REGISTRATION REPORT
Part A

Risk Management

Product Code:	**VVH 86 086**
Tradename:	**BELOUKHA**
Active Substance:	**680 g/L NONANOIC ACID (EC)**
	(CAS No.112-05-0)

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: AT

NATIONAL ASSESSMENT

Applicant:	**Belchim Crop Protection**
Submission date:	**12/08/2015**
Finalisation date:	**13/04/2018**

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of BELOUKHA containing pelargonic acid (nonanoic 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 Section 5 and 6. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to BELOUKHA where that data has not been considered in the EU review. Otherwise assessments for the safe use of BELOUKHA 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.

Appendix 1 should include the authorisation of the final product in Germany.

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

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 the herbicide BELOUKHA (code VVH 86 086), an emulsifiable concentrate (EC) containing 680 g/L Nonanoic acid, intended for professional use on vines and potatoes.

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 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 was claimed regarding information supporting the registration of Beloukha, it is indicated in the reference lists of the respective documents of the Registration Report.

1.5 Letters of Access

No LoA was needed.

2 Details of the authorisation

2.1 Product identity

Product Name	BELOUKHA (VVH 86 086)
Authorization Number (for re-registration)	008528-00/00
Function	Herbicide
Applicant	JADE
Composition	680 g/L pelargonic acid / nonanoic acid
Formulation type	Emulsifiable concentrate [EC]
Packaging	10 L bottles f-HDPE

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

No longer proposed.

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:

Hazard classes and categories:	
Skin Irrit. 2, Eye Dam. 1, Aquatic Chronic 2	
Hazard pictograms:	
GHS05	corrosion
GHS07	exclamation mark
GHS09	environment
Signal word:	
Danger	
Hazard statements:	
H315	Causes skin irritation.
H318	Causes serious eye damage.
H411	Toxic to aquatic life with long lasting effects
Precautionary statemtents:	
Not proposed by zRMS Germany, to be decided by applicant	
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.
P308+P313	IF exposed or concerned: Immediately call a POISON CENTER or a doctor/physician.
P391	Collect spillage.
P501	Dispose of contents/container to …

Special rule for labelling of PPP:	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	

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 prod-ucts" of the Federal Office of Consumer Protection and Food Safety (www.bvl.bund.de) must be observed.
SB166	Do not eat, drink or smoke when using this product.
SE110	Wear tight fitting eye protection when handling the undiluted 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.
SS110-1	Protective gloves (plant protection) must be worn when handling the undiluted product.
SS206	Working clothes (if no specific protective suit is required) and sturdy footwear (e.g. rubber boots) must be worn when applying/handling plant protection products.
SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.
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	
WH 9161 use 001	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 use 001	The product has no sustainable effect.
Ecosystem protection	
NW605-1 use 002	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*". Drift reduction by 90% * 75 % * 50% 5 m
NW606 use 002	The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters - except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro. Buffer zone of 10 m
NW609-1 uses 001 and 003	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water-bearing surface waters - the product must be applied observing the minimum buffer zone stated below. It is not necessary to observe this buffer zone if the product is applied using equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended. Irrespective of this, in addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times. Violations may be punished by fines of up to 50 000 EUR. Buffer zone of 5 m
NT101 uses 001 and 003	In a strip at least 20 m wide which is adjacent to other areas, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 50 % (except agriculturally or horticulturally used areas, roads, paths and public places). Loss reducing equipment is not required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide or the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures.

NT109 use 002	A buffer zone of at least 5 m must be kept from adjacent areas (except agriculturally or horticulturally used areas, roads, paths and public places). In addition, in an adjoining strip of at least 20 m, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 90 %. Neither loss reducing equipment nor a buffer zone of at least 5 m are required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide. A buffer zone of at least 5 m is also unnecessary if the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures, or if evidence can be shown that adjacent areas (e.g. field boundaries, hedges, groups of woody plants) were planted on agriculturally or horticulturally used areas.

2.3 Product uses

Reg.-No.: **008528-00/00** **GAP rev. 2, date: 2018-01-24**
PPP (product name/code): **BELOUKHA (VVH 86 086)** **Formulation type:** **EC (a, b)**
Active substance: **Pelargonsäure** **Conc. of as:** **680 g/L (c)**
Applicant: **JADE** **Professional use:** **Yes**
Zone(s): **central (d)** **Non-professional use:** **No**
Verified by MS: **Yes** **Field of use:** **Herbicide**

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:**
					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		e.g. g safener/synergist per ha (f)
001*	DE	grape vine (VITVI) utilisation as table and wine grape	F	annual monocotyledonous weeds (TTTMS), annual dicotyledonous weeds (TTTDS)	spraying	during growing season, for 10-15 cm height of weeds BBCH 00-77	a) 2 b) 2	2 to 4 week(s)	a) 16 L/ha b) 32 L/ha	a) 10.88 L/ha b) 21.76 kg/ha	200 - 400	F***	WH 9161 WW730
002**	DE	grape vine (VITVI) utilisation as table and wine grape	F	stump shoot (STOCKT) (BBCH 14-16)	spraying row treatment / trunk treatment / with screen	BBCH 11-65	a) 2 b) 2	15 to 21 days	a) 16 L/ha b) 32 L/ha	a) 10.88 L/ha b) 21.76 kg/ha	200 - 400	F	WH 9161 WW730
003	DE	potato (SOLTU)	F	haulm killing (YKRAU)	spraying (splitting-2 applications)	before harvest, after haulm stripping BBCH 81-91	a) 2 b) 2	5 to 7 days	a) 16 L/ha b) 32 L/ha	a) 10.88 L/ha b) 21.76 kg/ha	200 - 400	F	WH 9161 WW730

*The zRMS concluded as follows: "The presented data are not sufficient for a major pest in a major crop in the concerned member states."
**According to the zRMS, use No. 002 was only allowed in accordance with Article 51, because of insufficient data. Therefore, an authorization according to Article 29 is not possible in DE. So the application for use No. 002 has been reinterpreted in DE. It is removed from this application and dealt with in a separate authorization in accordance with Article 51 (GV3 008528-00/01).
*** The PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product and the use of the product (e. g. harvest) or the setting of a PHI in days is not required resp.

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 86 086 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 above 345 °C and a flash point of 131 °C. In 1% aqueous dilution, it has a pH value around 3.5. The plant protection product when packed in fluorinated HDPE bottles was found to be stable after accelerated storage for two weeks at 54 °C, one week at 0 °C and 2 years at ambient temperature. 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.

The investigations of the physical and chemical properties have shown that VVH 86 086 (BELOUKHA) meets the general requirements for an EC-formulation according to the FAO specifications. This indicates that no particular problems are to be expected if the preparation is used as recommended.

Implications for labelling: Due to the emulsion characteristics the following sentence shall be added to the use instructions:
“Spritzflüssigkeit unter ständigem Rühren ausbringen“ (Leave stirrer on during application).

Compliance with FAO guidelines:
The product Beloukha complies with the general requirements for EC formulations according to the FAO/WHO manual (2016).

Compatibility of mixtures:
No tank mixtures are recommended.

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 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 / Method 3 (Derivatisation)

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)

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.
As a result of the German assessment no additional evaluation is regarded necessary to cover the national situation. For further details please refer to the registration report of the zonal RMS AT.

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

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

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

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 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 BELOUKHA 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 NONANOIC ACID is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended uses of BELOUKHA 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 ≥ 0.1 µg/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:

None

3.1.5.3 Predicted Environmental Concentration in Surface Water (PECSW) (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 (PECAir) (Part B, Section 5, Point 9.9)

The vapour pressure at 20 °C of the active substance NONANOIC ACID is > 10^{-4} Pa. Hence the active substance NONANOIC ACID is regarded 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.

Implications for labelling resulting from environmental fate assessment:
none

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

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

Please refer to the core assessment.

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

The product BELOUKHA and the active substance pelargonic acid are toxic for aquatic organisms (pelargonic acid: *Anabaena flos-aquae* ErC_{50} of 3.0 mg a.i./L (65.5% w/w) corresponding to 4.6 mg form./L). 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.

In agreement with the German modelling scheme TERs are calculated for all relevant exposure routes; i.e. entry by spraydrift, run-off and drainage. Regarding the entry pathways run-off and drainage, calculation is based on the model Exposit 3.01. The regulatory endpoint for the risk to aquatic organisms is the ErC_{50} of 3.0 mg a.i./L for *Anabaena flos-aquae*, the relevant TER is 30.
For spray drift due to the use of BELOUKHA in vines for debudding (use 001), the calculated TER value for the active substance pelargonic acid will only exceed the trigger, if a buffer zone of 5 m is applied. Using spraying equipment with drift reduction, the minimum buffer zones stipulated by state law must be observed (**NW609-1**).

Assessment of the risk for aquatic organisms due to the use of BELOUKHA in vines (001) – exposure to entries of pelargonic acid via spray drift and volatilisation/deposition, considering risk mitigation measures

Active substance/product:			Pelargonic acid					
Intended use:			001					
Application parameters:			2 x 10880 g/ha, interval 14 d					
DisT$_{50}$ water phase (SFO):			3 d					
Scenario, drift percentile:			arable crops **, 82%-ile					
PEC type:			PECini/PECact					
Buffer zone (m)	**Spray drift**		**Deposition following volatilisation**		**PEC$_{sw}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**(µg/L)**	**(%)**	**(µg/L)**	**(µg/L)**			
3	2.38	89.713	0.518	18.751	108.464	63.607	41.179	27.722
5	0.47	17.716	0.417	15.080	32.797	23.939	19.510	16.852
Endpoint (µg/L) and AF:			ErC50 : 3.0 mg a.i./L$_{(mm)}$, (*Anabaena flos aquae)* AF: 30					
Buffer zone (m)					**TER / PEC**			
3					**27.7**	47.2	72.9	108.2
5					91.5	125.3	153.8	178.0
Risk mitigation measures:			**NW609-1 (50% - *m; 75% - *m; 90% - *m; Conv. – 5 m)**					

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger; AF: Assessment factor; * Value derived from a test with the formulation VVH 86 087 (500 g a.i./L); **scenario arable crops was used because the intended use is weed control in vines

For spray drift due to the use of BELOUKHA in vines against weeds (use 002), the calculated TER value for the active substance pelargonic acid will only exceed the trigger, if a buffer zone of 10 m or at least 50% drift reduction and a buffer zone of 5 m is applied. Using spraying equipment with drift reduction, the minimum buffer zones stipulated by state law must be observed (**NW605 and NW606**).

Assessment of the risk for aquatic organisms due to the use of BELOUKHA in vines (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:	2 x 10880 g/ha, interval 15 d							
DisT$_{50}$ water phase (SFO):	3 d							
Scenario, drift percentile:	Vines, 82%-ile							
PEC type:	PECini/PECact							
Buffer zone (m)	**Spray drift**		**Deposition following volatilisation**		**PEC$_{sw}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**(µg/L)**	**(%)**	**(µg/L)**	**(µg/L)**			
3	7.23	270.402	0.465	16.761	287.163	151.962	84.361	43.801
5	3.22	120.428	0.417	15.031	135.459	75.245	45.138	27.074
10	1.07	40.018	0.318	11.448	51.466	31.457	21.453	15.450
Endpoint (µg/L) and AF:	ErC50 : 3.0 mg a.i./L$_{(mm)}$, (*Anabaena flos aquae)* AF: 30							
Buffer zone (m)					**TER / PEC**			
3					**10.4**	**19.7**	35.6	68.5
5					**22.1**	39.9	66.5	110.8
10					58.3	95.4	139.8	194.2
Risk mitigation measures:	**NW605-1/606 (50% - 5m; 75% - *m; 90% - *m; Conv. – 10m)**							

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger; AF: Assessment factor; * Value derived from a test with the formulation VVH 86 087 (500 g a.i./L)

For spray drift due to the use of BELOUKHA in potatoes (use 003), the calculated TER value for the active substance pelargonic acid will only exceed the trigger, if a buffer zone of 5 m is applied. Using spraying equipment with drift reduction, the minimum buffer zones stipulated by state law must be observed (**NW609-1**).

Assessment of the risk for aquatic organisms due to the use of BELOUKHA in potatoes (003) exposure to entries of Pelargonic acid via spray drift and volatilisation/deposition, considering risk mitigation measures

Active substance/product:			Pelargonic acid					
Intended use:			003					
Application parameters:			2 x 10880 g/ha, interval 5 d					
DisT$_{50}$ water phase (SFO):			3 d					
Scenario, drift percentile:			arable crops, 82%-ile					
PEC type:			PECini/PECact					
Buffer zone (m)	**Spray drift**		**Deposition following volatilisation**		**PEC$_{sw}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**(µg/L)**	**(%)**	**(µg/L)**	**(µg/L)**			
1	2.38	113.502	0.518	18.751	132.253	75.502	47.126	30.101
5	0.47	22.414	0.417	15.080	37.495	26.288	20.684	17.322
Endpoint (µg/L) and AF:			ErC50 : 3.0 mg a.i./L$_{(mm)}$, (*Anabaena flos aquae)* AF: 30					
Buffer zone (m)					**TER / PEC**			
1					**22.7**	39.7	63.7	99.7
5					80.0	114.1	145.0	173.2
Risk mitigation measures:			**NW609-1 (50% - *; 75% - *m; 90% - *m; Conv. – 5m)**					

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger; AF: Assessment factor; * Value derived from a test with the formulation VVH 86 087 (500 g a.i./L)

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. Considering run-off and drainage, no risk is posed by water entering surface water bodies.

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

Bees

Toxicity

The toxicity data on the effects of Nonanoic acid on bees submitted by JADE in the framework of the Annex II dossier are summarized in Table 3.1.6.3-1. An acute oral and contact toxicity study was conducted on bees exposed to VVH 86 086 (product containing 680 g/L Nonanoic 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 Nonanoic 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 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 LD_{50} value (µg a.s./bee). Using the maximum recommended application rates 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 values for *Apis mellifera* exposed to Nonanoic acid

Species	Test material	Uses	Application rate [g a.s./ha]	LD_{50} [µg a.s./bee]	HQ_O	Trigger
Apis mellifera	VVH 86 086	vines, potatoes	10 880	> 226	< 48.1	50

The hazard quotient is below 50 for use on vines and potatoes, indicating an acceptable risk to bees for these uses.

The hazard quotient for contact exposure (HQ_C) is calculated by dividing the single dose (application rate, g a.s./ha) by the contact LD_{50} value (µg a.s./bee). Using the maximum recommended application rates and the results of the acute contact toxicity study to bees (Table 3.1.6.3-1) the contact exposure HQ_C values for bees are calculated (Table 3.1.6.3-3).

Table 3.1.6.3-3: HQ_C values for *Apis mellifera* exposed to Nonanoic acid

Species	Test material	Uses	Application rate [g a.s./ha]	LD_{50} [µg a.s./bee]	HQ_C	Trigger
Apis mellifera	VVH 86 086	vines, potatoes	10 880	> 210.7	< 51.6	50

The hazard quotient is slightly above 50 for all uses. However, as the true LD_{50}-value for the HQ_C of VVH 86 086 is less than 51.6 and the true LD_{50}-value is higher than 210.7 µg a.s./bee, the product is considered virtually non-toxic to bees.

Overall conclusion

The product is considered virtually non-toxic to bees, it does not pose an unacceptable risk to honeybees. Label NB6641 is granted 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 of the product BELOUKHA in potatoes and vines. 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 use of BELOUKHA in potatoes and vines according to the label.

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

Earthworms

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 BELOUHA in vines and potatoes. The calculated TER values do achieve the acceptability criterion TER ≥ 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 use of BELOUKHA in vines and potatoes according to the label.

Effects on other soil non-target macro-organisms

Not required since the DT_{90} of pelargonic acid is largely below 100 days, that means that this active substance is not persistent. Moreover, the risk to non-target arthropods, earthworms and micro-organisms is acceptable.

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

No special studies regarding the effects of the formulation on organic matter breakdown were submitted. Earthworms, other soil non-target macro and mesofauna as well as soil organisms are involved in the breakdown of dead organic matter. Since the risk for these groups of organisms is considered acceptable, no effects on organic matter breakdown are expected.

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 mineralization processes remained ≤ 25 % and were compared to calculated exposure concentrations in soil, according to the intended uses of the product BELOUKHA in vines and potatoes. 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 use of BELOUKHA in vines and potatoes 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

The product BELOUKHA and the active substance pelargonic acid are toxic for non-target terrestrial plants (pelargonic acid: *Cucumis sativus* vegetative vigor = 3862 g a.i./ha*)*. Concerning the use of BELOUKHA in vines for debudding (use 001), the resulting TER value for the active substance pelargonic acid will only exceed the relevant trigger of 10 if spraying equipment with 50 % drift reduction is used. Therefore, the condition of use **NT101** (50 % drift reduction) is assigned.

Assessment of the risk for non-target terrestrial plants due to the use of BELOUKHA in vines (001) considering risk mitigation measures

Active substance/product:			**Pelargonic acid**					
Intended use:			001					
Application parameters:			2 x 10880 g a.i./ha, interval 14 d					
MAF:			1.7					
Scenario, drift percentile:			arable crops*; 82%- ile					
Interception (off-crop):			0 %					
Buffer zone (m)	**Spray drift**		**Deposition following volatilisation**		**$PER_{off-field}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**(g/ha)**	**(%)**	**(g/ha)**	**(g/ha)**			
3	2.38%	450.512	0.518%	56.253	506.765	281.509	168.881	101.304
5	0.47%	88.967	0.417%	45.241	134.208	89.725	67.483	54.138
Endpoint (g/ha):			3862 g a.i./ha; *Cucumis sativus*; Vegetative vigor					
TER acceptability criterion:			10					
Buffer zone (m)					**TER**			
3					**7.6**	13.7	22.9	38.1
5					28.8	43.0	57.2	71.3
Risk mitigation measures:			**NT101**					

PER: predicted environmenral rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger; *scenario arable crops was used because the intended use is weed control in vines

Concerning the use of BELOUKHA in vines against weeds (use 002), the resulting TER value for the active substance pelargonic acid will only exceed the relevant trigger of 10 if spraying equipment with 90 % drift reduction and a buffer zone of 5 m is used. Therefore, the condition of use **NT109** (90 % drift reduction + 5 m buffer zone) is assigned.

Assessment of the risk for non-target terrestrial plants due to the use of BELOUKHA in vines (002), considering risk mitigation measures

Active substance/product:			**Pelargonic acid**					
Intended use:			002					
Application parameters:			2 x 10880 g a.i./ha, interval 15 d					
MAF:			1.7					
Scenario, drift percentile:			vines 82%- ile					
Interception (off-crop):			0 %					
Buffer zone (m)	**Spray drift**		**Deposition following volatilisation**		**PER$_{off-field}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**(g/ha)**	**(%)**	**(g/ha)**	**(g/ha)**			
3	7.23%	1368.573	0.465%	50.283	1418.855	734.569	392.426	187.140
5	3.22%	609.516	0.417%	45.094	654.610	349.852	197.473	106.045
Endpoint (g/ha):			3862 g a.i./ha; *Cucumis sativus*; Vegetative vigor					
TER acceptability criterion:			10					
Buffer zone (m)					**TER**			
3					2.7	5.3	9.8	20.6
5					5.9	11.0	19.6	36.4
Risk mitigation measures:			**NT109**					

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

Concerning the use of BELOUKHA in potatoes (use 003), the resulting TER value for the active substance pelargonic acid will only exceed the relevant trigger of 10 if spraying equipment with 50 % drift reduction is used. Therefore, the condition of use **NT101** (50 % drift reduction) is assigned.

Assessment of the risk for non-target terrestrial plants due to the use of BELOUKHA in vines (003), considering risk mitigation measures

Active substance/product:			**Pelargonic acid**					
Intended use:			003					
Application parameters:			2 x 10880 g a.i./ha, interval 5 d					
MAF:			1.7					
Scenario, drift percentile:			Arable crops 82%- ile					
Interception (off-crop):			0 %					
Buffer zone (m)	**Spray drift**		**Deposition following volatilisation**		**PER$_{off-field}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**(g/ha)**	**(%)**	**(g/ha)**	**(g/ha)**			
1	2.38%	450.512	0.518%	56.253	506.765	281.509	168.881	101.304
5	0.47%	88.967	0.417%	45.241	134.208	89.725	67.483	54.138
Endpoint (g/ha):			3862 g a.i./ha; *Cucumis sativus*; Vegetative vigor					
TER acceptability criterion:			10					
Buffer zone (m)					**TER**			
1					7.6	13.7	22.9	38.1
5					28.8	43.0	57.2	71.3
Risk mitigation measures:			**NT101**					

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

Other non-target species (Flora and Fauna)

No data available

Implications for labelling resulting from ecotoxicological assessment:

See chapter 2.2.

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

Information on the active substance

Nonanoic acid also named pelargonic acid is a fatty acid belonging to the C7-C20 group. After application of nonanoic acid on the plant tissues, the active substance removes plant cuticle and then disrupts normal cell membrane permeability. Uncontrolled leakage of cell content occurs. The cells collapse leading to death of the plant tissue (HRAC classification: Z).

Label WMZ is issued.

Because of this mode of action, nonanoic acid is a broad spectrum, non-persistent, non-systemic, contact herbicide with a fast action.

Efficacy

Use No. 001: Weed control in vine

The EPPO requirements are not fulfilled for a major pest in a major crop.

Use No. 002: Sucker control in vine

Agreement, that 4 trials with 16 l/ha are not sufficient for a major use.

Use No. 003: Potato haulm killing

According to the zRMS the minimum effective dose for haulm killing in potato with mandatory preceding mechanical haulm stripping seems to be 16 l/ha. Whereas the 1st application of 16 l/ha reaches sufficient control 21 DAA (≥ 98%), the 2nd application reaches sufficient control already 7 DAB (≥93%). Therefore, a 2nd application after mechanical stripping seems to be necessary for a total leaf and stem destruction in potato. Accordingly, the application technique is amended into "splitting (2 treatments)".

Possible development of resistance or cross-resistance

The overall risk of resistance for VVH 86087 is considered to be medium at current knowledge.

Adverse effects on treated crops

Use No. 001: Weed control in vine

The number of selectivity trials (4n) does not seem to be sufficient for a major use (EPPO PP 1/226, 8 selectivity trials required). The EPPO demands for a major use are not fulfilled.

Use No. 002: Sucker control in vine

The number of selectivity trials (2n) does not seem to be sufficient for a major use (EPPO PP 1/226). The EPPO demands for a major use are not fulfilled.

Use No. 003: Potato haulm killing

According to EPPO PP 1/143 Potato desiccants, observations on tubers (effects on quality) should be made as well as effects on germination (when product is used on seed potato crops) should be evaluated.
Effects on tubers will be discussed in chapter "Effects on yield on treated plants or plant products".

Effects on yield on treated plants or plant products

Use No. 001 and 002: Grapevine

According to EPPO PP 1/226, the number of harvested selectivity trials (weed control in grapevine) does not seem to be sufficient for a major use.

Use No. 003: Potato haulm killing

In total, 3 trials were provided for processing purpose of potatoes. At harvest, collected potatoes were subject to yield and dry matter measurement. No detrimental effect of VVH 86 086 could be observed, compared to a reference product (yield and dry matter content).

No detrimental effects were observed for quantitative yield testing.

The impact on quality parameters of yield/tuber quality (stem-end browning, browning of vascular ring, tuber weight loss, sprouts weight, sprouts length, sprouts number, starch content and dry matter content) was assessed in 27 trials. No detrimental effects of VVH 86 086 were observed for qualitative yield testing in potato.

Impact on the quality of plants and plant products/transformation processes

In total, 3 trials (FR, 2011) were carried out to assess effects of VVH 86 086 on transformation processes (Sensory test, culinary test). VVH 86 086 applied at 16 L/ha did not cause any significant modifications of the potato flavours, significant modifications regarding the disintegration of potatoes after cooking, blackening of potatoes, unacceptable colouring of potatoes after frying in comparison to the reference product.

It can be concluded that VVH 86 086 does not have any negative effect on the processing procedure.

Impact on treated plants or plant products to be used for propagation
On potato, no phytotoxic effect of VVH 86 086 on potato tubers was reported in the efficacy trials. No adverse effect on parts of plant used for propagating purposes is thus expected on potato.

Impact on succeeding crops
The zRMS concluded that VVH 86 086 will not have any adverse effect on succeeding crops when used according to Good Agricultural Practices.

Impact on other plants including adjacent crops
According to the zRMS the risk for non-target crops due to spray drift exposed to 16 l/ha is acceptable. Nevertheless, the applicant recommends avoiding spray drift to adjacent crops, which is however, considered to be good agricultural practice.

Adverse effects on beneficial arthropods (other than bees).
In the case of *Typhlodromus pyri* the LR50 was as low as 9 % of the maximum field rate, indicating high risk for predatory mites and spiders.
In the parasitoid wasp *Aphidius rhopalosiphi* the LR50 was as low as 4 % of the maximum application rate, indicating high risk to beneficial insects. However, repopulation of treated areas by *A. rhopalosiphi* was possible after 3 weeks.
Label warnings NN3001 and NN3002 are imposed 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 regard to efficacy/IPM and sustainable use including protection of honey bees and beneficial arthropods an authorization cannot be granted for uses 001 and 002, because efficacy data is insufficient. For use 001 the zRMS concluded that the presented data are not sufficient for a major pest in a major crop in the concerned member states and authorization is not granted in DE. Use 002 was only allowed in accordance with Article 51 by the zRMS, because of insufficient data. Therefore, an authorization according to Article 29 is not possible in DE. That is why the application for use 002 has been reinterpreted. It is removed from this application and dealt with in a separate authorization in accordance with Article 51 (GV3 008528-00/01). An authorization according to Article 29 can be granted for use 003 as BELOUKHA (VVH 86 086) was sufficiently effective for haulm killing in potatoes.

With respect to fate and ecotoxicology assessment, an authorisation can be granted. Considering an application in accordance with the evaluated use pattern and good agricultural practice as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

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

An authorisation according to Article 29 can be granted for use 003 only. Use 002 is dealt with in a separate authorization in accordance with Article 51 (GV3 008528-00/01).

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

No further information is required.

Appendix 1 – Copy of the product authorisation

See below.

Appendix 2 – Copy of the product label

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 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.

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

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

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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.008528-00/00.132244
(bitte bei Antwort angeben)

DATUM 8. Mai 2018

ZV3 008528-00/00

BELOUKHA

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit dem Wirkstoff:	680 g/l	Pelargonsäure
Zulassungsnummer:	008528-00	
Versuchsbezeichnungen:	BBL-86086-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):

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008528-00/00-003	Krautabtötung	Kartoffel	Speise-, Wirtschafts- und Industriekartoffeln

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 PflSchG sind für das Pflanzenschutzmittel die nachfolgend näher beschriebenen Verpackungen für den beruflichen Anwender zugelassen:

Verpackungs-art	Verpackungs-material	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Flasche	HDPE, fluoriert	1	72	10,00		l

Die Verpackungen für den beruflichen Anwender sind wie folgt zu kennzeichnen:
Anwendung nur durch berufliche Anwender zulässig.

Auflagen

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

Kennzeichnungsauflagen:

(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.

(SE110)
Dicht abschließende Schutzbrille tragen beim Umgang mit dem unverdünnten Mittel.

(SF245-02)
Es ist sicherzustellen, dass behandelte Flächen/Kulturen erst nach dem Abtrocknen des

Pflanzenschutzmittelbelages wieder betreten werden.

(SS110-1)
Beim Umgang mit dem unverdünnten Mittel sind Schutzhandschuhe (Pflanzenschutz) zu tragen.

(SS206)
Arbeitskleidung (wenn keine spezifische Schutzkleidung erforderlich ist) und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln.

(SS2101)
Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen beim Umgang mit dem unverdünnten Mittel.

(VA551)
Spritzflüssigkeit unter ständigem Rühren ausbringen.

(WMZ)
Wirkungsmechanismus (HRAC-Gruppe): Z

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

Sonstige Auflagen:

(WH952)
Auf der Verpackung und in der Gebrauchsanleitung ist die Angabe zur Kennzeichnung des Wirkungsmechanismus als zusätzliche Information direkt jedem entsprechenden Wirkstoff-namen 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:

(S2) Gefahr

Gefahrenpiktogramme:

(GHS05) Ätzwirkung

(GHS07) Ausrufezeichen

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(H315)

Verursacht Hautreizungen.

(H318)

Verursacht schwere Augenschäden.

(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.

(P308+P310)

BEI Exposition oder falls betroffen: Sofort GIFTINFORMATIONSZENTRUM oder Arzt anrufen.

(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):

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008528-00/00-001	Einjährige einkeim-blättrige Unkräuter, Einjährige zweikeim-blättrige Unkräuter	Weinrebe	Nutzung als Tafel- und Keltertraube

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
Die Anwendung 008528-00/00-002 wurde vom zRMS Österreich nach Art. 51 der Verordnung (EG) Nr. 1107/2009 zugelassen. Dies beruhte auf einer unzureichenden Datenlage im Bereich der Wirksamkeit. Auch im cMS Deutschland ist deswegen eine Zulassung nach Art. 29 der Verordnung (EG) Nr. 1107/2009 nicht möglich. Ausnahmsweise wurde der Antrag für die Anwendung 008528-00/00-002 umgedeutet. Diese Anwendung wird nun in einem separaten Zulassungsverfahren nach Art. 51 der Verordnung (EG) Nr. 1107/2009 geprüft (GV3 008528-00/01-001). Diese ausnahmsweise durchgeführte Umdeutung beruht darauf, dass der cMS Deutschland erst von der Änderung der Antragsart erfuhr, als der finale Bewertungsbericht und die Zulassung des zRMS eintrafen. Allein im vorliegenden Fall (008528-00/00-002) meldete sich der Antragsteller und bat um die Umdeutung des Antrags.

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: 008528-00/00-003

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Krautabtötung
Pflanzen/-erzeugnisse/Objekte:	Kartoffel
Verwendungszweck:	Speise-, Wirtschafts- und Industriekartoffeln

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	81 bis 91
Anwendungszeitpunkt:	Vor der Ernte, nach vorherigem Krautschlagen
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	5 bis 7 Tage
Anwendungstechnik:	spritzen
- Erläuterungen:	im Splittingverfahren (2 Behandlungen)
Aufwand:	
- Zeitpunkt 1:	16 l/ha in 200 bis 400 l Wasser/ha
- Zeitpunkt 2:	16 l/ha in 200 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(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.

2.3 Wartezeiten

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

3 Anwendungsbezogene Anwendungsbestimmungen

(NT101)
Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 50 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.
Begründung:
Wie vom erstbewertenden Mitgliedsstaat im core assessment ausgeführt, ist der Schutz von terrestrischen Nichtzielpflanzen bei Anwendung des o.g. Pflanzenschutzmittels zu beachten. Für die Festsetzung geeigneter Maßnahmen in Deutschland ist die EC50 von 3862 g a.i./ha für Cucumis sativus im vegetative vigour Test in Verbindung mit einem Sicherheitsfaktor von 10 heranzuziehen. Ausgehend von den in Deutschland geltenden Modellen zur Abdrift sowie zur Verflüchtigung von Zielflächen und anschließender Deposition (hier: EVA 3) ist nach dem Stand der wissenschaftlichen Erkenntnis die für das Risikomanagement in Deutschland etablierte o.g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen vor Auswirkungen des Wirkstoffs zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 9, Kapitel 9.10).

(NW609-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mindestens mit unten genanntem Abstand erfolgen. Dieser Abstand muss nicht eingehalten werden, wenn die Anwendung mit einem Gerät erfolgt, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Unabhängig davon ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu 50.000 Euro geahndet wer-

den.
5 m
Begründung:
Wie vom erstbewertenden Mitgliedsstaat im core assessment ausgeführt, ist der Schutz von Gewässerorganismen bei Anwendung des o.g. Pflanzenschutzmittels zu beachten. Für die Festsetzung geeigneter Maßnahmen in Deutschland ist abweichend von der Bewertung durch den erstzulassenden Mitgliedsstaat die ErC50 für Anabaena flos-aquae von 3000 µg a.i./L mit einem Sicherheitsfaktor von 30 heranzuziehen. Ausgehend von den in Deutschland geltenden Modellen zur Abdrift sowie zur Verflüchtigung von Zielflächen und anschließender Deposition (hier: EVA 3) und unter Berücksichtigung der vom erstbewertendem Mitgliedsstaat angegebenen charakteristischen Eigenschaften des Wirkstoffs sind nach dem Stand der wissenschaftlichen Erkenntnis die für das Risikomanagement in Deutschland etablierte o.g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 9, Kapitel 9.5).

Anlage 2 nicht zugelassene Anwendung: 008528-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Einjährige einkeimblättrige Unkräuter, Einjährige zweikeimblättrige Unkräuter
Pflanzen/-erzeugnisse/Objekte:	Weinrebe
Verwendungszweck:	Nutzung als Tafel- und Keltertraube

2 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Weinbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	00 bis 77
Anwendungszeitpunkt:	Während der Vegetationsperiode, bei 10-15 cm Unkrauthöhe
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	2 bis 4 Woche(n)
Anwendungstechnik:	spritzen
Aufwand:	
-	16 l/ha in 200 bis 400 l Wasser/ha

3 Begründung

Wirksamkeit/Nachhaltigkeit
Der zRMS kommt zu der Schlussfolgerung: "The presented data are not sufficient for a major pest in a major crop in the concerned member states. Furthermore there are no results after a second application as requested in the GAP. The EPPO requirements for a major use are not fulfilled."
Der Einschätzung des zRMS wird gefolgt.

REGISTRATION REPORT

Part B

Section 5

Environmental Fate

Detailed summary of the risk assessment

Product code: VVH86 086

Product name(s): BELOUKHA

Chemical active substance:

NONANOIC ACID 680 g/L

Central Zone

Zonal Rapporteur Member State: Austria

NATIONAL ADDENDUM – GERMANY

(authorisation)

Applicant: Jade

Submission date: August 2016

MS Finalisation date: March 2018

Version history

When	What
29.03..2018	Updated Risk Assessment
13.04.2018	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 BELOUKHA in its intended uses in Vineyard and Potatoes is documented in detail in the core assessment of the plant protection product BELOUKHA dated from August 2016 performed by Austria.
This national addendum has been produced to support a national decision on the authorisation of the product BELOUKHA 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 BELOUKHA 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
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)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					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			Groundwater
Intended for uses in Germany														
001	DE	Vineyard	F	Annual monocotyledonous and dicotyledonous weeds	Spraying	BBCH 00-77	a) 1 to 2 applications per use (14 – 15 days) b) 1 to 2 applications per year	14	a) 16 L/ha per application b) 32 L/ha per year	a) 10 880 g/ha b) 21 760 g/ha	200 L to 300 L			
002	DE	Vineyard	F	Vine suckering or debudding	Spraying	BBCH 11-65	a) 1 to 2 applications per use (15 – 21 d) b) 1 to 2 applications per year	15	a) 16 L/ha per application b) 32 L/ha per year	a) 10 880 g/ha b) 21 760 g/ha	150 L to 250 L			
003	DE	Potatoes	F	Potato Haulm killing	Spraying	BBCH 81 to 91	a) 1 to 2 application per use b) 1 to 2 applications per year	5	a) 16 L/ha per application b) 32 L/ha per year	a) 10 880 g/ha b) 21 760 g/ha	150 L to 500 L			

* 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 BELOUKHA 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 ≥ 0.1µg/L in the intended uses of BELOUKHA 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 ≥ 0.1 µg/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 BELOUKHA 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 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.

8.2 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 (July 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 (August 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 (August 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 (August 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 (August 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 (August 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 (August 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 (August 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 BELOUKHA and its intended uses in vineyards and potatoes 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 (DT_{90} < 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 use in vineyards and potatoes (weed control) following 2 applications with 10880 g a.s./ha is the worst-case scenario, leading to the highest initial PECsoil values when considering no foliar interception (38.152 mg a.s./kg soil).

Table 8.7-2: Results of PEC_{soil} calculation for the intended use in vineyards and potatoes accordimg to German risk assessment

Plant protection product:	BELOUKA
Use:	001
Number of applications/interval (d):	2/ 14

[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

Application rate (g as/ha):		Nonanoic Acid: 10880				
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	10880	2.5	30.155	5	-	-
Use:		002				
Number of applications/interval (d):		2/ 15				
Application rate (g as/ha):		10880				
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	10880	2.5	29.92	5	-	-
Use:		003				
Number of applications/interval (d):		2/ 5				
Application rate (g as/ha):		10880				
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	10880	2.5	38.152	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 intended uses of BELOUKHA in vineyards and potatoes 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 ≥ 0.1µg/L in the groundwater Scenario Hamburg relevant for authorisation in Germany in the intended uses of BELOUKA in vineyards and potatoes. That result covers the groundwater risk assessment for the intended uses of BELOUKA in Germany in vineyards and potatoes 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 BELOUKHA for PEC_{gw} and PEC_{sw} calculations with EXPOSIT 3.01

Use No.	001	002	003
Crop	vineyard	vineyard	potatoes
Application rate (g as/ha)	NONANOIC ACID: 10880	NONANOIC ACID: 10880	NONANOIC ACID: 10880
Number of applications/interval (d)	2/ 14	2/ 15	2/ 5

Crop interception (%)	0*	0*	0*

* worst case assumption

8.8.3.1 NONANOIC ACID

Table 8.8-2: Input parameters for NONANOIC ACID used for PEC_{gw} calculations with EXPOSIT 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 ≥ 0.1 µg/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 BELOUKHA 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 PECsw 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 90^{th} percentile of the drift values. For multiple applications, lower percentiles of the drift values for each application are applied, resulting in an overall 90^{th} percentile of drift probabilities. Only one volatilization event following the last use of pesticide is generally considered.

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

Use No.:	001	002	003
Number of applications/ interval:	2/ 14	2/ 15	2/ 5
Drift scenario/ Crop	arable crops	vine*	arable crops
Application rate (g a.s./ha)	NONANOIC ACID: 10880	NONANOIC ACID: 10880	NONANOIC ACID: 10880

*worst case scenario, suckering or debudding of vine requires the direct treatment of the vine plants up to 1 meter.

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 semivolatile (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 BELOUKHA related to the application used for PEC_{sw} calculations with Exposit 3 are summerised in Table 8.8-1.

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 chapter 8.8.3 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 (July 2016) part B, section 5, point IIIA 9.9. Significant volatilization is not expected to occur, especially since the estimated DT_{50} 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 86 086

Product name: BELOUKHA

Chemical active substance:

NONANOIC ACID, 680 g/L

Central Zone

Zonal Rapporteur Member State: Austria

National Addendum

Germany

(authorisation)

Applicant: Jade

Submission date: August 2016

MS Finalisation date: March 2018

Version history

When	What
29.03..2018	Updated Risk Assessment
13.04.2018	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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9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
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)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**						
					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			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro-	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
001	DE	Vineyard	F	Annual monocotyledonous and dicotyledonous weeds	Spraying	BBCH 00-77	a) 1 to 2 applications per use (14 – 15 days) b) 1 to 2 applications per year	5	a) 16 L/ha per application b) 32 L/ha per year	a) 10 880 g/ha b) 21 760 g/ha	200 L to 300 L			A	A	R		R	A	R
002	DE	Vineyard	F	Vine suckering or debudding	Spraying	BBCH 11-65	a) 1 to 2 applications per use (15 – 21 d) b) 1 to 2 applications per year	15	a) 16 L/ha per application b) 32 L/ha per year	a) 10 880 g/ha b) 21 760 g/ha	150 L to 250 L			A	A	R		R	A	R
003	DE	Potatoes	F	Potato Haulm killing	Spraying	BBCH 81 to 91	a) 1 to 2 application per use		a) 16 L/ha per application b) 32 L/ha	a) 10 880 g/ha b) 21 760	150 L to 500 L		1 to 2 applications could be made after	A	A	R		A	A	R

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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
							b) 1 to 2 applications per year		per year	g/ha			mechanical grinding							

* 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 – 21 "Conclusion"

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

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/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 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 001, 002 and 003 of the product BELOUKHA in vines and potatotes. The calculated TER values do achieve the accept-ability criterion the adjusted criterion TER ≥30 for effects on aquatic organisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.2, provided that risk miti-gation measures (spray drift reduction) are applied. The results of the assessment indicate an ac-ceptable risk for aquatic organisms due to the intended use of BELOUKHA in vines and potatoes 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 of the product BELOUKHA in vines. The calculated TER values do achieve the acceptability criterion TER ≥ 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, provided that risk mitigation measures (spray drift reduction) are applied. The results of the assessment indicate an acceptable risk for non-target arthropods in off-field habitats due to the intended use of BELOUKHA in vines according to the label.

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 of the product BELOUKHA in potatoes. The calculated TER values do achieve the acceptability criterion TER ≥ 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 use of BELOUKHA in potatoes 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 in vines and potatoes. The calculated TER values do achieve the acceptability criterion TER ≥ 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 use of BELOUKHA in vines and potatoes according to the label.

Concentrations of Pelargonic acid in soil were determined where effects on nitrogen and carbon mineralisation processes remained ≤ 25 % and were compared to calculated exposure concentra-tions in soil, according to the intended uses of the product BELOUKHA in vines and potatoes. The comparison indicates no exceedance of the acceptability criterion ≤ 25 % effects on soil microor-ganisms, 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 intend-ed use of BELOUKHA in vines and potatoes 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 of the product BELOUKHA in vines and potatoes. The calculated TER values do achieve the acceptability criterion 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, pro-vided that risk mitigation measures (spray drift reduction) are applied. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of BELOUKHA in vines and potatoes according to the label.

9.1.2 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 VVH 86 087 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.

Selection of relevant toxicity endpoint

The relevant endpoint chosen by the zRMS was the EyC50 of 9.56 mg a.i./L in an study with *Anabaena flos-aquae* by Kuhl, R. and Wydra, V. (2014). 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 assessement. Deviating from the assessment of the zRMS, Germany uses the ErC50 of 3.0 mg a.i./L (65.5% w/w) corresponding to 4.6 mg form./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:
RAC = (ErC 50 / EF 3) / AF 10 → ErC 50 / 30

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

Active substance/product:			Pelargonic acid					
Intended use:			001					
Application parameters:			2 x 10880 g/ha, interval 14 d					
DisT$_{50}$ water phase (SFO):			3 d					
Scenario, drift percentile:			arable crops **, 82%-ile					
PEC type:			PECini/PECact					
Buffer zone (m)	**Spray drift**		**Deposition following volatilisation**		**PEC$_{sw}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**(µg/L)**	**(%)**	**(µg/L)**	**(µg/L)**			
3	2.38	89.713	0.518	18.751	108.464	63.607	41.179	27.722
5	0.47	17.716	0.417	15.080	32.797	23.939	19.510	16.852
10	0.24	9.047	0.318	11.486	20.532	16.009	13.747	12.390
15	0.16	6.031	0.242	8.748	14.779	11.763	10.256	9.351
20	0.12	4.523	0.184	6.663	11.186	8.924	7.793	7.115
Endpoint (µg/L) and AF:			ErC50 : 3.0 mg a.i./L$_{(mm)}$, (*Anabaena flos aquae)* AF: 30					
Buffer zone (m)					**TER / PEC**			
3					**27.7**	47.2	72.9	108.2
5					91.5	125.3	153.8	178.0
10					146.1	187.4	218.2	242.1
15					203.0	255.0	292.5	320.8
20					268.2	336.2	384.9	421.7
Risk mitigation measures:			**NW 609 (50% - *m; 75% - *m; 90% - *m; Conv. – 5 m)**					

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger; AF: Assessment factor; * Value derived from a test with the formulation VVH 86 087 (500 g a.i./L); **scenario arable crops was used because the intended use is weed control in vines

Table 9.5-2: Assessment of the risk for aquatic organisms due to the use of BELOUKHA in vines (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:	2 x 10880 g/ha, interval 15 d							
DisT$_{50}$ water phase (SFO):	3 d							
Scenario, drift percentile:	Vines, 82%-ile							
PEC type:	PECini/PECact							
Buffer zone (m)	**Spray drift**		**Deposition following volatilisation**		**PEC$_{sw}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**(µg/L)**	**(%)**	**(µg/L)**	**(µg/L)**			
3	7.23	270.402	0.465	16.761	287.163	151.962	84.361	43.801
5	3.22	120.428	0.417	15.031	135.459	75.245	45.138	27.074
10	1.07	40.018	0.318	11.448	51.466	31.457	21.453	15.450
15	0.56	20.944	0.242	8.719	29.663	19.191	13.955	10.814
20	0.36	13.464	0.184	6.641	20.105	13.373	10.007	7.987
Endpoint (µg/L) and AF:	ErC50 : 3.0 mg a.i./L$_{(mm)}$, (*Anabaena flos aquae)* AF: 30							
Buffer zone (m)					**TER / PEC**			
3					**10.4**	**19.7**	35.6	68.5
5					**22.1**	39.9	66.5	110.8
10					58.3	95.4	139.8	194.2
15					101.1	156.3	215.0	277.4
20					149.2	224.3	299.8	375.6
Risk mitigation measures:	**NW 605/606 (50% - 5m; 75% - *m; 90% - *m; Conv. – 10m)**							

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger; AF: Assessment factor; * Value derived from a test with the formulation VVH 86 087 (500 g a.i./L)

Table 9.5-3: Assessment of the risk for aquatic organisms due to the use of BELOUKHA in potatoes (003) – exposure to entries of Pelargonic acid via spray drift and volatilisation/deposition, considering risk mitigation measures

Active substance/product:	Pelargonic acid							
Intended use:	003							
Application parameters:	2 x 10880 g/ha, interval 5 d							
DisT$_{50}$ water phase (SFO):	3 d							
Scenario, drift percentile:	arable crops, 82%-ile							
PEC type:	PECini/PECact							
Buffer zone (m)	**Spray drift**		**Deposition following volatilisation**		**PEC$_{sw}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**(µg/L)**	**(%)**	**(µg/L)**	**(µg/L)**			
1	2.38	113.502	0.518	18.751	132.253	75.502	47.126	30.101
5	0.47	22.414	0.417	15.080	37.495	26.288	20.684	17.322
10	0.24	11.446	0.318	11.486	22.931	17.208	14.347	12.630
15	0.16	7.630	0.242	8.748	16.378	12.563	10.655	9.511
20	0.12	5.723	0.184	6.663	12.385	9.524	8.093	7.235
Endpoint (µg/L) and AF:	ErC50 : 3.0 mg a.i./L$_{(mm)}$, (*Anabaena flos aquae)* AF: 30							
Buffer zone (m)					**TER / PEC**			
1					**22.7**	39.7	63.7	99.7
5					80.0	114.1	145.0	173.2
10					130.8	174.3	209.1	237.5
15					183.2	238.8	281.5	315.4
20					242.2	315.0	370.7	414.7
Risk mitigation measures:	**NW 609 (50% - *; 75% - *m; 90% - *m; Conv. – 5m)**							

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger; AF: Assessment factor; * Value derived from a test with the formulation VVH 86 087 (500 g a.i./L)

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 9.5-4: Assessment of the risk for aquatic organisms due to the use of BELOUKHA in vines (001) – exposure to entries of Pelargonic acid via run-off or drainage, considering risk mitigation measures

Active substance:	Pelargonic acid	
Intended use	001	
Application parameters:	2 x 10880 g/ha, interval 14 d	
Endpoint (µg/L) and AF:	ErC50 : 3.0 mg a.i./$L_{(mm)}$, (*Anabaena flos aquae)* AF: 30	
Run-off		
Buffer zone (m)	**PEC (µg/L)**	**TER / PEC**
0	32.84	91.36
5	28.46	105.41
10	24.39	122.98
20	17.08	175.69
Drainage		
Time of application	**PEC (µg/L)**	**TER / PEC**
Spring/summer	17.67	169.79
Autumn/winter	54.37	55.18
Risk mitigation measures:	none	

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger; AF: Assessment factor; * Value derived from a test with the formulation VVH 86 087 (500 g a.i./L)

Table 9.5-5: Assessment of the risk for aquatic organisms due to the use of BELOUKHA in vines (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:	2 x 10880 g/ha, interval 15 d	
Endpoint (µg/L) and AF:	ErC50 : 3.0 mg a.i./$L_{(mm)}$, (*Anabaena flos aquae)* AF: 30	
Run-off		
Buffer zone (m)	**PEC (µg/L)**	**TER / PEC**
0	32.58	92.08
5	28.24	106.24
10	24.20	123.95
20	16.94	177.07
Drainage		
Time of application	**PEC (µg/L)**	**TER / PEC**
Spring/summer	17.53	171.12

Autumn/winter	53.94	55.61
Risk mitigation measures:	none	

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger; AF: Assessment factor; * Value derived from a test with the formulation VVH 86 087 (500 g a.i./L)

Table 9.5-6: Assessment of the risk for aquatic organisms due to the use of BELOUKHA in potatoes (003) – exposure to entries of Pelargonic acid via run-off or drainage, considering risk mitigation measures

Active substance:	Pelargonic acid	
Intended use	003	
Application parameters:	2 x 10880 g/ha, interval 5 d	
Endpoint (µg/L) and AF:	ErC50 : 3.0 mg a.i./$L_{(mm)}$, (*Anabaena flos aquae)* AF: 30	
Run-off		
Buffer zone (m)	**PEC (µg/L)**	**TER / PEC**
0	41.55	72.21
5	36.01	83.32
10	30.86	97.21
20	21.60	138.87
Drainage		
Time of application	**PEC (µg/L)**	**TER / PEC**
Spring/summer	22.35	134.20
Autumn/winter	68.78	43.62
Risk mitigation measures:	none	

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger; AF: Assessment factor; * Value derived from a test with the formulation VVH 86 087 (500 g a.i./L)

9.5.3 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 001, 002 and 003 of the product BELOUKHA in vines and potatotes. The calculated TER values do achieve the acceptability criterion the adjusted criterion TER ≥30 for effects on aquatic organisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.2, provided that risk mitigation measures (spray drift reduction) are applied. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of BELOUKHA in vines and potatoes according to the label.

Consequences for authorisation

For the authorisation of the plant protection product BELOUKHA, labelling and conditions of use are mandatory as follows:

Table 9.5-7 Labelling requirements according to § 36 (3) PflSchG

NW 262	VVH 86 087; Pelargonic acid *Pseudokirchneriella subcapitata.* EyC50 = 0.66 mg/L

Table 9.5-8 Mandatory conditions of use according to § 36 (1) PflSchG for the protection of aquatic organisms (002)

NW 605/606	Drift-reduction technique– corresponding buffer zone: 50% - 5m; 75% - *m; 90% - *m; Conv. – 10m

Table 9.5-9 Mandatory conditions of use according to § 36 (1) PflSchG for the protection of aquatic organisms (001/003)

NW 609	Drift-reduction technique– corresponding buffer zone: 50% - *; 75% - *m; 90% - *m; Conv. – 5m

9.6 Effects on bees (KCP 10.3.1)

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

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 VVH 86 087in 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).

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

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 hedgerows[2] 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.

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

Active substance/product:	Pelargonic acid							
Intended use:	001							
Application parameters:	2 x 10880 g a.i./ha, interval 14 d							
MAF:	1.7							
Scenario, drift percentile:	Vines 82%-ile							
2D/3D correction factor:	5							
Buffer zone (m)	**Spray drift**		**Deposition following volatilisation**		**$PER_{off-field}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**(g/ha)**	**(%)**	**(g/ha)**	**(g/ha)**			
3	7.23	273.715	0.465	10.057	283.771	146.914	78.485	37.428
5	3.22	121.903	0.417	9.019	130.922	69.970	39.495	21.209
Endpoint (g/ha):	768 g a.i./ha (*Aphidius rhopalosiphi*) extended laboratory; 2D							
TER acceptability criterion:	5							
Buffer zone (m)					**TER**			
3					**2.7**	5.2	9.8	20.5
5					5.9	11.0	19.4	36.2
Risk mitigation measures:	**NT 104 (50% - *m; 75% - *m; 90% - *m; Conv. – 5m)**							

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

[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.

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

Active substance/product:	Pelargonic acid							
Intended use:	002							
Application parameters:	2 x 10880 g a.i./ha, interval 15 d							
MAF:	1.7							
Scenario, drift percentile:	Vines 82%-ile							
2D/3D correction factor:	5							
Buffer zone (m)	**Spray drift**		**Deposition following volatilisation**		**$PER_{off-field}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**(g/ha)**	**(%)**	**(g/ha)**	**(g/ha)**			
3	7.23	273.715	0.465	10.057	283.771	146.914	78.485	37.428
5	3.22	121.903	0.417	9.019	130.922	69.970	39.495	21.209
Endpoint (g/ha):	768 g a.i./ha (*Aphidius rhopalosiphi*) extended laboratory; 2D							
TER acceptability criterion:	5							
Buffer zone (m)					**TER**			
3					**2.7**	5.2	9.8	20.5
5					5.9	11.0	19.4	36.2
Risk mitigation measures:	**NT 104 (50% - *m; 75% - *m; 90% - *m; Conv. – 5m)**							

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

Table 9.7-3: Assessment of the risk for non-target arthropods in off-field habitats due to the use of BELOUKHA in vines (003), considering risk mitigation measures

Active substance/product:	Pelargonic acid							
Intended use:	003							
Application parameters:	2 x 10880 g a.i./ha, interval 5 d							
MAF:	1.7							
Scenario, drift percentile:	Arable crops 82%-ile							
2D/3D correction factor:	5							
Buffer zone (m)	**Spray drift**		**Deposition following volatilisation**		**$PER_{off-field}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**(g/ha)**	**(%)**	**(g/ha)**	**(g/ha)**			
1	2.38	90.102	0.518	11.251	101.353	56.302	33.776	20.261
5	0.47	17.793	0.417	9.048	26.842	17.945	13.497	10.828

Endpoint (g/ha):	768 g a.i./ha (*Aphidius rhopalosiphi*) extended laboratory; 2D			
TER acceptability criterion:	5			
Buffer zone (m)	**TER**			
1	7.6	13.6	22.7	37.9
5	28.6	42.8	56.9	70.9
Risk mitigation measures:	none			

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

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 of the product BELOUKHA in vines. The calculated TER values do achieve the acceptability criterion TER ≥ 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, provided that risk mitigation measures (spray drift reduction) are applied. The results of the assessment indicate an acceptable risk for non-target arthropods in off-field habitats due to the intended use of BELOUKHA in vines according to the label.

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 of the product BELOUKHA in potatoes. The calculated TER values do achieve the acceptability criterion TER ≥ 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 use of BELOKHA in potatoes according to the label.

Consequences for authorisation

Fore use No.: 003 (Potato Haulm killing): None

For the authorisation of the plant protection product BELOUKHA uses 001 and 002, conditions of use are mandatory as follows:

Table 9.7-4 Mandatory conditions of use according to § 36 (1) PflSchG for the protection of non-target arthropods (001/002)

NT 104	(50% - *m; 75% - *m; 90% - *m; Conv. – 5m)

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

9.8.1 Toxicity data

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

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.

Table 9.8-1: 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 in vines (001)

Intended use	Vines (weed control; two applications)		
Acute effects on earthworms			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
VVH 86 086	908	38.125	24

TER values shown in bold fall below the relevant trigger.

Table 9.8-2: 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 in vines (002)

Intended use	Vines (desiccation; two applications)		
Acute effects on earthworms			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
VVH 86 086	908	29.92	30

[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

TER values shown in bold fall below the relevant trigger.

Table 9.8-3: 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 in potatoes (003)

Intended use	Potatoes (two applications)		
Acute effects on earthworms			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
VVH 86 086	908	38.152	24

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 BELOUHA in vines and potatoes. The calculated TER values do achieve the acceptability criterion TER ≥ 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 use of BELOUKHA in vines and potatoes according to the label.

Consequences for authorisation

None

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

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

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 (PECSOIL) of BELOUKHA and Pelargonic acid.

Table 9.9-1: Assessment of the risk for effects on soil micro-organisms due to the use of BELOUKHA in vines (001)

Intended use	Vines (weed control, two applications)		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg a.i./kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
VVH 86 086	100 (at 28 d)	38.152	yes
C-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg a.i./kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
VVH 86 086	100 (at 41 d)	38.152	yes

Table 9.9-1: Assessment of the risk for effects on soil micro-organisms due to the use of BELOUKHA in vines (002)

Intended use	Vines (dessication, two applications)		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg a.i./kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
VVH 86 086	100 (at 28 d)	29.92	yes
C-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg a.i./kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
VVH 86 086	100 (at 41 d)	29.92	yes

Table 9.9-3: Assessment of the risk for effects on soil micro-organisms due to the use of BELOUKHA in potatoes (003)

Intended use	Potatoes (two applications)		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg a.i./kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
VVH 86 086	100 (at 28 d)	38.152	yes
C-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg a.i./kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
VVH 86 086	100 (at 41 d)	38.152	yes

9.9.3 Overall conclusions

Concentrations of Pelargonic acid in soil were determined where effects on nitrogen and carbon minerali-

sation processes remained ≤ 25 % and were compared to calculated exposure concentrations in soil, according to the intended uses of the product BELOUKHA in vines and potatoes. 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 use of BELOUKHA in vines and potatoes according to the label.

Consequences for authorisation

None

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

9.10.1 Toxicity data

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

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 addi-tional exposure route via volatilisation with subsequent deposition and addresses the availability of specific national risk mitigation measures.

For the basic toxicity data set with values for 6 plant species, an acceptability criterion TER ≥ 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 con-sidered as highly vulnerable; hence, a high level of safety is required in the risk assessment to en-sure 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 in vines (001) considering risk mitigation measures

Active substance/product:			**Pelargonic acid**					
Intended use:			001					
Application parameters:			2 x 10880 g a.i./ha, interval 14 d					
MAF:			1.7					
Scenario, drift percentile:			arable crops*; 82%- ile					
Interception (off-crop):			0 %					
Buffer zone (m)	**Spray drift**		**Deposition following volatilisation**		**PER$_{off-field}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**(g/ha)**	**(%)**	**(g/ha)**	**(g/ha)**			
3	2.38%	450.512	0.518%	56.253	506.765	281.509	168.881	101.304
5	0.47%	88.967	0.417%	45.241	134.208	89.725	67.483	54.138
Endpoint (g/ha):			3862 g a.i./ha; *Cucumis sativus*; Vegetative vigor					
TER acceptability criterion:			10					
Buffer zone (m)					**TER**			
3					**7.6**	13.7	22.9	38.1
5					28.8	43.0	57.2	71.3
Risk mitigation measures:			**NT 101 (50% - *m; 75% - *m; 90% - *m; Conv. – 5m)**					

PER: predicted environmenral rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger; *scenario arable crops was used because the intended use is weed control in vines

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

Active substance/product:			**Pelargonic acid**					
Intended use:			002					
Application parameters:			2 x 10880 g a.i./ha, interval 15 d					
MAF:			1.7					
Scenario, drift percentile:			vines 82%- ile					
Interception (off-crop):			0 %					
Buffer zone (m)	**Spray drift**		**Deposition following volatilisation**		**PER$_{off-field}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**(g/ha)**	**(%)**	**(g/ha)**	**(g/ha)**			
3	7.23%	1368.573	0.465%	50.283	1418.855	734.569	392.426	187.140
5	3.22%	609.516	0.417%	45.094	654.610	349.852	197.473	106.045

Endpoint (g/ha):	3862 g a.i./ha; *Cucumis sativus*; Vegetative vigor			
TER acceptability criterion:	10			
Buffer zone (m)	**TER**			
3	2.7	5.3	9.8	20.6
5	5.9	11.0	19.6	36.4
Risk mitigation measures:	**NT 109 (50% - 5 m; 75% - 5m; 90% - *m; Conv – insufficient)**			

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

Table 9.10-3: Assessment of the risk for non-target terrestrial plants due to the use of BELOUKHA in vines (003), considering risk mitigation measures

Active substance/product:	**Pelargonic acid**							
Intended use:	003							
Application parameters:	2 x 10880 g a.i./ha, interval 5 d							
MAF:	1.7							
Scenario, drift percentile:	Arable crops 82%- ile							
Interception (off-crop):	0 %							
Buffer zone (m)	**Spray drift**		**Deposition following volatilisation**		**$PER_{off-field}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**(g/ha)**	**(%)**	**(g/ha)**	**(g/ha)**			
1	2.38%	450.512	0.518%	56.253	506.765	281.509	168.881	101.304
5	0.47%	88.967	0.417%	45.241	134.208	89.725	67.483	54.138
Endpoint (g/ha):	3862 g a.i./ha; *Cucumis sativus*; Vegetative vigor							
TER acceptability criterion:	10							
Buffer zone (m)	**TER**							
1	7.6	13.7	22.9	38.1				
5	28.8	43.0	57.2	71.3				
Risk mitigation measures:	**NT 101 (50% - *m; 75% - *m; 90% - *m; Conv. – 5m)**							

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

9.10.3 Overall conclusions

9.10.4 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 of the product BELOUKHA in vines and potatoes. The calculated TER values do achieve the acceptability criterion 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, provided that risk mitigation measures (spray drift reduction) are applied. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of BELOUKHA in vines and potatoes according to the label.

Consequences for authorisation

For the authorisation of the plant protection product BELOUKHA, conditions of use are mandatory as follows:

Table 9.10-4 Mandatory conditions of use according to § 36 (1) PflSchG for the protection of non-target terrestrial plants (002)

NT 109	(50% - 5 m; 75% - 5m; 90% - *m)

Table 9.10-5 Mandatory conditions of use according to § 36 (1) PflSchG for the protection of non-target terrestrial plants (001/003)

NT 101	(50% - *m; 75% - *m; 90% - *m; Conv. – 5m)

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

No data available

9.12 Monitoring data (KCP 10.8)

No data available

9.13 Classification and Labelling

9.13.1 National labelling and conditions of use

Table 9.13-1 Labelling requirements according to § 36 (3) PflSchG

NW 262	VVH 86 087; Pelargonic acid *Pseudokirchneriella subcapitata.* EyC50 = 0.66 mg/L

Table 9.13-2 Mandatory conditions of use according to § 36 (1) PflSchG (002)

NT 109	Drift-reduction technique– corresponding buffer zone: 50% - 5 m; 75% - 5m; 90% - *m
NW 605/606	Drift-reduction technique– corresponding buffer zone: 50% - 5m; 75% - *m; 90% - *m; Conv. – 10m

Table 9.13-1 Mandatory conditions of use according to § 36 (1) PflSchG (001/003)

NT 101	Drift-reduction technique– corresponding buffer zone 50% - *m; 75% - *m; 90% - *m; Conv. – 5m
NW 609	Drift-reduction technique– corresponding buffer zone: 50% - *; 75% - *m; 90% - *m; Conv. – 5m