

REGISTRATION REPORT
Part A

Risk Management

Product name: BELOUKHA GARDEN
Product code: VVH 86 087
Active Substance: Pelargonic acid 500 g/L

COUNTRY: Germany
Central Zone
Zonal Rapporteur Member State: Austria

NATIONAL ASSESSMENT

Applicant: Belchim Crop Protection
Submission date: 12/08/2015
Finalisation date: 21/02/2018

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of BELOUKHA GARDEN containing pelargonic acid in Germany. This evaluation is required subsequent to the inclusion of pelargonic acid on Annex 1.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-8 and Part C and the national addendum for Germany, Part A and Part B Sections 5 and 6. The information, data and assessments provided in Registration Report, Parts B include 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 BELOUKHA GARDEN where that data has not been considered in the EU review. Otherwise assessments for the safe use of BELOUKHA GARDEN have been made using endpoints agreed in the EU review of pelargonic acid.

This document describes the specific conditions of use and labelling required for Germany for the registration of BELOUKHA GARDEN.

Appendix 1 should include the authorisation of the final product in Germany. Due to technical reasons, the authorisation of the final product in Germany is inserted under Appendix 4.

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 31 of Regulation (EC) No 1107/2009.

Appendix 3: Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

Appendix 4 of this document provides a copy of the final product authorisation from Germany.

1 Details of the application

1.1 Application background

This application was submitted by JADE on 12/08/2015. The applicant changed to Belchim Crop Protection during the course of the evaluation.

The application was for approval of BELOUKHA GARDEN (code VVH 86 087), an emulsifiable concentrate (EC) containing 500 g/L pelargonic acid, which is a herbicide and intended for amateur use in amenity: park alleyways, public gardens, sidewalk situations, as well as in ornamentals and shrubs.

1.2 Annex I inclusion

Nonanoic acid also named Pelargonic acid (CAS No.112-05-0) is approved under Regulation (EC) No 1107/2009 (Inclusion Directive of Fatty Acids C7 to C20 No.2008/127/EC, inclusion date: 01/01/2009, RMS: Ireland; Commission Implementing Regulation (EU) No 540/2011).

Commission Implementing Regulation (EU) No 540/2011 provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fatty acids (SANCO/2610/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.

Conditions of use shall include, where appropriate, risk mitigation measures.

These concerns were all addressed in the submission.

1.3 Regulatory approach

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

This application was submitted in order to allow the first approval of this product in Germany in accordance with the above.

1.4 Data protection claims

- Where data protection is being claimed regarding information supporting the registration of BELOUKHA GARDEN, it is indicated in the reference lists of the respective documents of the Registration Report.

1.5 Letters of Access

- The applicant submitted a LoA regarding data concerning the active ingredients pelargonic acid. The remaining data requirements were addressed by data provided by the applicant.

2 Details of the authorisation

2.1 Product identity

Product Name	VVH 86 087 (BELOUKHA GARDEN)
Authorization Number (for re-registration)	008529-00
Function	Herbicide
Applicant	JADE
Composition	500 g/L pelargonic acid / nonanoic acid
Formulation type	Emulsifiable concentrate [EC]
Packaging	<i>for non-professional users:</i> 0.1 – 0.9 L bottle, HDPE fluorinated 25 – 75 mL tube, HDPE fluorinated

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not proposed anymore.

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>	
Eye Irrit. 2, Aquatic Chronic 2	
<i>Hazard pictograms:</i>	
GHS07	exclamation mark
GHS09	environment
<i>Signal word:</i>	
Warning	
<i>Hazard statements:</i>	
H319	Causes serious eye irritation.
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.
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.
P337+P313	If eye irritation persists: Get medical advice/attention.
P391	Collect spillage
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>	
-	

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

None

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

2.2.4.1 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.
SB005	If medical advice is needed, have product container or label at hand.
SB010	Keep out of the reach of children.
SB111	Concerning the requirements for personal protective gear for handling the plant protection product the material safety data sheet and the instructions for use of the plant protection product as well as the guideline "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety (www.bvl.bund.de) must be observed.
SB166	Do not eat, drink or smoke when using this product.
SF245-02	It must be ensured that treated areas/crops may not be entered until the film of the plant protection product has dried.
SE126	Wear eye protection when applying/handling the product.
SS205-1	Wear long-sleeved shirt, long trousers and sturdy footwear during handling and applying plant protection products.
VH297	
VH298	
Integrated pest management (IPM)/sustainable use	
WMZ	Mode of action (HRAC-group): Z
NN3001	The product is classified as harmful for populations of relevant beneficial insects.
NN3002	The product is classified as harmful for populations of relevant beneficial predatory mites and spiders.
Ecosystem protection	
NW262	The product is toxic for algae.
NW468	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.

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

Integrated pest management (IPM)/sustainable use	
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)

2.2.4.2 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 all uses	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.
WW730 all uses	The product has no sustainable effect.
WW760 use 002	Restricted efficacy possible.
Ecosystem protection	
NW 642-1 all uses	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.
NS660-1 use 001 and 002	The product may only be applied on field areas which are not used for agricultural, forestry or horticultural purposes with the approval of the competent national authority. Such areas include all areas which are not permanently covered by buildings or roofing, including all traffic areas such as railway tracks, roads, paths, yards and business sites and other pieces of land changed by civil engineering measures. Violations may be punished by fines of up to 50 000 EUR.

2.3 Product uses

Reg.-No.: 008529-00/00 **GAP rev. 2, date:** 2018-02-07
PPP (product name/code): BELOUKHA GARDEN (VVH 86087) **Formulation type:** EC (a, b)
Active substance: Pelargonic acid **Conc. of as 1:** 500 g/L (c)
Applicant: JADE **Professional use:** No
Zone(s): central **Non-professional use:** Yes
Verified by MS: Yes **Field of use:** Herbicide

1 Use- No. (e)	2 Member state(s)	3 Crop and/ or situation (crop destination / purpose of crop)	4 F, Fn, Fpn G, Gn, Gp n or I	5 Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	6		7	8 Application Max. number a) per use b) per crop/ season	9 Min. interval between applications (days)	10 kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	11 Application rate g or kg as/ha		12 Water mL/m ² min / max	13 PHI (days)	14 Remarks: e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season					a) max. rate per appl. b) max. total rate per crop/season	a) max. rate per appl. b) max. total rate per crop/season			
001*	DE	hard and semi-permeable paths and places with trees and bushes (YMBAM)	Fn	annual monocotyledonous weeds (TTTMS), annual dicotyledonous weeds (TTTDS)	spraying	Spring till autumn, after emergence of weeds, for 10-15 cm height of weeds	a) 4 b) 4	2-4 week(s)	a) 2.25 mL/m ² b) 9.00 mL/m ²	a) 11.25 kg/ha b) 45.00 kg/ha	30 - 75	N**	A amateur gardening WH9161 WW730 NW642-1 NS660-1		
002	DE	hard and semi-permeable paths and places with trees and bushes (YMBAM)	Fn	mosses (MMMMM)	spraying for local treatment	During growing season, spring till autumn	a) 2 b) 2	6 month(s)	a) 1.8 mL/m ² b) 3.60 mL/m ²	a) 9.00 kg/ha b) 18.00 kg/ha	30 - 75	N**	A amateur gardening WH9161 WW730 WW760 NW642-1 NS660-1		
003*	DE	woody ornamentals	Fn	annual dicotyledonous weeds	spraying	Spring till autumn,	a) 4 b) 4	2-4 week(s)	a) 2.25 mL/m ² b) 9.00 mL/m ²	a) 11.25 kg/ha b) 45.00 kg/ha	30 - 75	N**	A amateur gardening WH9161		

	(NNNZG)	(TTTDS), annual monocotyledonous weeds (TTTMS)	after emergence of weeds, for 10-15 cm height of weeds						WW730 NW642-1
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* According to the zRMS data requirements for major crops, according to EPPO, are not covered for minimum effective dose, efficacy and phytotoxicity. As a consequence, data are not sufficient to support a major pest in a major crop.

** The setting of a PHI is without any relevance.

Remarks table heading:

- (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (b) Catalogue of pesticide formulation types and international coding system Crop Life International Technical Monograph n°2, 6th Edition Revised May 2008
- (c) g/kg or g/l

- (d) Select relevant
- (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

- (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

- 1 Numeration necessary to allow references
- 2 Use official codes/nomenclatures of EU Member States
- 3 For crops, the EU and Codex classifications (both) should be used, when relevant, the use situation should be described (e.g. fumigation of a structure)
- 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
- 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
- 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
- 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 38263-3152-4), including where relevant, information on season at time of application
- 8 The maximum number of application possible under practical conditions of use must be provided.
- 9 Minimum interval (in days) between applications of the same product
- 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
- 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
- 12 If water volume range depends on application equipment (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
- 13 PHI - minimum pre-harvest interval
- 14 Remarks may include: Extent of use/economic importance/restrictions

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:

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

VVH 86 087 is an emulsifiable concentrate formulation containing the active substance pelargonic acid. It is not explosive, has no oxidising properties. It has a self-ignition temperature of 345 °C and a flash point of 135 °C. In 1% aqueous dilution, it has a pH value around 4. The plant protection product when packed in PE bottles was found to be stable after accelerated storage for two weeks at 54 °C. A low temperature test for one week shows the stability at 0 °C. The product showed good physical and chemical stability with properties unchanged significantly from initial measurements. Therefore a minimum shelf life of 2 years is expected for this product according to FAO specifications.

Remark: The study on storage stability for two years has been submitted by the applicant in October 2017 to DE. The results are acceptable, but have not been evaluated by the ZRMS.

Implications for labelling: none

Compliance with FAO guidelines:

VVH 86 087 (BELOUKHA GARDEN) meets the general requirements for an EC-formulation according to the FAOWHO manual (2010).

Compatibility of mixtures:

No mixtures intended.

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 BELOUKHA GARDEN (VVH 86 087) 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)

Type	Analyte	Method	LOQ	Reference
Active substance	Pelargonic Acid	GC-FID	-	Core RR Part B, Section 2 IIIA 5.2.1

All provided analytical methods are acceptable.

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

Analytical methods for the determination of pelargonic acid residues in food of plants and animal origin are not required as pelargonic acid is included in Annex IV of Regulation 396/2005. Although pelargonic acid is a naturally occurring non-toxic compound, the outcome of the EU peer review indicated that data gaps exist for methods of analysis for water and air (EFSA Journal 2013;11(1):3023). Data gaps can be addressed in the context of the next renewal of the approval of pelargonic acid according to Reg. (EC) No 1107/2009. Methods for body fluids and tissues are not required.

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

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

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 AT.

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

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

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

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

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

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

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)

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

Germany agrees to the assessment of the zRMS AT. Please refer to the registration report of the zonal RMS AT for further information.

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

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

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

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

PEC_{soil} was calculated for the active substance pelargonic acid considering a soil depth of 2.5 cm. Due to the fast degradation of the active substance pelargonic acid in soil the accumulation potential of pelargonic acid was not considered.

The PEC_{soil} values for the active substance were used in the eco-toxicological risk assessment for the intended uses of the plant protection product BELOUKA GARDEN in Germany.

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

Direct leaching into groundwater

As indicated in the core assessment results of modelling with FOCUS PELMO / PEARL show that the active substance pelargonic acid is not expected to penetrate into groundwater at concentrations of $\geq 0.1 \mu\text{g/L}$ in the intended uses of BELOUKA GARDEN in Germany according to use No.001 - 003.

Groundwater contamination by bank filtration due to surface water exposure via runoff and drainage

According modelling with EXPOSIT 3, groundwater contamination at concentrations $\geq 0.1 \mu\text{g/L}$ by the active substance pelargonic acid due to surface runoff and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

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

Risk mitigation measures for the intended uses of plant protection products in Germany due to exposure of surface water consider two routes of entry (i) spray drift and volatilization with subsequent deposition and (ii) runoff, drainage separately.

Surface water exposure including effects of risk mitigation via spray drift and volatilization with subsequent deposition was estimated with the model EVA 3 using drift data by Rautmann and Ganzelmeier.

Surface water exposure including effects of risk mitigation via surface runoff and drainage was estimated using the model EXPOSIT 3.0.

The results of the specific national exposure assessment for the active substance were used in the eco-toxicological risk assessment.

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

The vapour pressure at 20 °C of the active substance pelargonic acid is $> 10^{-4}$ Pa. Hence the active substance pelargonic acid is regarded as volatile (volatilisation from soil and plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance pelargonic acid due to volatilization with subsequent deposition was considered.

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

For all uses on hard and semi-permeable paths and places with trees and bushes a special instruction for users is necessary saying that uses on paths and places with trees and bushes have to be approved by authorities of the federal states. The condition of use NS660-1 is assigned to uses 001 and 002.

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

Birds

TER values for birds were calculated for dietary exposure, exposure via drinking water and by secondary poisoning, taking into account the relevant toxicity data for pelargonic acid/BELOUKHA GARDEN and calculated exposure levels for the different routes of exposure, according to the intended uses of the product BELOUKHA GARDEN. The calculated TER values do achieve the acceptability criterion $TER \geq 10$ for acute effects and the acceptability criterion $TER \geq 5$ for long-term/reproductive effects on birds, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.1. The results of the assessment indicate an acceptable risk for birds due to the intended use of BELOUKHA GARDEN according to the label.

Terrestrial vertebrates (other than birds)

TER values for mammals were calculated for dietary exposure, exposure via drinking water and by secondary poisoning, taking into account the relevant toxicity data for pelargonic acid/BELOUKHA GARDEN and calculated exposure levels for the different routes of exposure, according to the intended uses of the product BELOUKHA GARDEN. The calculated TER values do achieve the acceptability criterion $TER \geq 10$ for acute effects and the acceptability criterion $TER \geq 5$ for long-term/reproductive effects on birds, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.1. The results of the assessment indicate an acceptable risk for mammals due to the intended use of BELOUKHA GARDEN according to the label.

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

The product BELOUKHA GARDEN and the active substances are toxic to the aquatic environment:

pelargonic acid: ErC50: 1.14 mg/L, *Pseudokirchneriella subcapitata*.

Subsequently no additional entries as those according to the evaluated use pattern and good agricultural practise are acceptable, and the conditions of use NW262 and NW468 are assigned.

TER values for aquatic organisms were calculated, taking into account the relevant toxicity data for pelargonic acid (ErC50: 1.14 mg/L (*Pseudokirchneriella subcapitata*)) and calculated exposure levels, according to the intended uses of the product BELOUKHA GARDEN. The results of the risk assessment indicate an acceptable risk for aquatic organisms due to spray drift according to the intended uses of BELOUKHA GARDEN according to the label. However, the application of PPP in the immediate vicinity of surface or coastal waters is not permitted in Germany, minimum buffer zones stipulated by state law must be observed. The condition of use **NW642-1** is assigned.

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

Bees

Toxicity data

The toxicity data on the effects of pelargonic acid on bees have been submitted by JADE in the framework of the Annex II dossier. An acute oral and contact toxicity study was conducted on bees exposed to VVH 86 086 (product containing 680 g/L pelargonic acid). The toxicity study conducted with the preparation VVH 86 086 is considered representative to properties of active substance.

Table 3.1.6.3-1: Toxicity values of pelargonic acid for bees

Test substance	Acute oral toxicity (LD ₅₀ µg/bee)	Acute contact toxicity (LD ₅₀ µg/bee)	Reference
Laboratory studies			
VVH 86 086	> 226.1 µg a.s./bee	> 210.7 µg a.s./bee	Schmitzer S. and Sekine T.2012

Hazard quotients for bees

The hazard quotient for oral exposure (HQ_O) is calculated by dividing the single dose (application rate, g a.s./ha) by the oral LD₅₀ value (µg a.s./bee). Using the maximum recommended application rate and the results of the acute oral toxicity study to bees (Table 3.1.6.3-1), the oral exposure HQ_O values for bees are calculated (Table 3.1.6.3-2).

Table 3.1.6.3-2: HQ_O value for *Apis mellifera* exposed to pelargonic acid

Species	Test material	Use	Application rate [g a.s./ha]	LD ₅₀ [µg a.s./bee]	HQ _O	Trigger
<i>Apis mellifera</i>	VVH 86 087	Amenity/nursery	11 250	> 226.1	< 49.8	50

The hazard quotient (application rate (g a.s./ha) / LD₅₀ (µg a.s./bee)) is below 50 for the proposed use, indicating an acceptable risk to bees.

The hazard quotient for contact exposure (HQ_C) is calculated by dividing the single dose (application rate, g a.s./ha) by the contact LD₅₀ value (µg a.s./bee). Using the maximum recommended application rate and the results of the acute contact toxicity study to bees (Table 3.1.6.3-1) the contact exposure HQ_C value for bees is calculated (Table 3.1.6.3-3).

Table 3.1.6.3-3: HQ_C value for *Apis mellifera* exposed to pelargonic acid

Species	Test material	Use	Application rate [g a.s./ha]	LD ₅₀ [µg a.s./bee]	HQ _C	Trigger
<i>Apis mellifera</i>	VVH 86 087	Amenity/nursery	11 250	> 210.7	< 53.4	50

The hazard quotient (application rate (g a.s./ha) / LD₅₀ (µg a.s./bee)) is slightly above 50.

Overall conclusion

Because herbicide use in amateur gardening will usually be restricted to the application on single weed plants and/or limited areas, honey bee colonies are not deemed at risk by this kind of application if exposed to VVH 86 087.

Label NB6641 is assigned to the product.

Other non-target arthropods

TER values for non-target arthropods in off-field habitats were calculated, taking into account the relevant toxicity data for pelargonic acid and calculated exposure concentrations in off-field habitats, according to the intended uses 001, 002 and 003 of the product BELOUKHA GARDEN. The calculated TER values do achieve the acceptability criterion $TER \geq 5$ (extended toxicity database) for effects on non-target arthropods, according to agreed EU Guidance in Document SAN-CO/10329/2002 rev 2 (as modified by specific German guidance) that overrides the prescriptions of Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.4. The results of the assessment indicate an acceptable risk for non-target arthropods in off-field habitats due to the intended uses 001, 002 and 003 of BELOUKHA GARDEN according to the label.

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

TER values for earthworms were calculated, taking into account the relevant toxicity data for pelargonic acid and calculated exposure concentrations in soil, according to the intended uses of the BELOUKHA GARDEN. The calculated TER values do achieve the acceptability criterion $TER \geq 10$ for acute effects on earthworms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5. The results of the assessment indicate an acceptable risk for earthworms due to the intended uses of BELOUKHA GARDEN according to the label.

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

Please refer to core assessment.

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

Concentrations of pelargonic acid in soil were determined where effects on nitrogen and carbon mineralisation processes remained $\leq 25\%$ and were compared to calculated exposure concentrations in soil, according to the intended uses of the product BELOUKHA GARDEN. The comparison indicates no exceedance of the acceptability criterion $\leq 25\%$ effects on soil microorganisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.6. The results of the assessment indicate an acceptable risk for soil microorganisms due to the intended uses of BELOUKHA GARDEN according to the label.

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

TER values for non-target terrestrial plants were calculated, taking into account the relevant toxicity data for pelargonic acid and calculated exposure concentrations in off-field habitats, according to the intended uses 001, 002 and 003 of the product BELOUKHA GARDEN. The calculated TER values do achieve the $TER \geq 10$ for effects on non-target plants, according to agreed EU Guidance in Document

SANCO/10329/2002 rev 2 (as modified by specific German guidance) that insofar amends Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended uses 001, 002 and 003 of BELOUKHA GARDEN according to the label.

Other non-target species (Flora and Fauna)

Please refer to the core assessment.

Implications for labelling resulting from ecotoxicological assessment:

Please refer to chapter 2.2 of this document.

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

Information on the active substance

Pelargonic acid, also named as nonanoic acid, has a unique mode of action. It is a non-systemic contact herbicide. It belongs to the HRAC (Herbicide Resistance Action Committee) group Z which means that no mode of action is clearly known for this active substance.

After application of pelargonic acid on the plant tissues, the active substance disrupts normal cell membrane permeability. Uncontrolled leakage of cell contents occurs. The cells collapse which leads to the death of the plant tissue.

Use 001

Data requirements for major crops, according to EPPO, are not covered for minimum effective dose, efficacy and phytotoxicity. Explanations can be found below. As a consequence, data are not sufficient to support a major pest in a major crop in the cMS.

Minimum effective dose, Efficacy

In total, 10 minimum effective dose trials were provided for the Maritime EPPO zone (2012-2014, conducted in BE, DE, NL, UK, intended dose rate 1-4x22.5 l VVH 86087/ha). The number of trials/weed species (mono- and dicotyledonous weeds) is very low (in most cases only 1 trial/weed species), therefore the EPPO demands according to EPPO PP 1/225 are not fulfilled. The presented data are not sufficient to support a major pest in a major crop in the cMS.

Label requirement WH9161 and label warning WW730 are assigned to the use.

Phytotoxicity

The test product did not cause any relevant phytotoxicity symptoms in efficacy trials of the Maritime EPPO Zone. 4 selectivity trials, provided in nursery and shrubs (use 3), can be extrapolated to cover tree growth on paths and open areas. These trials were even conducted with an application rate of 22.5 l/ha (N) and 45 l/ha (NN). Moreover, crop safety is not covered for ≥ 2 applications. For a major pest in a major crop, 4 selectivity trials are not sufficient (EPPO PP1/226). Therefore, the EPPO requirements for a major crop (nursery and shrubs) are not fulfilled.

Risk of Resistance

The overall risk of resistance for VVH 86087 is considered to be low at current knowledge. Further refinements may be considered at national level.

Succeeding crops

The risk for succeeding crops was assessed by two field trials (2013, FR, BE). A soil mix test was not provided by the applicant. It can be concluded that VVH 86087 will not have any adverse effect on succeeding crops when used according to Good Agricultural Practices. Additionally, a label phrase, addressing the time interval for succeeding crops, may be considered on national level.

Adjacent crops

Regarding the possibility of damaging neighbouring crops due to spray drift, the risk for non-target plants exposed to 18 l/ha is acceptable. Nevertheless, the applicant recommends avoiding spray drift to adjacent crops. Therefore, following label phrase may be considered at national level: Do not apply the product, if there is a risk of spray drift to adjacent crops.

Use 002

Data requirements for major crops, according to EPPO, are not covered for minimum effective dose, efficacy and phytotoxicity. Explanations can be found below. As a consequence, data may not be sufficient to support a major pest in a major crop in the cMS.

Minimum effective dose, Efficacy

In total, 17 efficacy trials were conducted in the Maritime EPPO zone to assess the control of moss species on paths and open areas (2012-2013, N-FR, BE, UK, DE, NL, intended dose rate 18 l/ha). According to the GAP, one to two applications of 18 l/ha are applied for authorization in the Maritime EPPO zone. Autumn application: Moderate moss control could be achieved after an autumn application of 18 l VVH 86087/ha. The spring application of 18 l VVH 86087/ha did not show sufficient control against moss species ($\leq 69\%$). The presented data (spring application) may not be sufficient for a major pest in a major crop in the cMS. Label requirement WH9161 and label warnings WW730 and WW760 are assigned to the use.

Phytotoxicity

The test product did not cause any relevant phytotoxicity symptoms in efficacy trials of the Maritime EPPO Zone. 4 selectivity trials (DE, NL, UK, N-FR) were conducted during 2013. According to EPPO 226, crop safety trials are usually required over two years. Therefore, the EPPO standard is not fully met. The crop tolerance to VVH 86087 was very good, no detrimental effects (0%) could be observed on *Thuja occidentalis*, *Buxus sempervirens*, *Rosa species*, *Photinia x fraseri*, *Viburnum tinus* and *Prunus laurocerasus* treated with 18 l/ha (N) and 36 l/ha (NN). The test product was applied twice (this is in line with the GAP). For a major pest in a major crop, 4 selectivity trials are not sufficient (EPPO PP1/226). Therefore, the EPPO requirements for a major crop (nursery and shrubs) are not fulfilled.

Risk of Resistance

The overall risk of resistance for VVH 86087 is considered to be low at current knowledge. Further refinements may be considered at national level.

Succeeding crops

The risk for succeeding crops was assessed by two field trials (2013, FR, BE). A soil mix test was not provided by the applicant. It can be concluded that VVH 86087 will not have any adverse effect on succeeding crops when used according to Good Agricultural Practices. Additionally, a label phrase, addressing the time interval for succeeding crops, may be considered on national level.

Adjacent crops

Regarding the possibility of damaging neighbouring crops due to spray drift, the risk for non-target plants exposed to 18 l/ha is acceptable. Nevertheless, the applicant recommends avoiding spray drift to adjacent

crops. Therefore, following label phrase may be considered at national level: Do not apply the product, if there is a risk of spray drift to adjacent crops.

Use 003

Data requirements for major crops, according to EPPO, are not covered for minimum effective dose, efficacy and phytotoxicity. Explanations can be found below. As a consequence, data are not sufficient to support a major pest in a major crop in the cMS.

Minimum effective dose, Efficacy

In total, 3 efficacy trials were conducted in the Maritime EPPO zone to assess the control of annual monocotyledonous and dicotyledonous weeds in nurseries and shrubs (2014, DE, UK, NL, intended dose rate 22.5 l VVH 86087/ha). For a major pest in a major crop, 3 efficacy trials are not sufficient (EPPO PP1/226). Therefore, the EPPO requirements for a major crop (nursery and shrubs) are not fulfilled. Label requirement WH9161 and label warning WW730 are assigned to the use.

Phytotoxicity

The test product did not cause any relevant phytotoxicity symptoms in efficacy trials. 4 selectivity trials (2 trials DE, 1 trial UK, 1 trial NL) were conducted during 2012-2014. The crop tolerance to VVH 86087 was very good (3 trials 0%), only slight phytotoxic effects (max. 1%) could be assessed in one trial using the single dose (22.5 l/ha=N). The double dose showed max. effects of 2% (45 l/ha=NN). For a major pest in a major crop, 4 selectivity trials are not sufficient (EPPO PP1/226). Therefore, the EPPO requirements for a major crop (nursery and shrubs) are not fulfilled.

Risk of Resistance

The overall risk of resistance for VVH 86087 is considered to be low at current knowledge. Further refinements may be considered at national level.

Succeeding crops

The risk for succeeding crops was assessed by two field trials (2013, FR, BE). A soil mix test was not provided by the applicant. It can be concluded that VVH 86087 will not have any adverse effect on succeeding crops when used according to Good Agricultural Practices. Additionally, a label phrase, addressing the time interval for succeeding crops, may be considered on national level.

Adjacent crops

Regarding the possibility of damaging neighbouring crops due to spray drift, the risk for non-target plants exposed to 18 l/ha is acceptable. Nevertheless, the applicant recommends avoiding spray drift to adjacent crops. Therefore, following label phrase may be considered at national level: Do not apply the product, if there is a risk of spray drift to adjacent crops.

Adverse effects on non-target arthropods other than bees

VVH 86087 caused > 50% effects even at application rates below the maximum amount of a single treatment in extended laboratory experiments with *Typhlodromus pyri*, *Aphidius rhopalosiphi* and *Orius laevigatus*. Complete repopulation with *A. rhopalosiphi* was possible after 3 weeks.

The results indicate, that short-term effects of > 50% on populations of relevant beneficial insects or relevant predatory mites and spiders cannot be ruled out.

Label warnings NN3001 and NN3002 are assigned to the product.

3.2 Conclusions

With regard to identity, physical, chemical and technical properties, further information and analytical methods (product and residues) an authorisation can be granted.

With respect to efficacy/IPM and sustainable use incl. protection of honeybees and beneficial arthropods an authorisation cannot be granted for the uses 001 and 003 as described under chapter 2.4, because according to the zRMS data requirements for major crops, according to EPPO, are not covered for minimum effective dose, efficacy and phytotoxicity. As a consequence, data are insufficient to support a major pest in a major crop in the cMS. Authorisation can be granted for the use 002, only.

With respect to fate and ecotoxicology assessment, an authorisation can be granted. Considering an application of the product in accordance with the intended and evaluated use pattern and good agricultural practice as well as compliance with imposed risk mitigation measures no harmful effects on groundwater or unacceptable effects on non-target organisms are to be expected.

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

An authorisation can be granted for the 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 Appendix 4)

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 31 of Regulation (EC) No 1107/2009.

Appendix 3 – Letter of Access

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

Appendix 4 – Copy of the product authorisation



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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.008529-00/00.132247
(bitte bei Antwort angeben)

DATUM 22. März 2018

ZV3 008529-00/00

BELOUKHA GARDEN

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit dem Wirkstoff: 500 g/l Pelargonsäure

Zulassungsnummer: 008529-00

Versuchsbezeichnungen: BBL-86087-H-0-EC

Antrag vom: 12. August 2015

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 2021.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

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

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008529-00/00-002	Moose	Wege und Plätze mit Holzgewächsen	

Festgesetzte Anwendungsbestimmungen

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

(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 Perlagonsäure 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 und 2 PflSchG sind für das Pflanzenschutzmittel die nachfolgend näher beschriebenen Verpackungen für die Anwendung durch nichtberufliche Anwender zugelassen:

Verpackungsart	Verpackungsmaterial	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Flasche	HDPE, fluoriert	1		0,10	0,90	l
Tube	HDPE, fluoriert	1		25,00	75,00	ml

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

Anwendung durch nichtberufliche Anwender zulässig.

Auflagen

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

Kennzeichnungsauflagen:

(NN3001)

Das Mittel wird als schädigend für Populationen relevanter Nutzinsekten eingestuft.

(NN3002)

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

(NW262)

Das Mittel ist giftig für Algen.

(SB001)

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

(SB005)

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

(SB010)

Für Kinder unzugänglich aufbewahren.

(SB111)

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

(SB166)

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

(SE126)

Schutzbrille tragen bei der Ausbringung/Handhabung des Mittels.

(SF245-02)

Es ist sicherzustellen, dass behandelte Flächen/Kulturen erst nach dem Abtrocknen des Pflanzenschutzmittelbelages wieder betreten werden.

(SS205-1)

Langärmeliges Hemd, lange Hose und festes Schuhwerk tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln.

(WMZ)

Wirkungsmechanismus (HRAC-Gruppe): Z

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

Sonstige Auflagen:

(VH297)

Verpackungen/Behälter für den Haus- und Kleingartenbereich müssen mit einem kindergesicherten Verschluss versehen sein.

(VH298)

Verpackungen/Behälter für den Haus- und Kleingartenbereich müssen mit einem ertastbaren Warnzeichen versehen sein.

(WH952)

Auf der Verpackung und in der Gebrauchsanleitung ist die Angabe zur Kennzeichnung des Wirkungsmechanismus als zusätzliche Information direkt jedem entsprechenden Wirkstoffnamen zuzuordnen.

Vorbehalt

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

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

Signalwort:

(S1) Achtung

Gefahrenpiktogramme:

(GHS07) Ausrufezeichen

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(H319)

Verursacht schwere Augenreizung.

(H411)

Giftig für Wasserorganismen, mit langfristiger Wirkung.

(EUH 401)

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

Sicherheitshinweise (P-Sätze):

(P101)

Ist ärztlicher Rat erforderlich, Verpackung oder Kennzeichnungsetikett bereithalten.

(P102)

Darf nicht in die Hände von Kindern gelangen.

(P280)

Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.

(P305+P351+P338)

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

(P337+P313)

Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

(P391)

Verschüttete Mengen aufnehmen.

(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
008529-00/00-001	Einjährige einkeimblättrige Unkräuter, Einjährige zweikeimblättrige Unkräuter	Wege und Plätze mit Holzgewächsen	
008529-00/00-003	Einjährige zweikeimblättrige Unkräuter, Einjährige einkeimblättrige Unkräuter	Ziergehölze	

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).

Weitere Hinweise und Bemerkungen

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: 008529-00/00-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Moose

Pflanzen/-erzeugnisse/Objekte: Wege und Plätze mit Holzgewächsen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Nichtkulturland
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Ja
Anwendungszeitpunkt:	Während der Vegetationsperiode, Frühjahr bis Herbst
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	6 Monat(e)
Anwendungstechnik:	spritzen
- Erläuterungen:	zur Teilflächenbehandlung
Aufwand:	
-	1,8 ml/m ² in 30 bis 75 ml Wasser/m ²

2.2 Sonstige Kennzeichnungsauflagen

(NS660-1)

Die Anwendung des Mittels auf Freilandflächen, die nicht landwirtschaftlich, forstwirtschaftlich oder gärtnerisch genutzt werden, ist nur mit einer Genehmigung der zuständigen Behörde zulässig. Zu diesen Flächen gehören alle nicht durch Gebäude oder Überdachungen ständig abgedeckten Flächen, wozu auch Verkehrsflächen jeglicher Art wie Gleisanlagen, Straßen-, Wege-, Hof- und Betriebsflächen sowie sonstige durch Tiefbaumaßnahmen veränderte Landflächen gehören. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

(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.

(WW730)

Das Mittel besitzt keine nachhaltige Wirkung.

(WW760)

Eingeschränkte Wirksamkeit möglich.

2.3 Wartezeiten

(N)

Freiland: Wege und Plätze mit Holzgewächsen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 2 nicht zugelassene Anwendung: 008529-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Einjährige einkeimblättrige Unkräuter, Einjährige zweikeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Wege und Plätze mit Holzgewächsen

Verwendungszweck:

2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Nichtkulturland

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich:

Ja

Anwendungszeitpunkt: Frühjahr bis Herbst, nach dem Auflaufen der Unkräuter, bei 10-15 cm Unkrauthöhe

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 2 bis 4 Woche(n)

Anwendungstechnik: spritzen

Aufwand:

- 2,25 ml/m² in 30 bis 75 ml Wasser/m²

3 Begründung

Diese Anwendung wurde in AT (zRMS) nicht zugelassen. Aufgrund der vorgelegten Ergebnisse schließt sich Deutschland der negativen Bewertung des zRMS an.

Anlage 2 nicht zugelassene Anwendung: 008529-00/00-003

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Einjährige zweikeimblättrige Unkräuter, Einjährige einkeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Ziergehölze

Verwendungszweck:

2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich:

Ja

Anwendungszeitpunkt: Frühjahr bis Herbst, nach dem Auflaufen der Unkräuter, bei 10-15 cm Unkrauthöhe

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 2 bis 4 Woche(n)

Anwendungstechnik: spritzen

Aufwand:

- 2,25 ml/m² in 30 bis 75 ml Wasser/m²

3 Begründung

Diese Anwendung wurde in AT (zRMS) nach Artikel 51 zugelassen. Im Verfahren stellte sich heraus, dass die eingereichten Unterlagen keine ausreichende Grundlage für eine Zulassung nach Artikel 29 bildeten. Aus dem gleichen Grund sind auch in Deutschland die Voraussetzungen für eine Zulassung nach Artikel 29 nicht gegeben.

REGISTRATION REPORT

Part B

Section 5

Environmental Fate

Detailed summary of the risk assessment

Product code: VVH 86 087

Product name(s): BELOUKA GARDEN

Chemical active substance:

Nonanoic acid 500 g/L

Central Zone

Zonal Rapporteur Member State: Austria

NATIONAL ADDENDUM – GERMANY
(authorisation and extension of use)

Applicant: JADE

Submission date: August 2015 and April 2017

MS Finalisation date: Januar 2018

Version history

When	What
9.1.2018	Title Page changed to comply with the template used by the zRMS. Numbering inside the document remained according to the new template.

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8 Fate and behaviour in the environment (KCP 9)

The exposure assessment of the plant protection product BELOUKA GARDEN in its non professional intended uses in weed and moss control is documented in detail in the core assessment of the plant protection product BELOUKA GARDEN dated from January 2016 performed by Austria.

This national addendum has been produced to support a national decision on the authorisation of the product BELOUKA GARDEN in Germany for the uses listed below. It reflects the impact of specific German environmental or agricultural circumstances on the exposure and risk assessment for BELOUKA GARDEN including risk mitigation measures.

8.1 Critical GAP and overall conclusions

8.1.1 Table of critical GAPs

Table 8.1-1: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8		9	10	11		12	13	14	15
							Application				Application rate					
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn, G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max	PHI (days)	Remarks: e.g. g safener/ synergist per ha	Conclusion		
Intended for uses in Germany																
001	DE	Paths and open areas with tree growth	Fn	Weed control (Annual broadleaved and grass weeds)	Spraying with backpack sprayer	All year Weeds: Post-emergence	a) 1 application per use b) 1 to 4 applications per season (spaced 2 to 4 weeks)	14	a) 22.5 L/ha per application b) 90 L/ha per season	a) 11 250 g/ha b) 45 000 g/ha	300 L to 750 L/ha					
002	DE	Paths and open areas with tree growth	Fn	Moss control	Spraying with backpack sprayer	During the vegetation period : spring and autumn	a) 1 application per use b) 1 to 2 applications per season (1 in spring, 1 in autumn)	5 month	a) 18 L/ha per application b) 36 L/ha per year	a) 9 000 g/ha b) 18 000 g/ha	300 L to 750 L/ha					
003	DE	Nursery and Shrubs (including rose trees)	Fn	Weed control (Annual broadleaved and grass weeds)	Spraying with backpack sprayer	All year Weeds: Post-emergence	a) 1 application per use b) 1 to 4 applications per season	14	a) 22.5 L/ha per application b) 90 L/ha per season	a) 11 250 g/ha b) 45 000 g/ha	300 L to 750 L/ha					

											(spaced 2 to 4 weeks)							
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* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
 ** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
N	No safe use

8.1.2 Overall conclusion

8.1.2.1 Predicted environmental concentrations in soil (PEC_{soil})

PEC_{soil} was calculated for the active substance Nonanoic acid considering a soil depth of 2.5 cm. Due to the fast degradation of the active substance Nonanoic acid in soil the accumulation potential of Nonanoic acid was not considered.

The PEC_{soil} values for the active substance were used in the eco-toxicological risk assessment for the intended uses of the plant protection product BELOUKA GARDEN in Germany.

8.1.2.2 Predicted environmental concentrations in groundwater (PEC_{gw})

Direct leaching into groundwater

As indicated in the core assessment results of modelling with FOCUS PELMO / PEARL show that the active substance Nonanoic acid is not expected to penetrate into groundwater at concentrations of $\geq 0.1 \mu\text{g/L}$ in the intended uses of BELOUKA GARDEN in Germany according to use No 001-003.

Consequences for authorization:

None.

Groundwater contamination by bank filtration due to surface water exposure via runoff and drainage

According modelling with EXPOSIT 3, groundwater contamination at concentrations $\geq 0.1 \mu\text{g/L}$ by the active substance Nonanoic acid due to surface runoff and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization:

The authorization of the plant protection product BELOUKA GARDEN is linked with following labelling:

Use No. 001-003 NG None

8.1.2.3 Predicted environmental concentrations in surface water (PEC_{sw})

Risk mitigation measures for the intended uses of plant protection products in Germany due to exposure of surface water consider two routes of entry (i) spray drift and volatilization with subsequent deposition and (ii) runoff, drainage separately.

Surface water exposure including effects of risk mitigation via spray drift and volatilization with subsequent deposition was estimated with the model EVA 3 using drift data by Rautmann and Ganzelmeier.

Surface water exposure including effects of risk mitigation via surface runoff and drainage was estimated using the model EXPOSIT 3.0.

The results of the specific national exposure assessment for the active substance were used in the eco-toxicological risk assessment.

8.1.2.4 Fate and behaviour in air

The vapour pressure at 20 °C of the active substance Nonanoic acid is $> 10^{-4}$ Pa. Hence the active substance Nonanoic acid is regarded as volatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Nonanoic acid due to volatilization with subsequent deposition was considered.

8.1.3 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011). For the estimation of surface runoff and drainage into an adjacent ditch with EXPOSIT 3.01 no grouping of the intended uses was performed, because in case of runoff and non professional use only 30% of the area will be treated with BELOUKA GARDEN. Respectively the application rate of use No. 003 is reduced up to 70%.

Table 8.1-2: Critical use pattern of BELOUKA GARDEN grouped according to soil.

Grouping according to soil			
Group	Intended uses	Application rate (g/ha) (interception, %)	Soil-relevant effective applic. rate, cumulative (g/ha)
1	001, 003	11250 (0)	45000
2	002	9000 (0)	9000

Table 8.1-3: Critical use pattern of BELOUKA GARDEN grouped according to spray drift

Grouping according to spray drift			
Group	Intended uses	Application rate (g/ha) (interval, d)	Drift scenario
1	001, 003	11250 (14, d)	74 %-ile
2	002	9000	90 %-ile

8.2 Metabolites considered in the assessment

Not applicable. No major metabolites are known.

8.3 Rate of degradation in soil (KCP 9.1.1)

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

Please refer to the core assessment (January 2016) part B, section 5, point IIIA 9.1.1.

Table 8.3.1-1 : Agreed EU End-points (EFSA Journal 2013)

End-Point	Pelargonic acid (from fatty acids)	No major metabolites
DT _{50lab} (days) normalised to 20°C	3 (mean value, n=2, r ² = 0.98)	-

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Not relevant for assessment.

8.4 Field studies (KCP 9.1.1.2)

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

Please refer to the core assessment (January 2016) part B, section 5, point IIIA 9.2.1

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Please refer to the core assessment (January 2016) part B, section 5, point IIIA 9.2.3

8.5 Mobility in soil (KCP 9.1.2)

8.5.1 Adsorption and desorption in soil (KCP 9.1.2.1)

Please refer to the core assessment (January 2016) part B, section 5, point IIIA 9.3

Table 8.5.1-1: Agreed EU End-points used in the Evaluation (EFSA, 2013)

End-Point	Pelargonic acid	no metabolites
K _{oc} (L/kg)	47.3 (n=1)	-

8.5.2 Column leaching (KCP 9.1.2.1)

Please refer to the core assessment (January 2016) part B, section 5, point IIIA 9.3.1

8.5.3 Lysimeter studies (KCP 9.1.2.2)

Please refer to the core assessment (January 2016) part B, section 5, point IIIA 9.3.2

8.5.4 Field leaching studies (KCP 9.1.2.3)

Please refer to the core assessment (January 2016) part B, section 5, point IIIA 9.3.3

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

8.6.1 Water/sediment study (KCP 9.2.2)

Please refer to the core assessment (January 2016) part B, section 5, point IIIA 9.7

No specific experimental data were submitted by the notifier to address the rate and pathway of degradation

of fatty acids (including pelargonic acid) in natural water/sediment systems. It is expected that degradation of fatty acids in aquatic systems will be similar to the degradation of fatty acids in soil. The determination of fatty acids and their salts as readily biodegradable indicates that fatty acids will not persist in aquatic environments.

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

Results of PEC_{soil} calculation for BELOUKA GARDEN and its non professional intended uses for weed and moss control according to EU assessment considering 5 cm soil depth are given in the core assessment, part B, section 8, chapter 8.7. In the German exposure assessment, the considered soil layer depth is based on experimental data.¹ Generally, a soil layer depth of 2.5 cm is applied in the calculation for active substances with a $K_{f,oc} < 500$, whereas a soil layer depth of 1 cm is applied for active substances with a $K_{f,oc} > 500$. A soil bulk density of 1.5 g/cm³ is assumed as in the core assessment.

8.7.1 Justification of new endpoints

Not applicable as no new endpoints used.

8.7.2 Active substance

The PEC_{soil} calculations were performed with Excel based on the input parameters as presented in the tables below.

Table 8.7-1: Input parameters for active substance for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT ₅₀ (days) EU endpoint	DT ₅₀ (days) updated endpoint
Nonanoic Acid	158.24	-	3 (SFO, Maximum, laboratory study, EFSA 2013;11(1):3023	not applicable

Due to the fast degradation of Nonanoic Acid in soil (DT₉₀ < 365 d, laboratory) the accumulation potential of Nonanoic Acid does not need to be considered.

8.7.2.1 PEC_{soil}

The calculated PEC_{soil} used for German risk assessment for Nonanoic acid is summarized in Table 8.7-2. The non professional use on path and open areas (weed control) following 4 applications with 11250 g a.s./ha is the worst-case scenario, leading to the highest initial PEC_{soil} values when considering no foliar interception (31.230 mg a.s./kg soil).

Table 8.7-2: Results of PEC_{soil} calculation for the non professional intended use in paths, open areas, nursery and shrubs used for weed control according to German risk assessment

Plant protection product:	BELOUKA GARDEN
Use:	001, 003

¹ 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

* worst case

** As the DT₅₀ of Pelargonic acid is 3d, one application is used in the risk assessment assuming an interval of 6 month between the intended 2 applications according GAP.

Number of applications/interval (d):		4/ 14				
Application rate (g as/ha):		Nonanoic Acid: 11250				
Crop interception (%):		0*				
Active substance/ formulation	Soil relevant ap- plication rate (g as/ha)	Soil depth_{act} (cm)	PEC_{act} (mg/kg)	Tillage depth (cm)	PEC_{bkgd} (mg/kg)	PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)
Nonanoic Acid	11250	2.5	31.230	5	-	-
Use:		002				
Number of applications/interval (d):		1/ 0**				
Application rate (g as/ha):		9000				
Crop interception (%):		0*				
Active substance/ formulation	Soil relevant application rate (g as/ha)	Soil depth_{act} (cm)	PEC_{act} (mg/kg)	Tillage depth (cm)	PEC_{bkgd} (mg/kg)	PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)
Nonanoic Acid	9000	2.5	24.0	5	-	-

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

Results of the PEC_{gw} calculation of Nonanoic acid for the non professional intended uses of BELOUKA GARDEN in paths, open areas, nursery and shrubs according to EU assessment using FOCUS PELMO / PEARL are given in the core assessment, part B, section 5, chapter 9.6.

Risk assessment for groundwater for authorisation of plant protection products in Germany considers two pathways, (i) direct leaching of the active substance into the groundwater after soil passage and (ii) surface runoff and drainage of the active substance into an adjacent ditch with subsequent bank filtration into the groundwater. The latter pathway was not addressed neither by core assessment nor for EU assessment of the active substances.

The risk assessment for groundwater of the pathway direct leaching after soil passage follows the recommendation of the Ground Water Work Group of FOCUS as provided by the Commission Services (Sanco/13144/2010, version 3, 10 October 2014) as also done by the zRMS in the core assessment.

Risk assessment for groundwater for the pathway surface runoff and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.01 stipulating also risk mitigation measures, if applicable.

8.8.1 Justification of new endpoints

Not applicable as no new endpoints used.

8.8.2 Active substance and relevant metabolite(s) (KCP 9.2.4.1) Direct Leaching into groundwater

Results of the groundwater modelling in the core assessment show that the active substance nonanoic acid is not expected to penetrate into groundwater at concentrations of $\geq 0.1 \mu\text{g/L}$ in the groundwater Scenario Hamburg relevant for authorisation in Germany in the intended uses of BELOUKA GARDEN in paths, open areas, nursery and shrubs. That result covers the groundwater risk assessment for the intended uses of BELOUKA GARDEN in Germany in paths, open areas, nursery and shrubs according to use No. 001 – 003.

Consequences for authorisation:

none

8.8.3 Groundwater contamination by bank filtration due to surface water exposure via runoff and drainage

Surface runoff and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.01.

Table 8.8-1: Input parameters related to application of BELOUKA GARDEN for PEC_{gw} calculations with EXPOSIT 3.01

Use No.	001	002	003
Crop	Paths and open areas with tree growth (weed control)	Paths and open areas with tree growth (weed control)	Nursery and shrubs, including rose trees (weed control)
Application rate (g as/ha)	Nonanoic Acid: 11250	Nonanoic Acid: 9000	Nonanoic Acid: 11250

Number of applications/interval (d)	4/ 12	1**	4/ 14
Crop interception (%)	0*	0*	0*

* worst case assumption

** As the DT50 of Pelargonic acid is 3d, one application is used in the risk assessment assuming an interval of 6 month between the intended 2 applications according GAP.

8.8.3.1 Nonanoic acid

Table 8.8-2: Input parameters for Nonanoic acid used for PEC_{gw} calculations with EX-POSIT 3.01

Parameter	Nonanoic Acid	Reference
Molecular weight (g/mol)	158.24	see core assessment (January 2016)
$K_{Foc, Runoff} / K_{Foc mobility class}$	47.3	calculated (US EPA EPIWin suite), see core assessment (January 2016)
DT ₅₀ soil (d)	3	see core assessment (January 2016)
Solubility in water (mg/L)	201.7 (20°C)	see core assessment (January 2016)
Mobility class	4	calculated, Exposit 3.01
Reduction by bank filtration	100%	calculated, Exposit 3.01

PEC_{gw} of Nonanoic Acid due to bank filtration

As the reduction by bank filtration is assumed to be 100 % for Nonanoic Acid, no calculation is necessary.

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations $\geq 0.1 \mu\text{g/L}$ by the active substance Nonanoic Acid due to surface runoff and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization:

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

Use No. 001- 003

NG: None

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

Risk mitigation measures for the intended uses of plant protection products in Germany due to exposure of surface water consider the two routes of entry (i) spray drift and volatilization with subsequent deposition and (ii) runoff, drainage separately.

Surface water exposure including effects of risk mitigation via spray drift and volatilization with subsequent deposition is estimated with the model EVA. Surface water exposure including effects of risk mitigation via surface runoff and drainage is estimated using the model EXPOSIT.

8.9.1 Justification of new endpoints

Not applicable as no new endpoints used.

8.9.2 PEC_{sw} after exposure by spray drift and volatilization with subsequent deposition

The calculation of PEC_{sw} after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 3. 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.

Table 8.9-1: Input parameters for BELOUKA GARDEN related to the application used for PEC_{sw} calculations with EVA 3

Use No.:	001, 003	002
Number of applications/ interval:	4/ 14 (d)	1*
Application rate (g a.s./ha)	Nonanoic Acid: 11250	Nonanoic Acid: 9000

* As the DT50 of Pelargonic acid is 3d, one application is used in the risk assessment assuming an interval of 6 month between the intended 2 applications according GAP

8.9.2.1 Nonanoic acid

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 Nonanoic Acid is > 10⁻⁴ Pa. Hence the active substance Nonanoic Acid is regarded as volatile (volatilization from soil and plant surfaces). Therefore exposure of surface water by the active substance Nonanoic Acid due to volatilization with subsequent deposition needs to be considered.

The input parameters used for modelling of surface water exposure via spray drift and volatilization with subsequent deposition with EVA 3 are summarized below.

Table 8.9-2: Input parameters for Nonanoic acid used for the PEC_{sw} calculations with EVA 3

Parameter	Nonanoic Acid	Reference
Vapour pressure at 20°C (Pa)	0.9	LoEP (2013)
Solubility in water at 20°C (mg/L)	202.7	LoEP (2013)

DissT ₅₀ water (d)	3	SFO, LoEP (2013)
-------------------------------	---	------------------

For PEC_{sw/sed} due to spray drift and volatilization with subsequent deposition for Nonanoic Acid please refer to national Addendum Germany, Part B, Section 9, chapter 9.5.

8.9.3 PEC_{sw} after exposure by surface runoff and drainage

The concentration of the active substance Nonanoic acid in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3. The input parameters for BELOUKA GARDEN related to the application used for PEC_{sw} calculations with Exposit 3 are summarised in Table 8.8-13.

Table 8.99-3: Input parameters related to application of BELOUKA GARDEN PEC_{sw} calculations with EXPOSIT 3.01

Use No.	001	002	003
Crop	Paths and open areas with tree growth (weed control)	Paths and open areas with tree growth (weed control)	Nursery and shrubs, including rose trees (weed control)
Application rate (g as/ha)	Nonanoic Acid: 3375 (0.3 x 11250)***	Nonanoic Acid: 2700 (0.3 x 9000)***	Nonanoic Acid: 3375 (0.3 x 11250)***
Number of applications/interval (d)	4/ 12	1**	4/ 14
Crop interception (%)	0*	0*	0*

* worst case assumption

** As the DT50 of Pelargonic acid is 3d, one application is used in the risk assessment assuming an interval of 6 month between the intended 2 applications according GAP.

*** correction factor of 0.3 for non professional uses on paths and open areas as soon as for ornamentals (nursery and shrubs) due to runoff mitigation which not affects the whole treated area.

The substance specific input parameters used for modelling surface water exposure via runoff and drainage in an adjacent ditch with EXPOSIT 3 are summarized in table 8.8.36 of this document.

For PEC_{sw/sed} due to surface runoff and drainage please refer to national Addendum Germany, Part B, Section 9, chapter 9.5.

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Please refer to chapter 8.9.2. and to core assessment (January 2016) part B, section 5, point IIIA 9.9. Significant volatilization is not expected to occur, especially since the estimated DT₅₀ value in air is low. Furthermore, a rapid photochemical oxidative degradation in air is expected. Therefore calculation of PECa is not deemed necessary. No adverse effects are expected from concentration in air.

8.11 Classification and labelling

8.11.1 GHS Classification and labelling

Please refer to the core assessment Part B Section 9.

8.11.2 National labelling

No specific labelling required.

8.11.3 Standard phrases under Regulation (EU) No 547/2011

Use No.	Safety precautions related to the environment

REGISTRATION REPORT

Part B

Section 6

Ecotoxicology

Detailed summary of the risk assessment

Product code: VVH 86 087

Product name(s): BELOUKHA GARDEN

Chemical active substance:

Nonanoic acid, 500 g/L

Central Zone

Zonal Rapporteur Member State: Austria

National Addendum

Germany

(authorisation and extension of use)

Applicant: JADE

Submission date: August 2015 and April 2017

MS Finalisation date: February 2018

VVH 86 087 / BELOUKHA GARDEN
Part B – Section 9 - National Addendum
Germany

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5.2.2018	Updated Risk Assessment

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1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
003	DE	Nursery and Shrubs (including rose trees)	F	Weed control (Annual broadleaved and grass weeds)	Spraying with backpack sprayer	All year Weeds: Post-emergence	a)1 application per use b) 1 to 4 applications per season (spaced 2 to 4 weeks)		a) 22.5 L/ha per application b) 90 L/ha per season	a) 11 g/ha b) 45 000 g/ha	300 L to 750 L/ha			A	A	A		A	A	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fr: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gp: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 – 21 “Conclusion”

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by eMS
N	No safe use

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Remarks table:	
(1)	Numeration necessary to allow references
(2)	Use official codes/nomenclatures of EU
(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)	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
(5)	Scientific names and Eppo-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
(6)	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7)	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8)	The maximum number of application possible under practical conditions of use must be provided
(9)	Minimum interval (in days) between applications of the same product.
(10)	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also Eppo-Guideline PP 1/239 Dose expression for plant protection products
(11)	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
(12)	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
(13)	PHI - minimum pre-harvest interval
(14)	Remarks may include: Extent of use/economic importance/restrictions

9.1.1 Overall conclusions

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Please refer to the core assessment.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

TER values for aquatic organisms were calculated, taking into account the relevant toxicity data for Pelargonic acid and calculated exposure levels, according to the intended uses of the product BELOUKHA GARDEN. The calculated TER values do achieve the adjusted criterion $TER \geq 30$ for effects on aquatic organisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.2. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended uses of BELOUKHA GARDEN according to the label.

9.1.1.3 Effects on bees (KCP 10.3.1)

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

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

TER values for non-target arthropods in off-field habitats were calculated, taking into account the relevant toxicity data for Pelargonic acid and calculated exposure concentrations in off-field habitats, according to the intended uses 001, 002 and 003 of the product BELOUKHA GARDEN. The calculated TER values do achieve the acceptability criterion $TER \geq 5$ (extended toxicity database) for effects on non-target arthropods, according to agreed EU Guidance in Document SAN-CO/10329/2002 rev 2 (as modified by specific German guidance) that overrides the prescriptions of Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.4. The results of the assessment indicate an acceptable risk for non-target arthropods in off-field habitats due to the intended uses 001, 002 and 003 of BELOUKHA GARDEN according to the label.

9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

TER values for earthworms were calculated, taking into account the relevant toxicity data for Pelargonic acid and calculated exposure concentrations in soil, according to the intended uses of the BELOUKHA GARDEN. The calculated TER values do achieve the acceptability criterion $TER \geq 10$ for acute effects on earthworms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5. The results of the assessment indicate an acceptable risk for earthworms due to the intended uses of BELOUKHA GARDEN according to the label.

Concentrations of Pelargonic acid in soil were determined where effects on nitrogen and carbon mineralisation processes remained $\leq 25\%$ and were compared to calculated exposure concentrations in soil, according to the intended uses of the product BELOUKHA GARDEN. The comparison indicates no exceedance of the acceptability criterion $\leq 25\%$ effects on soil microorganisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.6. The results of the assessment indicate an acceptable risk for soil microorganisms due to the intended uses of BELOUKHA GARDEN according to the label.

9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)

TER values for non-target terrestrial plants were calculated, taking into account the relevant toxicity data for Pelargonic acid and calculated exposure concentrations in off-field habitats, according to the intended uses 001, 002 and 003 of the product BELOUKHA GARDEN. The calculated TER values do achieve TER ≥ 10 for effects on non-target plants, according to agreed EU Guidance in Document SANCO/10329/2002 rev 2 (as modified by specific German guidance) that insofar amends Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended uses 001, 002 and 003 of BELOUKHA GARDEN according to the label.

9.1.2 Grouping of intended uses for risk assessment

Table 9.1-2: Critical use pattern of KATOUN GOLD grouped according to application rate

Grouping according to application rate		
Group	Intended uses	relevant use parameters for grouping
1	001, 003	a) 22.5 L/ha per application b) 90 L/ha per season
2	002	a) 18 L/ha per application b) 36 L/ha per year

9.1.3 Consideration of metabolites

No data available.

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Please refer to the core assessment.

9.2.2 Risk assessment for spray applications

Please refer to the core assessment.

9.2.2.1 Effects of secondary poisoning

Please refer to the core assessment.

9.2.2.2 Biomagnification in terrestrial food chains

Please refer to the core assessment.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.4 Overall conclusions

Please refer to the core assessment.

Consequences for authorisation

None

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Please refer to the core assessment.

9.3.2 Risk assessment for spray applications

Please refer to the core assessment.

9.3.2.1 Drinking water exposure

Please refer to the core assessment.

9.3.2.2 Effects of secondary poisoning

Please refer to the core assessment.

9.3.2.3 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.4 Overall conclusions

Please refer to the core assessment.

Consequences for authorization

None

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

No data available.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

For the choices of relevant endpoints, please refer to the core assessment of the zRMS.

9.5.2 Risk assessment

For authorisation in Germany, three entry routes are considered separately in the exposure assessment for surface water: (i) spray drift together with volatilisation and subsequent deposition (where relevant), (ii) run-off, and (iii) drainage. Consequently, specific risk mitigation measures are defined and can be imposed separately for each entry route. Thus, the risk assessment from the core assessment is replaced by a specific national assessment for Germany, which is described below.

Exposure of surface water bodies via spray drift and volatilisation with subsequent deposition

Exposure assessment

Concentrations of BELOUKHA GARDEN in surface water due to spray drift and volatilisation with subsequent deposition are calculated using the model EVA3, which refers to spray drift data by Rautmann and Ganzelmeier and an empirical model for volatilisation/deposition, based on vapour-pressure classes. Pelargonic acid has a vapour pressure of $> 10^{-4}$ Pa (0.9 Pa) and is therefore classified as volatile. Hence, deposition following volatilisation must be considered in the exposure assessment. The model input parameters for Pelargonic acid are provided in the Environmental Fate section.

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Selection of relevant toxicity endpoint

Please refer to the core assessment.

The relevant endpoint chosen by the zRMS was the EyC50 of 4.36 mg a.i./L in an study with *Pseudokirchneriella subcapitata* by Kuhl, R. and Frank, C. (2015). The zRMS recalculated the effect values based on mean measured value because the measured concentrations fall below 80 % at the test end. These values were not used in the risk assessment of the core assesement. Deviating from the assessment of the zRMS, Germany uses the ErC50 of 1.14 mg a.i./L based on mean measured concentrations.

The ErC50 is considered for the risk assessment but there are some uncertainties regarding the level of protection reached for primary producers. This is indicated for macrophytes in the aquatic Guidance Document (EFSA Journal 2013;11(7):3290) that recommends: "... a proper calibration between different tiers (higher and lower tier data) for macrophytes should be performed in the future". Such calibration should be extended to algae. Until available relevant information on the level of protection reached is considered at EU level, it is recommended to address this uncertainty at each Member State level in the National Addendum if considered necessary, although it would be highly appreciated to have a harmonized approach in the Central zone.

Hence Germany considers an interim approach within the national assessment and derives the Tier 1 RAC as follows:

$$\text{RAC} = (\text{ErC } 50 / \text{EF } 3) / \text{AF } 10 \rightarrow \text{ErC } 50 / 30$$

Table 9.5-1: Assessment of the risk for aquatic organisms due to the use of BELOUKHA GARDEN in use 001 and 003 – exposure to entries of Pelargonic acid via spray drift and volatilisation/deposition, considering risk mitigation measures

Active substance/product:		Pelargonic acid						
Intended use:		001; 003						
Application parameters:		4 x 11250 g/ha, interval 14 d						
DisT₅₀ water phase (SFO):		3						
Scenario, drift percentile:		gardening, plants <50cm, 74%-ile						
PEC type:		PECini/PECact						
Buffer zone (m)	Spray drift		Deposition following volatilisation		PEC _{sw} ; conventional and drift-reducing technique			
	(%)	(µg/L)	(%)	(µg/L)	0 % red.	50 % red.	75 % red.	90 % red.
					(µg/L)			
1	0.13	5.075	0.518%	19.434	24.509			
5	0.01	0.390	0.417%	15.630	16.020			
10	0.002	0.078	0.318%	11.904	11.982			
15	0.001	0.039	0.242%	9.066	9.105			
20	0.001	0.020	0.184%	6.905	6.925			
Endpoint (µg/L) and AF:		ErC50 :1.14 mg/L (<i>Pseudokirchneriella subcapitata</i>); AF: 30						
Buffer zone (m)					TER / PEC			
1					46.5			
5					71.2			
10					95.1			

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15	125.2			
20	164.6			
Risk mitigation measures:	none			

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

Table 9.5-2: Assessment of the risk for aquatic organisms due to the use of BELOUKHA GARDEN in use 002 – exposure to entries of Pelargonic acid via spray drift and volatilisation/deposition, considering risk mitigation measures

Active substance/product:		Pelargonic acid							
Intended use:		002							
Application parameters:		1** x 9000 g/ha							
DisT₅₀ water phase (SFO):		3							
Scenario, drift percentile:		gardening, plants <50cm, 90%-ile							
PEC type:		PECini/PECact							
Buffer zone (m)	Spray drift		Deposition following volatilisation		PEC _{sw} ; conventional and drift-reducing technique				
	(%)	(µg/L)	(%)	(µg/L)	0 % red.	50 % red.	75 % red.	90 % red.	
					(µg/L)				
1	0.42	12.600	0.518%	15.547	28.147				
5	0.02	0.600	0.417%	12.504	13.104				
10	0.005	0.150	0.318%	9.523	9.673				
15	0.002	0.060	0.242%	7.253	7.313				
20	0.001	0.030	0.184%	5.524	5.554				
Endpoint (µg/L) and AF:		ErC50 :1.14 mg/L (<i>Pseudokirchneriella subcapitata</i>); AF: 30							
Buffer zone (m)					TER / PEC				
1					40.5				
5					87				
10					117.9				
15					155.9				
20					205.3				
Risk mitigation measures:		none							

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

** As the DT50 of Pelargonic acid is 3d, one application is used in the risk assessment assuming an interval of 6 month between the intended 2 applications

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Exposure of surface water bodies via run-off or drainage

Exposure assessment

The concentrations of the active substance Pelargonic acid in an adjacent ditch due to surface run-off or drainage are calculated using the model EXPOSIT 3.01. The relevant input parameters for exposure modelling are provided in the Environmental Fate section.

Selection of relevant toxicity endpoint

See above (assessment for exposure via spray drift and volatilisation with subsequent deposition).

Table 9.5-3: Assessment of the risk for aquatic organisms due to the use of BELOUKHA GARDEN in use 001 and 003 – exposure to entries of Pelargonic acid via run-off or drainage, considering risk mitigation measures

Active substance:	Pelargonic acid	
Intended use	001/003	
Application parameters:	4 x 3375* g a.i./ha, 14 d interval	
Endpoint (µg/L) and AF:	ErC50 :1.14 mg/L (<i>Pseudokirchneriella subcapitata</i>); AF: 30	
Run-off		
Buffer zone (m)	PEC (µg/L)	TER / PEC
0	10.20	111.74
5	8.84	128.93
10	7.58	150.42
20	5.31	214.89
Drainage		
Time of application	PEC (µg/L)	TER / PEC
Spring/summer	5.49	207.67
Autumn/winter	16.89	67.49
Risk mitigation measures:	none	

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

*correction factor of 0.3 for non-professional uses

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Table 9.5-4: Assessment of the risk for aquatic organisms due to the use of BELOUKHA GARDEN in use 002 – exposure to entries of Pelargonic acid via run-off or drainage, considering risk mitigation measures

Active substance:	Pelargonic acid	
Intended use	002	
Application parameters:	1** x 2700 g a.i./ha *	
Endpoint (µg/L) and AF:	ErC50 :1.14 mg/L (<i>Pseudokirchneriella subcapitata</i>); AF: 30	
Run-off		
Buffer zone (m)	PEC (µg/L)	TER / PEC
0	7.84	145.40
5	6.80	167.77
10	5.82	195.73
20	4.08	279.62
Drainage		
Time of application	PEC (µg/L)	TER / PEC
Spring/summer	4.22	270.22
Autumn/winter	12.98	87.82
Risk mitigation measures:	none	

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

*correction factor of 0.3 for non-professional uses

** As the DT50 of Pelargonic acid is 3d, one application is used in the risk assessment assuming an interval of 6 month between the intended 2 applications

9.5.1 Overall conclusions

TER values for aquatic organisms were calculated, taking into account the relevant toxicity data for Pelargonic acid and calculated exposure levels, according to the intended uses of the product BELOUKHA GARDEN. The calculated TER values do achieve the adjusted criterion $TER \geq 30$ for effects on aquatic organisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.2. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended uses of BELOUKHA GARDEN according to the label.

Consequences for authorization

None

9.6 Effects on bees (KCP 10.3.1)

Please refer to the core assessment.

Consequences for authorization:

none

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Please refer to the core assessment.

9.7.2 Risk assessment

9.7.2.1 Risk assessment for off-field exposure

A risk assessment according to the recommendations of the “Guidance Document on Terrestrial Ecotoxicology” (SANCO/10329/2002) and in consideration of the recommendations of the guidance document ESCORT 2 is documented in the core assessment. For authorisation in Germany, a modified off-field risk assessment is relevant that takes into account the possible additional exposure route via volatilisation with subsequent deposition and addresses the availability of specific national risk mitigation measures.¹

Exposure assessment

Exposure levels of BELOUKHA GARDEN in terrestrial off-field habitats due to spray drift and volatilisation with subsequent deposition are calculated using the model EVA3 (see chapter on effects on aquatic organisms for further explanations).

To extrapolate from exposure in a 2-dimensional toxicity test system to exposure in 3-dimensional field vegetation structures, a 2D/3D correction factor analogous to the ESCORT 2 ‘vegetation distribution factor’ (vdf) is applied in the risk assessment for national authorisations in Germany. This factor is derived from experimental data on spray drift deposits on meadows and hedgerows² and recalculated quotients of theoretically expected vs. measured residues. While several quotients were found to be lower than the ESCORT 2 vdf of 10, a 2D/3D correction factor of 5 was considered to appropriately define the required realistic worst case for a risk assessment.

¹ Schulte et al., UWSF (5) 261-266 (1999), Bewertungskriterien des Umweltbundesamtes: Auswirkungen von Pflanzenschutzmitteln auf terrestrische Arthropoden.

² Koch H, Weißer P and Landfried M (2003): Effect of drift potential on drift exposure in terrestrial habitats. Nachrichtenblatt Deut. Pflanzenschutzd., 55, 181-188.

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Table 9.7-1: Assessment of the risk for non-target arthropods in off-field habitats due to the use of BELOUKHA GARDENin use 001 / 003, considering risk mitigation measures

Active substance/product:		Pelargonic acid						
Intended use:		001/003						
Application parameters:		4 x 11250 g a.i./ha (14 d interval)						
MAF:		2.7						
Scenario, drift percentile:		Gardening, plants < 50 cm, 74%-ile						
2D/3D correction factor:		5						
Buffer zone (m)	Spray drift		Deposition following volatilisation		PER _{off-field} ; conventional and drift-reducing technique			
	(%)	(g/ha)	(%)	(g/ha)	0 % red.	50 % red.	75 % red.	90 % red.
					(g/ha)			
1	0.13	7.874	0.518	11.660	19.535		-	-
5	0.01	0.606	0.417	9.378	9.984		-	-
Endpoint (g/ha):		768 g a.i./ha* (<i>Aphidius rhopalosiphi</i>) extended laboratory; 2D						
TER acceptability criterion:		5						
Buffer zone (m)					TER			
1					39.3	-	-	-
5					76.9	-	-	-
Risk mitigation measures:			none					

PER: predicted environmental rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger
 * Value derived from an extended laboratory test with the Formulation VVH 86 086 (680 g a.i./l)

Table 9.7-2: Assessment of the risk for non-target arthropods in off-field habitats due to the use of BELOUKHA GARDENin use 002, considering risk mitigation measures

Active substance/product:		Pelargonic acid						
Intended use:		002						
Application parameters:		1** x 9000 g a.i./ha						
MAF:		1						
Scenario, drift percentile:		Gardening, plants < 50 cm, 90%-ile						
2D/3D correction factor:		5						
Buffer zone (m)	Spray drift		Deposition following volatilisation		PER _{off-field} ; conventional and drift-reducing technique			
	(%)	(g/ha)	(%)	(g/ha)	0 % red.	50 % red.	75 % red.	90 % red.
					(g/ha)			
1	0.42	7.56	0.518	9.328	16.888	-	-	-
5	0.02	0.36	0.417	7.502	7.862	-	-	-

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Endpoint (g/ha):	768 g a.i./ha* (<i>Aphidius rhopalosiphi</i>) extended laboratory; 2D			
TER acceptability criterion:	5			
Buffer zone (m)	TER			
1	45.5	-	-	-
5	97.7	-	-	-
Risk mitigation measures:	none			

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

* Value derived from an extended laboratory test with the Formulation VVH 86 086 (680 g a.i./l)

** As the DT50 of Pelargonic acid is 3d, one application is used in the risk assessment assuming an interval of 6 months between the intended 2 applications

9.7.2.2 Additional higher-tier risk assessment

Not relevant.

9.7.3 Overall conclusions

TER values for non-target arthropods in off-field habitats were calculated, taking into account the relevant toxicity data for Pelargonic acid and calculated exposure concentrations in off-field habitats, according to the intended uses 001, 002 and 003 of the product BELOUKHA GARDEN. The calculated TER values do achieve the acceptability criterion $TER \geq 5$ (extended toxicity database) for effects on non-target arthropods, according to agreed EU Guidance in Document SANCO/10329/2002 rev 2 (as modified by specific German guidance) that overrides the prescriptions of Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.4. The results of the assessment indicate an acceptable risk for non-target arthropods in off-field habitats due to the intended uses 001, 002 and 003 of BELOUKHA GARDEN according to the label.

Consequences for authorisation

None

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Please refer to the core assessment

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) 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).

Exposure assessment

In the German exposure assessment, the considered soil layer depth is based on experimental data.³ Generally, a soil layer depth of 2.5 cm is applied in the calculation for active substances with a $K_{f,oc} < 500$, whereas a soil layer depth of 1 cm is applied for active substances with a $K_{f,oc} > 500$. A soil bulk density of 1.5 g/cm³ is assumed as in the core assessment.

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for Pelargonic acid.

In the context of risk envelope approach, the use on paths and open areas with tree growth to control weed (Intended use 001) is considered as a worst-case with 4 applications and a minimum interval of 2 weeks.

Table 9.7-1: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of BELOUKHA GARDEN for all intended uses.

Intended use	All uses		
Acute effects on earthworms			
Product/active substance	LC ₅₀ (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _a (criterion TER ≥ 10)
Pelargonic acid	>1600	31.23	51

TER values shown in bold fall below the relevant trigger.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

TER values for earthworms were calculated, taking into account the relevant toxicity data for Pelargonic acid and calculated exposure concentrations in soil, according to the intended uses of the BELOUKHA GARDEN. The calculated TER values do achieve the acceptability criterion $TER \geq 10$ for acute effects on earthworms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5. The results of the assessment indicate an acceptable risk for earthworms due to the intended uses of BELOUKHA GARDEN according to the label.

Consequences for authorisation

None

³ 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

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9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Please refer to the core assessment.

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

Please refer to above for the predicted environmental concentrations in soil (PEC_{SOIL}) of BELOUKHA GARDEN and Pelargonic acid.

Table 9.9-1: Assessment of the risk for effects on soil micro-organisms due to the use of BELOUKHA GARDEN for all intended uses.

Intended use	All uses		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg a.i./kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Pelargonic acid	100 (at 28 d)*	31.23	yes
C-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg a.i./kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Pelargonic acid	100 (at 41 d)*	31.23	yes

*Value derived from a test with the formulation VVH 86 086 (680 g a.i./l)

9.9.3 Overall conclusions

Concentrations of Pelargonic acid in soil were determined where effects on nitrogen and carbon mineralisation processes remained ≤ 25 % and were compared to calculated exposure concentrations in soil, according to the intended uses of the product BELOUKHA GARDEN. The comparison indicates no exceedance of the acceptability criterion ≤ 25 % effects on soil microorganisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.6. The results of the assessment indicate an acceptable risk for soil microorganisms due to the intended uses of BELOUKHA GARDEN according to the label.

Consequences for authorisation

None

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9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

Please refer to the core assessment.

9.10.2 Risk assessment

A risk assessment according to the recommendations of the “Guidance Document on Terrestrial Ecotoxicology” (SANCO/10329/2002) is documented in the core assessment. For authorisation in Germany, a modified off-field risk assessment is relevant that takes into account the possible additional exposure route via volatilisation with subsequent deposition and addresses the availability of specific national risk mitigation measures.⁴

For the basic toxicity data set with values for 6 plant species, an acceptability criterion $TER \geq 10$ is used in the risk assessment for national authorisations in Germany. This takes account for the lack of information on chronic effects from the standard tests as well as the great diversity of the plant realm, for which the test species stand as representatives. Due to a tendency towards large fields and intensive farming, plant biocoenoses in the German agricultural landscape typically have to be considered as highly vulnerable; hence, a high level of safety is required in the risk assessment to ensure that the legally defined protection goal is met.

Table 9.10-1: Assessment of the risk for non-target terrestrial plants due to the use of BELOUKHA GARDEN in use 001/003, considering risk mitigation measures

Active substance/product:		Pelargonic acid						
Intended use:		001/003						
Application parameters:		4 x 11250 g a.i./ha						
MAF:		2.7						
Scenario, drift percentile:		Gardening, plants < 50 cm						
Interception (off-crop):		0%						
Buffer zone (m)	Spray drift		Deposition following volatilisation		PER _{off-field} ; conventional and drift-reducing technique			
	(%)	(g/ha)	(%)	(g/ha)	0 % red.	50 % red.	75 % red.	90 % red.
					(g/ha)			
1	0.13	39.371	0.518	58.302	97.673	-	-	-
5	0.01	3.029	0.417	46.889	49.918	-	-	-
Endpoint (g/ha):		3862 g a.i./ha; <i>Cucumis sativus</i> ; Vegetative vigor*						
TER acceptability criterion:		10						
Buffer zone (m)					TER			
1					39.5	-	-	-

⁴ Füll et al., UWSF (11) 145-149 (1999), Prüfanforderungen des Umweltbundesamtes zur Bewertung der Auswirkungen von Pflanzenschutzmitteln auf terrestrische Pflanzen.

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5	77.4	-	-	-
Risk mitigation measures:	none			

PER: predicted environmental rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger
 * Value derived from an extended laboratory test with the Formulation VVH 86 086 (680 g a.i./l)

Table 9.10-2: Assessment of the risk for non-target terrestrial plants due to the use of BELOUKHA GARDEN in use 002, considering risk mitigation measures

Active substance/product:		Pelargonic acid							
Intended use:		002							
Application parameters:		1** x 9000 g a.i./ha							
MAF:		1							
Scenario, drift percentile:		Gardening, plants < 50 cm, 90%-ile							
Interception (off-crop):		0%							
Buffer zone (m)	Spray drift		Deposition following volatilisation		PER_{off-field}; conventional and drift-reducing technique				
	(%)	(g/ha)	(%)	(g/ha)	0 % red.	50 % red.	75 % red.	90 % red.	
					(g/ha)				
1	0.42	37.8	0.518%	46.641	84.441	-	-	-	
5	0.02	1.8	0.417%	37.512	39.312	-	-	-	
Endpoint (g/ha):		3862 g a.i./ha; <i>Cucumis sativus</i> ; Vegetative vigor*							
TER acceptability criterion:		10							
Buffer zone (m)					TER				
1					45.7	-	-	-	
5					98.2	-	-	-	
Risk mitigation measures:		none							

PER: predicted environmental rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger
 * Value derived from an extended laboratory test with the Formulation VVH 86 086 (680 g a.i./l)

** As the DT50 of Pelargonic acid is 3d, one application is used in the risk assessment assuming an interval of 6 month between the intended 2 applications

9.10.3 Overall conclusions

TER values for non-target terrestrial plants were calculated, taking into account the relevant toxicity data for Pelargonic acid and calculated exposure concentrations in off-field habitats, according to the intended uses 001, 002 and 003 of the product BELOUKHA GARDEN. The calculated TER values do achieve TER ≥ 10 for effects on non-target plants, according to agreed EU Guidance in Document SANCO/10329/2002 rev 2 (as modified by specific German guidance) that insofar amends Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended uses 001, 002 and 003 of BELOUKHA GARDEN according to the label.

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Consequences for authorisation

None

9.11 Classification and Labelling

9.11.1 National labelling and conditions of use

Table 9.116-1 Labelling requirements according to § 36 (3) PflSchG

NW 262	Pelargonic acid <i>Pseudokirchneriella subcapitata</i> . EyC50 = 0.66 mg/L _(mm)
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