “reasonable worst case”. If a risk is indicated in the screening step, then one or several refinement steps (Tier 1, Tier2) may follow. According to the Guidance Document, no further assessment is required if all uses are safe in the screening step.

6.2.1.1 *Screening assessment*

In the screening step, the risk to indicator bird species from an exposure to Beetix WG is assessed. These indicators are considered to have highest exposure in a specific crop at a particular time due to their size and feeding habits and represent a worst case scenario.

To estimate the daily dietary doses, following equations were used:

Daily dietary dose (DDD):

$$DDD_{\text{single application}} = \text{application rate [kg a.s./ha]} \times \text{shortcut value}^1$$

¹ see section 4.1 of EFSA/2009/1438

In case of multiple applications, the daily dietary dose for a single application is multiplied with an appropriate multiple application factor for 90th percentile residue data (MAF₉₀; see Table 7 of EFSA/2009/1438). A specific MAF₉₀ may be calculated according to Appendix H of EFSA/2009/1438 for non-standard application intervals.

$$DDD_{\text{multiple application}} = DDD_{\text{single application}} \times \text{MAF}_{90}^1$$

Toxicity exposure ratio (acute):

$$\text{TER}_A = \frac{\text{LD}_{50} \text{ (mg/kg bw/day)}}{\text{Acute DDD (mg/kg bw/day)}}$$

The results of the acute and reproductive screening risk assessments are summarized in the following tables.

Table 6.1.2.1-1: Acute screening assessment for birds

Intended use [g/ha]	Indicator species	Endpoint [mg/kg bw]	SV	MAF ₉₀	DDD	TER
Metamitron						
Intended use 00-001	Small granivorous bird	1325	24.7	1.6	82.99	16
	Small omnivorous bird	1325	158.8	1.6	533,57	2,5
Intended use 00-002	Small omnivorous bird	1325	158.8	1.6	177.86	7.4

SV: shortcut value; MAF₉₀: multiple application factor (90th percentile); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 6.2-2: Reproductive screening assessment for birds

Intended use [g/ha]	Indicator species	Endpoint [mg/kg bw/d]	SV	MAF _m	DDD	TER
Metamitron						
Intended use 00-001	Small omnivorous bird	81.5	64.8	2	272	0,3
Intended use 00-002	Small omnivorous bird	81.5	64.8	2	90.72	0,9

SV: shortcut value; MAF₉₀: multiple application factor (90th percentile); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

6.2.1.2 Tier 1 risk assessment

In the Tier 1 risk assessment step, the defined daily dietary doses and TER values were calculated for so-called generic focal species (see EFSA 1438/2009, Annex I). As for the indicator species, the generic focal species are considered to be representative for all species potentially at risk. In the Tier 1 assessment, a mixed diet approach is followed when appropriate and interception of the spray by the crop is taken into account for the calculation of residue levels for different food types.

If more than one generic focal species is relevant for the crop, the one that is relevant in terms of time of application or growth stage should be selected. If more than one generic focal species is relevant in terms of application time and growth stage, then the risk should be assessed for all relevant generic focal species. If the same generic focal species is relevant for several application times according to the BBCH growth stages, the risk assessment for this generic focal species is conducted once using the highest mean short-cut value, since this mirrors a realistic worst case scenario.

For metamidon, the TER values were below the trigger of 10 resp. 5 in the screening step for the intended uses in sugar and fodder beet. Therefore, a Tier 1 risk assessment step will be performed for these uses.

The results of the acute and reproductive Tier 1 risk assessments are summarized in the following tables.

Table 6.2-3: Acute tier 1 risk assessment for birds for metamidon

Intended use	Generic focal species	Endpoint [mg/kg bw/d]	SV	MAF ₉₀	DDD _A [mg/kg bw/d]	TER
Intended use 00-001						
BBCH < 10	Small granivorous bird	1325	24.7	1.13	58.55	22.6
BBCH < 10	Small omnivorous bird	1325	17.4	1.13	41.24	32.1
BBCH < 10	Small insectivorous bird	1325	10.9	1.13	25.84	51.3
BBCH 10 – 19	Small omnivorous bird	1325	24	1.13	56.89	23.3
BBCH 10 – 19	Small insectivorous bird	1325	10.9	1.13	25.84	51.3
Intended use 00-002						
BBCH 10 – 19	Small omnivorous bird	1325	24	2.59	43.55	30.4
BBCH 10 – 19	Small insectivorous bird	1325	10.9	2.59	19.78	67

SV: shortcut value; MAF₉₀: multiple application factor (90th percentile); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 6.2-4: Reproductive Tier-1 risk assessment for birds for metamidon

Intended use	Generic focal species	Endpoint [mg/kg bw/d]	SV	MAF x twa	DDD _A [mg/kg bw/d]	TER
Intended use 00-001						
BBCH < 10	Small granivorous bird	81.5	11.4	0.78	18.7	4.4
BBCH < 10	Small omnivorous bird	81.5	8.2	0.78	13.45	6.1
BBCH < 10	Small insectivorous bird	81.5	5.9	0.78	9.68	8.4
BBCH 10 – 19	Small omnivorous bird	81.5	10.9	0.78	17.88	4.6
BBCH 10 – 19	Small insectivorous bird	81.5	5.9	0.78	9.68	8.4
Intended use 00-002						
BBCH 10 – 19	Small omnivorous bird	81.5	10.9	2.29	17.47	4.7
BBCH 10 – 19	Small insectivorous bird	81.5	5.9	2.29	9.46	8.6

SV: shortcut value; MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

6.2.1.3 Higher tier risk assessment for metamitron in sugar and fodder beet

Table 6.2-5: Refinement of reproductive risk assessment for birds exposed to metamitron according to EFSA Journal (2009) in sugar and fodder beet.

Intended use	Species/BBCH stage	Diet composition	MAF x twa	FIR/bw	PD	RUD	PT	DDD [mg/kg bw/d]	Endpoint [mg/kg bw/d]	TER
intended use 00-001										
metamitron	<i>Carduelis cannabina</i> < 10	100% Weed seeds	0.78	0.28		40.2	0.5	9.38	81.5	8.7
		25% crop leaves	0.78	0.13		28.7	0.5	2.44	81.5	11.4
	25% weed seeds	0.78	0.13		40.2	0.5	3.42			
	50% ground arthropods	0.78	0.26		7.5	0.5	1.28			
intended use 00-002										
metamitron	<i>Lullula arborea</i> / 10 – 19	25% crop leaves	2.29	0.13		28.7		4.78	81.5	5.8
		25% weed seeds	2.29	0.13		40.2		6.69		
		50% ground arthropods	2.29	0.26		7.5		2.5		

FIR: Food intake rate; MAF: multiple application factor; RUD: Residue unit dose; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

6.2.1.4 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 when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg).

6.2.1.5 Effects of secondary poisoning (MIIIA 10.1.9)

Not relevant (log KOW = 0.85, trigger for calculation ≥ 3).

Consequences for authorization:

None

6.3 Effects on Terrestrial Vertebrates Other Than Birds (MIIIA 10.3, KPC 10.1, KPC 10.1.2)

The risk assessment for terrestrial vertebrates other than birds of the zRMS UK cannot be reproduced or assessed. In the dRR of UK reference has been made to a risk assessment of another plant protection product. In the respective dRR another reference to a further plant protection product is made. The relevant assessment was not provided and could not be found. Therefore DE has to perform its own risk assessment for terrestrial vertebrates other than birds.

Table 6.3-1: EU agreed endpoints and new endpoints

Species	Substance	Exposure System	Results	Reference	Internal code
Mouse	Technical metamitron	Acute toxicity	LD ₅₀ = 644 mg/kg bw (females) LD ₅₀ = 691 mg/kg bw (males)	Dreist, M. 1996 25596; T 8060723	77874
Rat	Desaminometamitron	Acute toxicity	LD ₅₀ = 4325 mg/kg bw	Thyssen, J. 1976 MO-00-007413	76451
Rat	Technical metamitron	Reproductive toxicity	NOAEL = 36.4 mg/kg bw/d (in males)	Suresh, T.P. 1993 TOXI: ES-991-RP-G2	76422

6.3.1 Risk assessment (MIIIA 10.3.1) for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

6.3.1.1 Screening assessment

The results of the acute and reproductive screening risk assessments are summarized in the following tables.

Table 6.3-2: Acute screening assessment for mammals

Intended use	Indicator species	Endpoint [mg/kg bw/d]	SV	MAF ₉₀	DDD [mg/kg bw/d]	TER
Metamitron						
Intended use 00-001	Small granivorous mammal	644	14.4	1.6	34.13	13.3
	Small herbivorous mammal	644	118.4	1.6	280.65	1.6
Intended use 00-002	Small herbivorous mammal	644	118.4	1.6	132.61	4.9

SV: shortcut value; MAF₉₀: multiple application factor (90th percentile); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Considering the worst-case-assumptions of the screening step the TER of 4.9 for the intended use 00-002 is acceptable.

Table 6.3-3: Reproductive screening assessment for mammals

Intended use [g/ha]	Indicator species	Endpoint [mg/kg bw/d]	SV	MAF _m	DDD [mg/kg bw/d]	TER
Metamitron						
Intended use 00-001	Small granivorous mammal	36.4	6.6	2	27.72	1.3
	Small herbivorous mammal	36.4	48.3	2	202.86	0.2
Intended use 00-002	Small herbivorous mammal	36.4	48.3	2	67.62	0.5

SV: shortcut value; MAF_m: multiple application factor (mean); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

6.3.1.2 Tier-1 risk assessment

The results of the acute and reproductive Tier 1 risk assessments are summarized in the following tables.

Table 6.3-4: Acute dietary tier 1 risk assessment for terrestrial vertebrates other than birds for metamitron

Intended use	Generic focal species	Endpoint [mg/kg bw/d]	SV	MAF ₉₀	DDD _A [mg/kg bw/d]	TER
Intended use 00-001						
BBCH 10 - 19	Small insectivorous mammal	644	7.6	1.13	18.01	35.7
BBCH 10 - 39	Large herbivorous mammal	644	35.1	1.13	83.2	7.7
BBCH 10 - 39	Small omnivorous mammal	644	17.2	1.13	40.77	15.8

SV: shortcut value; MAF₉₀: multiple application factor (90th percentile); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 6.3-5: Reproductive Tier-1 risk assessment for terrestrial vertebrates other than birds for metamitron

Intended use [g/ha]	Generic focal species	Endpoint [mg/kg bw/d]	SV	MAF x twa	DDD	TER
Intended use 00-001						
BBCH < 10	Small omnivorous mammal	36.4	5.7	0.78	9.35	3.9*
BBCH 10 - 19	Small insectivorous mammal	36.4	4.2	0.78	6.89	5.3
BBCH 10 - 39	Large herbivorous mammal	36.4	14.3	0.78	23.46	1.6
BBCH 10 - 39	Small omnivorous mammal	36.4	7.8	0.78	12.79	2.8*
Intended use 00-002						
BBCH 10 - 19	Small insectivorous mammal	36.4	4.2	2.29	6.73	5.4
BBCH 10 - 39	Large herbivorous mammal	36.4	14.3	2.29	22.92	1.6
BBCH 10 - 39	Small omnivorous mammal	36.4	7.8	2.29	12.5	2.9*

SV: shortcut value; MAF: multiple application factor. DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

*: In cases where the relevant model species for assessment of the risk from the intended uses of metamitron is a mouse or a vole, the TER acceptability criterion may be modified. In terms of size and potential exposure, mice and voles already represent the ‘worst case’ for agricultural areas in Europe’s central zone. Furthermore, the toxicological endpoints and effect values for the assessment are determined on phylogenetically closely related species. Hence, a TER \geq 5 in the acute exposure scenario and a TER \geq 2 in the long-term exposure scenario may be accepted as sufficient. It should additionally be noted that there are currently no indications for a significant impact of pesticides on the population dynamics of mice or voles in the agricultural landscape, which are apparently determined by other biological factors (e.g. periodical increases in vole populations creating the necessity for control measures).

6.3.1.3 Higher tier risk assessment for metamitron in sugar and fodder beet (KPC 10.1.2.2)

Table 6.3-6: Refinement of acute risk assessment for mammals exposed to metamitron according to EFSA Journal (2009) in sugar and fodder beet.

Intended use	Species/ BBCH stage	Diet composition	MAF	FIR/ bw	PD	RUD	PT	DDD _a	Endpoint	TER
								[mg/kg bw/d]	[mg/kg bw/d]	
intended use 00-001										
metamitron	<i>Oryctolagus cuniculus/ 10 - 39</i>	100% non-grass weeds	1*	0.5	771	70.3	---	59.17	644	10.9

FIR: Food intake rate; MAF: multiple application factor; RUD: Residue unit dose; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

* Assuming an DT50 of 1.9 days (see EFSA Scientific Report (2008) 185, 1 - 95)

Intended use	Species/ BBCH stage	Diet composition	MAF x t _{wa}	FIR/ bw	PD	RUD	PT	DDD	Endpoint	TER
								[mg/kg bw/d]	[mg/kg bw/d]	
intended use 00-001										
metamitron	<i>Oryctolagus cuniculus/ 10 - 39</i>	100% non-grass weeds	0.22*	0.5	771	28.7	---	5.19	36.4	7
intended use 00-002										
metamitron	<i>Oryctolagus cuniculus/ 10 - 39</i>	100% non-grass weeds	0.64*	0.5	771	28.7	---	5.15	36.4	7.1

FIR: Food intake rate; MAF: multiple application factor; RUD: Residue unit dose; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

* Assuming an DT50 of 1.9 days (see EFSA Scientific Report (2008) 185, 1 - 95)

6.3.1.4 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 when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case

of less sorptive substances ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg).

6.3.1.5 *Effects of secondary poisoning (MIIIA 10.3.2.3)*

Not relevant ($\log K_{OW} = 0.85$, trigger for calculation ≥ 3).

Consequences for authorization:

None

6.4 **Effects on aquatic organisms (MIIIA 10.2, KPC 10.2, KPC 10.2.1)**

6.4.1 **Overview**

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route. Hence, aquatic risk assessment differs from those in the core assessment.

The risk assessment for aquatic organism for authorization of Beetix WG is outlined in the following chapters.

6.4.2 **Toxicity**

Please refer to the core assessment.

6.4.3 **Toxicity to exposure ratios for aquatic species (MIIIA 10.2.1)**

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance Document on Aquatic Ecotoxicology”, as provided by the Commission Services (SANCO/3268/2001 rev.4 (final), 17 October 2002).

6.4.3.1 *TER values for the entry into surface water via spraydrift and deposition following volatilization*

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. Metamitron has a vapour pressure of $< 10^{-5}$ Pa and is therefore classified as non-volatile. Hence, deposition following volatilization has not been considered. The input parameters for metamitron are given in Section 5.6.1.

Several ecotoxicological endpoints are available to assess the risk of the active substance metamitron and the formulation Beetix WG (see chapter 6.4.2). The choice of the relevant scenario is based on the ratio of

endpoint to the highest PEC for each active substance and the formulation, related to the relevant trigger TER value.

Table 6.4-1: Decision making of the relevant scenario for risk assessment of aquatic organisms based on the lowest ratio of TER to safety factor

Substance	Max. application rate [g/ha]	Drift factor %	Max. PEC (act) [µg/L]	Endpoint, Species, safety factor [µg/L]	TER	TER/SF
metamitron	1 x 2100, 2 x 700 resp. 1 x 700, 2 x 1400 = 3500	2.01 (77 th percentile)	0.014	380 (<i>Lemna minor</i>); 10	27143	2714.29
Beetix WG	1 x 3000, 2 x 1000 resp. 1 x 1000, 2 x 2000 = 5000	2.01 (77 th percentile)	0.02	620 (<i>Pseudokirchneriella subcapitata</i>); 10	31000	3100

PEC: predicted environmental concentration; TER: Toxicity exposure ratio; SF: Safety factor

Based on the table above, *Lemna minor* provides for metamitron the lowest TER/SF ratio and is therefore the relevant scenario for risk assessment.

Table 6.4-2: Risk assessment for metamitron for aquatic organisms for the entry route via spraydrift and deposition following volatilization under the implementation of different risk mitigation measures

Compound:		Metamitron						
Crop/Application rate:		Sugar and fodder beet/						
Growth stage and season		BBCH 00 - 18						
Intended use group:		00-001						
DT ₅₀ water (SFO):		11.4						
PEC-selection:		actual						
Drift-Percentile:		77 th						
Buffer zone [m]	Entry via spraydrift		Entry via deposition following volatilization		PEC _{sw} ; conventional and drift reducing technique			
	[%]	[g/ha]	[%]	[µg/L]	0% conv.	50% red.	75% red.	90% red.
[µg/L]								
1	2.01	0.014	---	---	0.014	0,007	0,004	0,001
5	0.41	0.003	---	---	0.003	0,001	0,001	0,000
10	0.20	0.001	---	---	0.001	0,001	0,000	0,000
15	0.14	0.001	---	---	0.001	0,000	0,000	0,000
20	0.10	0.001	---	---	0.001	0,000	0,000	0,000
Relevant toxicity endpoint: E _b C ₅₀ = 380 µg a.i./L (<i>Pseudokirchneriella subcapitata</i>)								
Relevant TER: 10								
Buffer zone [m]					TER			
1					27.0	54.0	108.0	270.1
5					132.4	264.8	529.6	1324.0
10					271.4	542.9	1085.7	2714.3

15	387.8	775.5	1551.0	3877.6
20	542.9	1085.7	2171.4	5428.6
Risk mitigation measures		None		

Compound:		Metamitron						
Crop/Application rate:		Sugar and fodder beet/						
Growth stage and season		BBCH 10 - 18						
Intended use group:		00-002						
DT₅₀ water (SFO):		11.4						
PEC-selection:		actual						
Drift-Percentile:		77 th						
Buffer zone [m]	Entry via spraydrift		Entry via deposition following volatilization		PECsw; conventional and drift reducing technique			
	[%]	[g/ha]	[%]	[µg/L]	0% conv.	50% red.	75% red.	90% red.
					[µg/L]			
1	2.01	0.018	---	---	0.018	0,009	0,004	0,002
5	0.41	0.004	---	---	0.004	0,002	0,001	0,000
10	0.20	0.002	---	---	0.002	0,001	0,000	0,000
15	0.14	0.001	---	---	0.001	0,001	0,000	0,000
20	0.10	0.001	---	---	0.001	0,000	0,000	0,000
Relevant toxicity endpoint: E _b C ₅₀ = 380 µg a.i./L (<i>Pseudokirchneriella subcapitata</i>)								
Relevant TER: 10								
Buffer zone [m]					TER			
1					21.6	43.2	86.3	215.8
5					105.8	211.6	423.2	1057.9
10					216.9	433.7	867.5	2168.7
15					309.8	619.6	1239.2	3098.1
20					433.7	867.5	1734.9	4337.3
Risk mitigation measures		None						

PEC: predicted environmental concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.4.3.2 TER values for the entry into surface water via run-off and drainage

The concentration of the active substance metamitron in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01. The input parameters for metamitron for exposure modelling with EXPOSIT 3.01 are given in the German National Addendum Section 5, chapter 5.6.2.

Table 6.4-3: Risk assessment for metamitron for aquatic organisms for the entry route via run-off and drainage under the implementation of different risk mitigation measures

Compound:	metamitron
Application rate:	1 x 2100, 2 x 700 g/ha
Intended use	00-001

Relevant toxicity endpoint:	E _b C ₅₀ = 380 µg a.s./L (<i>Lemna minor</i>)	
Relevant TER:	10	
Run-off		
Buffer zone	PEC	TER
[m]	[µg/L]	
0	21.37	17.78
5	18.52	20.52
10	15.87	23.94
20	11.11	34.20
Drainage		
Time of application	PEC	TER
	[µg/L]	
Autumn/winter/early spring	21.54	17.64
Spring/summer	7.00	54.28
Risk mitigation measures	None	

Compound:	metamitron	
Application rate:	1 x 700, 2 x 1400 g/ha	
Intended use	00-002	
Relevant toxicity endpoint:	E _b C ₅₀ = 380 µg a.s./L (<i>Lemna minor</i>)	
Relevant TER:	10	
Run-off		
Buffer zone	PEC	TER
[m]	[µg/L]	
0	21.09	18.01
5	18.28	20.79
10	15.67	24.25
20	10.97	34.64
Drainage		
Time of application	PEC	TER
	[µg/L]	
Autumn/winter/early spring	21.26	17.87
Spring/summer	6.91	54.98
Risk mitigation measures	None	

PEC: predicted environmental concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.4.3.3 *Consideration of Metabolites*

Please refer to the core assessment.

6.4.4 Overall conclusions

Based on the calculated concentrations of met amitron in surface water (EVA 3.0, EXPOSIT 3.0.1), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to met amitron according to the GAP of the formulation Beetix WG achieve the acceptability criteria $TER \geq 100$ and $TER \geq 10$, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of Beetix WG in sugar and fodder beet according to the label.

Consequences for authorization:

For the authorization of the plant protection product Beetix WG following labeling and conditions of use are mandatory:

Required Labelling

NW262	met amitron: <i>Pseudokirchneriella subcapitata</i> NOEC < 0.12 mg/L Beetix WG: <i>Pseudokirchneriella subcapitata</i> NOEC = 0.03
NW263	met amitron: <i>Daphnia magna</i> EC ₅₀ = 5.7 mg/L
NW265	met amitron: <i>Lemna minor</i> NOEC = 0.04 mg/L

Conditions for use

Beetix WG	NW 468
-----------	--------

6.5 Effects on bees (MIIIA 10.4, KPC 10.3.1)

Please refer to the core assessment and the risk assessment outcome as provided by JKI.

6.6 Effects on arthropods other than bees (MIIIA 10.5, KPC 10.3.2)

The applicant has submitted data on the effect of Beetix WG on non-target arthropods. According to the herbicidal effect of the formulation these effect values are substantially higher than those effects determined for non-target terrestrial plants, which are therefore relevant for the risk assessment for terrestrial biocoenosis. A quantitative risk assessment for non-target arthropods is for that reason not conducted in this national addendum.

Consequences for authorization:

None

6.7 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.

6.7.1 Justification for new endpoints

Please refer to the core assessment.

6.7.2 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. The resulting maximum PEC_{soil} values for the active substances metamitron and the major soil degradation products are presented in the table below.

For German exposure assessment the applied soil depth is based on experimental data (Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittelwirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999). Generally for active substances with a $K_{f,oc} < 500$ a soil depth of 2.5 cm is applied whereas for active substances with a $K_{f,oc} > 500$ a soil depth of 1 cm is applied. As soil bulk density 1.5 g cm⁻³ is assumed.

The acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to Beetix WG/metamitron as well as the major soil degradation products of metamitron was assessed by comparing the maximum PEC_{SOIL} with the 14-day LC₅₀ value to generate acute TER values. The TER_A was calculated as follows:

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

The chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breakdown resulting from an exposure to Beetix WG/metamitron as well as the major soil degradation products of metamitron was assessed by comparing the maximum PEC_{SOIL} with the NOEC value to generate chronic TER values. The TER_{LT} was calculated as follows:

$$TER_{LT} = \frac{NOEC \text{ (mg/kg)}}{PEC_{soil} \text{ (mg/kg)}}$$

The results of the risk assessment are summarized in the following table.

Table 6.7-1: TER values for earthworms and other soil macro- and mesofauna (Tier-1) for the use in sugar and fodder beet

Use no 00-001

Species	Test item	Time scale	Endpoint [mg/kg soil dw]	Max. PECSOIL [mg/kg soil dw]	TER
<i>Eisenia fetida</i>	Metamitron	Acute	914	6.56	139.33
	Desamino-metamitron	Acute	> 1000	1.16	862.07
	Desamino-metamitron	Chronic	5.5	1.16	4.74
	Beetix WG*	Chronic	160	9.38	17.06
<i>Folsomia candida</i>	Desamino-metamitron	Chronic	100	1.16	86.21

TER values shown in bold fall below the relevant trigger.

Use no 00-002

Species	Test item	Time scale	Endpoint [mg/kg soil dw]	Max. PECSOIL [mg/kg soil dw]	TER
<i>Eisenia fetida</i>	Metamitron	Acute	914	6.48	141.05
	Desamino-metamitron	Acute	> 1000	1.09	917.43
	Desamino-metamitron	Chronic	5.5	1.09	5.05
	Beetix WG*	Chronic	160	11.21	14.27
<i>Folsomia candida</i>	Desamino-metamitron	Chronic	100	1.09	91.74

TER values shown in bold fall below the relevant trigger.

*: The notifier submitted a chronic study on earthworms with the formulation Beetix WG (Lührs, 2012). The validity criteria of the study are met according to the OECD 222. However, it is important to note that food (cattle manure) has been additionally mixed to the soil one day before the start of the test (i.e. 5g cattle manure to 500 g soil; refer to the original study page 16). This addition of food is not conform to the OECD guideline 222, where manure is spread on the soil surface first one day after adding the worms and the active substance, and then weekly. Whether the study is reliable without restrictions cannot be assessed, but the endpoint is not absolutely necessary for the risk assessment because of the presented data for the active substance.

6.7.3 Higher tier risk assessment

Not relevant.

6.7.4 Overall conclusions

Based on the predicted concentrations of metamidon/Beetix WG in soils, the TER values describing the acute and long-term risk for earthworms and other non-target soil organisms following exposure to metamidon/Beetix WG according to the GAP of the formulation Beetix WG achieve the acceptability criteria $TER \geq 10$ resp. $TER \geq 5$ according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of Beetix WG in sugar and fodder beet according to the label.

Consequences for authorization:

None

6.8 Effects on soil microbial activity (MIIIA 10.7, KPC 10.5)

Please refer to the core assessment performed by UK.

Consequences for authorization:

None

6.9 Effects on non-target plants (MIIIA 10.8, KPC 10.6)

6.9.1 Effects on non-target terrestrial plants (MIIIA 10.8.1)

6.9.2 Toxicity

Please refer to the core assessment.

6.9.3 Justification for new endpoints

Please refer to the core assessment.

6.9.4 Risk assessment

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SAN-CO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. Spray drift from the treated areas may lead to residues of a product in off-crop areas.

Exposure

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile

estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000). Any dilution over the 3-dimensional vegetation surface is accounted for in the study design. Therefore, in contrast to the assessment of risks to arthropods from standard laboratory tests, no vegetation distribution factor is considered here.

$$PER_{\text{off-field}} = \text{Maximum } PER_{\text{in-field}} (\text{including MAF}) \times \% \text{drift}$$

Tier 1 assessment

The assessment of the risk to non-target plants due to an exposure to Beetix WG is performed on basis of the calculation of toxicity-exposure ratios (TER values) according the following formula:

$$TER = \frac{ER50 (L \text{ product} / ha)}{\text{Off - field } PER (L \text{ product} / ha)}$$

The results of the risk assessment are summarized in the following table.

Table 6.9-1: Risk assessment for metamitron for non-target plants for the entry route via spray-drift and deposition following volatilization under the implementation of different risk mitigation measures

Compound:			Metamitron						
Intended use group:			00-001						
Drift-Percentile:			77 th						
Buffer zone [m]	Entry via spraydrift		Entry via deposition following volatilization		PER _{off-field} ; conventional and drift reducing technique				
	[%]	[g/ha]	[%]	[g/ha]	0% conv.	90% red.	75% red.	50% red.	
					[g/ha]				
1	2.01	23,791	---	---	23,791	2.379	5.948	11.895	
5	0.41	4,853	---	---	4,853	0.485	1.213	2.426	
Relevant toxicity endpoint: ER ₅₀ = 54.9 g a.s./ha (<i>Lactuca sativa</i>)									
Relevant TER: 10									
Buffer zone [m]					TER				
1					2.3	23.1	9.2	4.6	
5					11.3	113.1	45.3	22.6	
Risk mitigation measures			NW103 (conv. 5 m, 50% drift red. 5 m, 75% drift red. 5 m, 90% drift red. *)						

Compound:			Metamitron						
Intended use group:			00-002						
Drift-Percentile:			77 th						
Buffer zone [m]	Entry via spraydrift		Entry via deposition following volatilization		PER _{off-field} ; conventional and drift reducing technique				
	[%]	[g/ha]	[%]	[g/ha]	0% conv.	90% red.	75% red.	50% red.	
					[g/ha]				
1	2.01	28.329	---	---	28.329	2.833	7.082	14.165	
5	0.41	5.779	---	---	5.779	0.578	1.445	2.889	
Relevant toxicity endpoint: ER ₅₀ = 54.9 g a.s./ha (<i>Lactuca sativa</i>)									
Relevant TER: 10									

Buffer zone [m]		TER			
1		1.9	19.4	7.8	3.9
5		9.5	95	38	19.0
Risk mitigation measures	NW103 (conv. insufficient, 50% drift red. 5 m, 75% drift red. 5 m, 90% drift red. *)				

PER: predicted environmental rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.9.5 Conclusion

Based on the predicted rates of metamitron in off-field areas, the TER values describing the risk for non-target plants following exposure to metamitron according to the GAP of the formulation Beetix WG achieve the acceptability criterion $TER \geq 10$ according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of Beetix WG in sugar and fodder beet according to the label.

Consequences for authorization:

Conditions for use

use No. 00-001	NT103 (conv. 5 m, 50% drift red. 5 m, 75% drift red. 5 m, 90% drift red. *)
use No. 00-002	NT103 (conv. insufficient, 50% drift red. 5 m, 75% drift red. 5 m, 90% drift red. *)

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product Code: Beetix WG

Reg. No.: 007671-00/00

Active Substance: 700 g/kg metamitron

Central Zone

Zonal Rapporteur Member State: UK

National Addendum Germany

Applicant: United Phosphorus Ltd.

Date: February 2012

Evaluator: Julius Kühn-Institut

Date: 2014-08-27

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IIIA1 6 Efficacy Data and Information on the Plant Protection Product

General information

Refer to Registration Report for further information.

Recent registration situation/history of the PPP

Refer to Registration Report for further information.

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

Refer to Registration Report for further information.

Information on crops and pests

Refer to Registration Report for further information.

Information on the intended uses

Date: 2014-07-09

Product: Beetix WG

Use No.

007671-00/00-001

Field of use

Agriculture (field crops)

Crop(s)/object(s)

fodder beet (BEAVC), sugar beet (BEAVA)

Crop stage(s) (BBCH)

00 to 18

Pest(s)/target(s)

Poa annua (POAAN), annual dicotyledonous weeds (TTTDS) (excluded: *Galium aparine* (GALAP), *Polygonum spec.* (POLSS))

Area of application

Outdoors

Timing of application

Spring, before emergence (1st treatment), after emergence (2nd treatment) and after emergence (3rd treatment)

Max. number of treatments for the use

3

Max. number of treatments per crop or season

3

Interval between treatments

6 to 14 days

Application method/kind of treatment

spraying (*)

Application rate(s)

timing 1: 3 kg/ha in 200 to 300 L water/ha
timing 2: 1 kg/ha in 200 to 300 L water/ha
timing 3: 1 kg/ha in 200 to 300 L water/ha

Use No.

007671-00/00-002

Field of use

Agriculture (field crops)

Crop(s)/object(s)

fodder beet (BEAVC), sugar beet (BEAVA)

Crop stage(s) (BBCH)

10 to 18

Pest(s)/target(s)

Poa annua (POAAN), annual dicotyledonous weeds (TTTDS) (excluded: *Galium aparine* (GALAP), *Polygonum spec.* (POLSS))

Area of application

Outdoors

Timing of application

Spring, after emergence

Max. number of treat-

3

ments for the use	
Max. number of treat- ments per crop or sea- son	3
Interval between treat- ments	6 to 14 days
Application meth- od/kind of treatment	spraying (*)
Application rate(s)	timing 1: 1 kg/ha in 200 to 300 L water/ha timing 2: 2 kg/ha in 200 to 300 L water/ha timing 3: 2 kg/ha in 200 to 300 L water/ha
Notes on dose rate -----	maximum application rate for the intended crop per year: 5 kg/ha -----

(*) Remarks on application method: splitting (3 applications) should be amended

IIIA1 6.1 Efficacy data

Refer to Registration Report for further information.

IIIA1 6.1.1 Preliminary range-finding tests

Refer to Registration Report for further information.

IIIA1 6.1.2 Minimum effective dose tests

Refer to Registration Report for further information.

IIIA1 6.1.3 Efficacy tests

Use 007671-00/00-002

For some weeds which are described in the label as being controlled well, only a few or no efficacy results exist. The label warning WH9161 (The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.) is proposed.

Refer to Registration Report for further information.

IIIA1 6.1.4 Effects on yield and quality

Refer to Registration Report for further information.

IIIA1 6.1.4.1 Impact on the quality of plants and plant products

Refer to Registration Report for further information.

IIIA1 6.1.4.2 Effects on the processing procedure

Refer to Registration Report for further information.

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

Refer to Registration Report for further information.

IIIA1 6.2 Adverse effects

Refer to Registration Report for further information.

IIIA1 6.2.1 Phytotoxicity to host crop

Concerning Use No. 001:

The selectivity of a pre-emergence application of 2100 g/ha metamitron is not verified by the provided data. Since there is no comparable registered use in Germany there are no data and experiences for this use. The Registration Report includes data of 4 selectivity trials of which only 1 is reasonably valid according to the EPPO standards (this trial was conducted in the maritime zone and also the double dosage was tested). All selectivity trials were done in just one year (2011). Only 1 trial (from Hungary) has been harvested. Due to different dosages a bridging of use no. -002 is not possible. Considering also that crop damages occurred in some selectivity and efficacy trials a registration in Germany is not possible.

Concerning Use No. 002:

Refer to Registration Report for further information.

IIIA1 6.2.2 Adverse effects on health of host animals

Refer to Registration Report for further information.

IIIA1 6.2.3 Adverse effects on site of application

Refer to Registration Report for further information.

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

The herbicide Beetix WG (HBT05, 700 g/kg metamitron) has been proposed for a split application in sugar and fodder beets with a total application rate of 5 kg/ha and year (three applications with intervals of 6-14 days, BBCH 00-18), which corresponds to 3500 g/ha metamitron. Taking into account the potential dissipation of the active ingredients between applications, worst-case application rate can be calculated to be approximately 4.5 kg/ha (using maximum default MAF of 2.7 for 3 applications) which corresponds to 3150 g/ha metamitron.

During the course of the trials on effectiveness and selectivity observations indicating any effects whatsoever on beneficial organisms were not reported.

Appropriate studies on the potential adverse effects of the test product on beneficial arthropods were available from Registration Report Part B, Section 6, Annex Point IIIA 10.5 (Effects on Arthropods Other Than Bees), Core Assessment.

For the evaluation of adverse effects of the test product on beneficial organisms, laboratory studies on inert substrates with the two indicator species (*Aphidius rhopalosiphi* and *Typhlodromus pyri*) were conducted with a liquid formulation, Metafol 700 SC (= HBT01, 697 g/L metamitron, Table 6.2.4-1). The formulation has the same content of metamitron as HBT05, but differs in small amounts of inert co-formulants.

The proposed rate of Metafol 700 SC caused no mortality of the parasitoid wasp *Aphidius rhopalosiphi* and affected its parasitisation capacity only marginally (< 30%).

It caused only marginal mortality of the predatory mite *Typhlodromus pyri* but decreased its reproduction by 42%. However no relation between doses (rates from 2-21 L/ha) and reproduction was visible.

Table 6.2.4-1: Effects of Metafol 700 SC (= HBT01; 697 g/L metamidron) on beneficial organisms

Species (Exposed Stage)	Substrate	Rate Product [L/ha]	Corrected Mortality [%]	Sublethal Effect (Re) [%]	Reference
<i>A. rhopalosiphi</i> (A)	Glass	2	0	13	C37951 (Jeker, 2009)
		5	0	25	
		7	-2.8	46	
		14	0	25	
		21	17	38	
<i>T. pyri</i> (PN)	Glass	2	0	34	C37962 (Jeker, 2009)
		5	2.7	42	
		7	1.3	35	
		14	4	40	
		21	-2.7	39	

PN = protonymphs, A = adults, Re = reproduction

Further laboratory studies on inert substrates with two indicator species (*Aphidius rhopalosiphi* and *Typhlodromus pyri*) and two relevant antagonists (*Coccinella septempunctata*, *Pardosa* spp.) using another SC-formulation of metamidron, GOLTIX SC 700, were reported in the EFSA “Conclusion on the peer review of metamidron”, EFSA Scientific Report (2008) 185, 1-95, cited in Registration Report Part B, Section 6, Annex Point IIIA 10.5. As the complete results are known, they are represented in Table 6.2.4-2:

In the range of the proposed rate, the metamidron-formulation caused no or only a negligible mortality of the four test species.

As sublethal endpoints, the parasitization capacity of *Aphidius rhopalosiphi*, the fecundity of *Typhlodromus pyri* and the food consumption of spiders of the genus *Pardosa* (*P. agrestis*, *P. agricola*) were only marginally (< 30%) affected.

Already at 0.44-fold the proposed rate as well as in the range of the proposed rate, metamidron had sublethal effects on the fertility of the ladybird *Coccinella septempunctata* slightly above 30%. However, the number of fertile eggs per female in the metamidron treatment was within the historical data base of egg-laying performance in untreated controls, so these effects are to consider as not impacted by the treatment.

Table 6.2.4-2: Effects of Metamidron SC 700 (GOLTIX SC 700) (685 - 704 g/L Metamidron) on beneficial arthropods in laboratory studies

Species (Exposed Stage)	Substrate	Rate Product [L/ha]	Corrected Mortality [%]	Sublethal Effect [%]	Reference
<i>A. rhopalosiphi</i> (A)	Glass	0.35	6		BAY-99-13
		2	0		
		5	0		
		7	0	9 (Re)	
		14	0	5 (Re)	
		21	0	5 (Re)	
<i>T. pyri</i> (PN)	Glass	0.35	2	17 (Re)	IRL70751
		2	0	5 (Re)	
		5	3	10 (Re)	
		7	8	34 (Re)	
		14	2	14 (Re)	

		21	7	13 (Re)	
Pardosa spp. (A)	Quartz sand	5	0	8 (FC)	971048077
<i>C. septempunctata</i> (La)	Glass	2	12	32 (Re)*	20011021 /01-NLCs
		5	5	33 (Re)*	
		6	10	67 (Re)*	

PN = protonymphs, A = adults, La = larvae, Re = reproduction, FC = Food consumption

The validity criteria were met in all studies.

* Study 20011021/01-NLCs: As the number of fertile eggs per female in the metamitron treatment was within the historical data base of egg-laying performance in untreated controls, the effects are to consider as not impacted by the treatment.

Conclusion

Studies with the test product itself were not available.

On the basis of laboratory studies with SC-formulations with the same content of metamitron as Beetix WG, the proposed application rate of the test product can be considered as not harmful for the parasitoid wasp *Aphidius rhopalosiphi* and as (at most) slightly harmful for the predatory mite *Typhlodromus pyri*. These sensitive indicator species are not relevant antagonists for the proposed crops, hence no classification is proposed for them.

For the ladybird *Coccinella septempunctata* and for spiders of the genus *Pardosa* as relevant antagonists, the test product is to classify as not harmful.

Classification according to IOBC:

Laboratory tests on artificial substrates

< 30%	= not harmful
30 – 79%	= slightly harmful
≥ 80%	= harmful

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

Refer to Registration Report for further information.

IIIA1 6.2.6 Impact on succeeding crops

Refer to Registration Report for further information.

IIIA1 6.2.7 Impact on other plants including adjacent crops

Refer to Registration Report for further information.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

As resistance in *Chenopodium album* to metamitron has been detected in Belgium, France, Netherlands, Sweden and Germany and because the number of resistance cases in Germany has increased in the last years, the resistance risk of Beetix WG has to be rated as high. This is also due to the high number of resistance cases reported for Germany in the HRAC group C1.

In addition, many target species especially *Amaranthus* spp., *Chenopodium album*, *Senecio vulgaris*, *Solanum nigrum* and *Poa annua* can be regarded as high risk species. The general resistance risk of Beetix WG under German conditions is therefore assessed as being high. The label warning WH951 (The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared) is proposed.

IIIA1 6.3 Economics

Refer to Registration Report for further information.

IIIA1 6.4 Benefits

Refer to Registration Report for further information.

IIIA1 6.4.1 Survey of alternative pest control measures

This is not an EC data requirement.

IIIA1 6.4.2 Compatibility with current management practices including IPM

This is not an EC data requirement.

IIIA1 6.4.3 Contribution to risk reduction

This is not an EC data requirement.

IIIA1 6.5 Other/special studies

Refer to Registration Report for further information.

IIIA1 6.6 Summary and assessment of data according to points 6.1 to 6.5

Refer to Registration Report for further information.

IIIA1 6.7 List of test facilities including the corresponding certificates

Refer to Registration Report for further information.

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

No additional studies submitted.

Appendix 2: GAP table

Reg.-No. 007671-00/00

GAP rev.1, date: 2014-07-09

PPP (product name/code) Beetix WG
active substance 1 Metamitron
active substance 2 0
active substance 3 0
active substance 4 0
active substance 5 0

Formulation Type: WG
Conc. of a.s. 1: 700 g/kg
Conc. of a.s. 2: 0
Conc. of a.s. 3: 0
Conc. of a.s. 4: 0
Conc. of a.s. 5: 0

Applicant: United Phosphorus GmbH
Zone(s): central/EU

professional use Yes
non professional use No

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use -No.	Mem-ber 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	fodder beet (BEAVC), sugar beet (BEAVA)	F	<i>Poa annua</i> (POAAN), annual dicotyledonous weeds (TTTDS) (excluded: <i>Galium aparine</i> (GALAP), <i>Polygonum spec.</i> (POLSS)) 00 to 18	spraying (*)	Spring, before emergence (1st treatment), after emergence (2nd treatment) and after emergence (3rd treatment)	a) 3 (6 to 14 days)	a) timing 1: 3 kg/ha	a) a.s. 1: 2.100 kg/ha	timing 1 200 - 300		
							b) 3	a) timing 2: 1 kg/ha	a) a.s. 2: 0.700 kg/ha	timing 2 200 - 300		
								a) timing 3: 1 kg/ha	a) a.s. 3: 0.700 kg/ha	timing 3 200 - 300		
								b) 5.00 kg/ha	b) 3.50 kg/ha			

002	DE	fodder beet (BEAVC), sugar beet (BEAVA)	F	<i>Poa annua</i> (POAAN), annual dicotyledonous weeds (TTTDS) (excluded: <i>Galium aparine</i> (GALAP), <i>Polygonum spec.</i> (POLSS) 10 to 18	spraying (*)	Spring, after emergence	a) 3 (6 to 14 days)	a) timing 1: 1 kg/ha	a) a.s. 1: 0.700 kg/ha	timing 1 200 - 300		
							b) 3	a) timing 2: 2 kg/ha	a.s. 1: 1.400 kg/ha	timing 2 200 - 300		
								a) timing 3: 2 kg/ha	a.s. 1: 1.400 kg/ha	timing 3 200 - 300		
								b) 5.00 kg/ha	b) 3.50 kg/ha			

(*) Remarks on application method: splitting (3 applications) should be amended