

REGISTRATION REPORT

Part A

Risk Management

Product code: VVH 86 087

Product name(s): Beloukha Garden

Chemical active substance:

Pelargonic Acid , 500 g/L

Central Zone

Zonal Rapporteur Member State: AT

NATIONAL ASSESSMENT Germany

(extension of use)

Applicant: Belchim Crop Protection NV/SA

Submission date: 09/06/2017

MS Finalisation date: 01/03/2018

Version history

When	What
February 2018	Final version of cMS DE, for the extension of use

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

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

1.2 Letters of Access

No LoA was submitted by the applicant.

1.3 Justification for submission of tests and studies

Not relevant.

1.4 Data protection claims

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

2 Details of the authorization decision

2.1 Product identity

Product code	VVH 86 087
Product name in MS	Beloukha Garden
Authorization number	008529-01
Function	herbicide
Applicant	Belchim Crop Protection
Active substance(s) (incl. content)	500 g/L pelargonic acid / nonanoic acid
Formulation type	Emulsifiable concentrate [EC]
Packaging	for non-professional users: 0.1 - 0,9 L bottle, HDPE fluorinated 25 – 75 mL tube, HDPE fluorinated
Coformulants of concern for national authorizations	none
Restrictions related to identity	none

Mandatory tank mixtures	none
Recommended tank mixtures	none

2.2 Conclusion

With respect to identity, physical, chemical and technical properties, further information and analytical methods for the formulation an authorisation can be granted.

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

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

With respect to fate and ecotoxicology assessment, an authorisation can be granted.

With respect to efficacy/IPM and sustainable use incl. protection of honey bees and beneficial arthropods an authorisation can be granted to the uses as described in the GAP-Table under chapter 2.6.

The evaluation of the application for Beloukha Garden resulted in the decision to grant the authorization for the applied extension of use.

2.3 Substances of concern for national monitoring

Not relevant.

2.4 Classification and labelling

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

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

<i>Hazard classes and categories:</i>	
Eye Irrit. 2	
<i>Hazard pictograms:</i>	
GHS07	exclamation mark
<i>Signal word:</i>	
Warning	
<i>Hazard statements:</i>	
H319	Causes serious eye irritation.
<i>Precautionary statements:</i>	
P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.
P501	Dispose of contents/container to
<i>Special rule for labelling of PPP:</i>	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

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

None.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

2.5.1 Restrictions linked to the PPP

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

Human health protection:	
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
SB005	If medical advice is needed, have product container or label at hand.
SB010	Keep out of the reach of children.
SB111	Concerning the requirements for personal protective gear for handling the plant protection product the material safety data sheet and the instructions for use of the plant protection product as well as the guideline "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety (www.bvl.bund.de) must be observed.
SB166	Do not eat, drink or smoke when using this product.
SF245-01	Treated areas/crops may not be entered until the spray coating has dried.
SE126	Wear eye protection when applying/handling the product.
SS205-1	Wear long-sleeved shirt, long trousers and sturdy footwear during handling and applying plant protection products.
VH297	Packaging/containers for use in amateur gardening must be provided with a childproof seal.
VH298	The packaging/container must be provided with a warning which can be identified by touching for home and garden use.
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.
Environmental protection	
NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

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)

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
WH9161	The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.	001
WW730	The product has no sustainable effect.	001
Environmental protection:		Relevant for use no.
NW 642-1	The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed. Violations may be punished by fines of up to 50 000 EUR	use number 001
Other specific restrictions:		Relevant for use no.
NS660-1	The product may only be applied on field areas which are not used for agricultural, forestry or horticultural purposes with the approval of the competent national authority. Such areas include all areas which are not permanently covered by buildings or roofing, including all traffic areas such as railway tracks, roads, paths, yards and business sites and other pieces of land changed by civil engineering measures. Violations may be punished by fines of up to 50 000 EUR.	use number 001
respective code if available	e.g.	use number from GAP table in 2.6

2.6 Intended uses (only NATIONAL GAP)

Reg.-No.: 008529-00/01
PPP (product name/code): BELOUKHA GARDEN
Active substance 1: Pelargonsäure
Applicant: Belchim Crop Protection NV/SA
Zone(s): central (d)
Verified by MS: Yes

GAP rev. 2, date: 2018-02-09
EC (a, b)
500 g/L (c)
No
Yes
Herbicide

Formulation type:
Conc. of as 1:
Professional use:
Non-professional use:
Field of use:

1	2	3	4	5	6		7	8	9	10	11	12	13	14
					Method / Kind	Application / Timing / Growth stage of crop & season								
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 / 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 mL/m ² min / max	PHI (days)	Remarks:			
001	DE	walks and places (YXBAM), hard and semi-permeable paths and places with trees and bushes (YMBAM), non-cultivated land without woody plants (YKOB)	Fn	annual dicotyledonous weeds (TTTDS), annual monocotyledonous weeds (TTTMS)	a) 4 b) 4	2 to 4 week(s)	a) 2.25 ml/m ² b) 9.00 mL/m ²	a) 1.25 kg/ha b) 45.00 kg/ha	20-50 mL/m ²	N*	e.g. g safener/ synergist per ha (f) Amateur gardening WH9161, WW730			

*The setting of a PHI is without any relevance.

**Non-cultivated land without woody plants (YKOB) has been canceled in accordance with the authorization of the zRMS

Remarks table heading:	<p>(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) Catalogue of pesticide formulation types and international coding system Crop Life International Technical Monograph n°2, 6th Edition Revised May 2008 g/kg or g/l</p>	<p>(d) Select relevant Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1 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.</p>
Remarks columns:	<p>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</p>	<p>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</p>

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

No new studies were submitted.

The following evaluation is taken from the base authorisation:

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

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

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

3.2 Efficacy (Part B, Section 3)

In order to support the extension of use of Beloukha Garden for the weeds control on paths and open areas, 24 efficacy trials and 7 safety trials were conducted. These trials are presented in dRR Part B3 and in the Biological Assessment Dossier. According to the zRMS the trials support the label extension. The resistance risk as well as the impact on succeeding and adjacent crops were also assessed.

3.3 Efficacy data

To determine the minimum effective dose of Beloukha Garden for the control of weeds in paths and open areas, 24 efficacy trials were set up from 2012 to 2016, in the Maritime EPPO climatic zone.

Beloukha Garden was tested at the rates 18 L/ha (80 %), 22.5 L/ha (100 %) and 27 L/ha (120 %). Beloukha Garden was applied up to four times, depending on the trials. Results demonstrated that after one, two, three or four applications:

- Beloukha Garden at 22.5 L/ha allowed a gain in efficacy in comparison to the lower rate of 18 L/ha, on a large range of weeds (dicotyledonous and grasses);
- Most of the time, no significant difference was observed between the rates of 22.5 L/ha and 27 L/ha for the control of the target weeds and thus not justify to increase the dose rate to 27 L/ha;

As a conclusion, the proposed dose of Beloukha Garden can reasonably be considered as the minimum effective dose for the control of a wide range of weeds in paths and open areas.

Furthermore, the knock-down effect was assessed in 5 trials. These trials allowed to confirm the fast action of this contact herbicide on a range of weeds representative of the non-crop areas. The spray volume effect was measured in 5 trials and the optimum spray volume of Beloukha Garden for weed control in non-crop areas ranged from 300 L/ha to 750 L/ha. However, in all effectiveness trials the product was applied with a water volume of 300 l/ha.

The extension of use was supported by 24 efficacy trials where the product Beloukha Garden was com-

pared to standard reference. The data reveal that for a lot of weed species there is only one trial available, whereas for weed species substantiated by several trials a great variation in control results/single trial results was seen.

Beloukha Garden applied at the proposed rate of 22.5 L/ha up to four times in post-emergence of the weeds provided higher control effects comparable to that of the standard references, however, far below 90 % compared to the untreated control.

With regard to perennial weed species, no long term assessments were conducted.

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

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

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

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

The zRMS concluded that the risk of resistance related to the use of Beloukha Garden for weed control can be considered as low.

As the risk of resistance is low and as maximum 4 applications per year are requested, no other management strategies are proposed.

3.3.2 Adverse effects on treated crops

Regarding the phytotoxicity to target plants, possible effects of Beloukha Garden were evaluated in 7 crop safety trials. Beloukha Garden applied up to four times at the rates of 22.5 L/ha and 45 L/ha did not show any symptom of phytotoxicity when applied on the following crops: *Thuja occidentalis*, *Buxus sempervirens*, *Rosa* sp., *Abies nordmanniana* and turf plants. In one trial, transient phytotoxicity symptom (up to 2% necrosis) was observed on *Thuja occidentalis* variety 'Columna' and disappear one month after the second application.

Beloukha Garden is used on non-agricultural areas and is not intended to be used in crops used for propagation.

3.3.3 Observations on other undesirable or unintended side-effects

The impact on succeeding crops was evaluated in three field trials where Beloukha Garden was applied on bare soil before sowing or planting other crops (lawn, garden beans, lettuce, peas and tomatoes). No negative impact was observed with Beloukha Garden and therefore, it can be concluded that Beloukha Garden will have no adverse effect on succeeding crops when used according the GAP.

The impact on adjacent crops was evaluated in 5 trials. Beloukha Garden applied at 18 L/ha is perfectly safe to adjacent crops such as lawn plants, *Rosa* sp., *Carex flaccosperma*, *Potentilla* sp., *Cotoneaster* sp. and *Chaenomeles japonica*. The impact of Beloukha Garden application on other plants including adjacent crops will depend on the quality of the spray. Regarding the use on paths and open areas with tree growth and on nursery and shrubs, users will anyway avoid any spray drift to avoid any negative impact on adjacent crops.

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

The results indicate, that short-term effects of > 50% on populations of relevant beneficial insects or relevant predatory mites and spiders might occur.
Label warnings NN3001 and NN3002 are assigned to the product.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

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

All provided analytical methods are acceptable.

3.4.2 Analytical methods for residues

No further information necessary for this application. Please refer to main application.

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected. For further details please refer to the registration report of the zonal RMS AT.

3.5.2 Operator exposure

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

3.5.3 Worker exposure

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

3.5.4 Bystander and resident exposure

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

3.6 Residues and consumer exposure (Part B, Section 7)

3.6.1 Residues

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

3.6.2 Consumer exposure

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

3.7 Environmental fate and behaviour (Part B, Section 8)

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

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

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

3.7.2 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 pelargonic acid is not expected to penetrate into groundwater at concentrations of $\geq 0.1 \mu\text{g/L}$ in the intended uses of BELOUKA GARDEN in Germany according to use No.001.

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

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

3.7.3 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 ecotoxicological risk assessment.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

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

3.8 Ecotoxicology (Part B, Section 9)

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

3.8.1 Effects on terrestrial vertebrates

Birds

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

Terrestrial vertebrates (other than birds)

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

3.8.2 Effects on aquatic species

The product BELOUKHA GARDEN and the active substances are toxic to the aquatic environment:
pelargonic acid: ErC50 :1.14 mg/L, *Pseudokirchneriella subcapitata*.

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

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

3.8.3 Effects on bees

Toxicity data

The toxicity data on the effects of pelargonic acid on bees have been submitted by JADE in the framework of the Annex II dossier. An acute oral and contact toxicity study was conducted on bees exposed to

VVH 86 086 (product containing 680 g/L pelargonic acid). The toxicity study conducted with the preparation VVH 86 086 is considered representative to properties of active substance.

Table 3.8.3-1: Toxicity values of pelargonic acid for bees

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

Hazard quotients for bees

The hazard quotient for oral exposure (HQ_O) is calculated by dividing the single dose (application rate, g a.s./ha) by the oral LD₅₀ value (µg a.s./bee). Using the maximum recommended application rate and the results of the acute oral toxicity study to bees (Table 3.8.3-1), the oral exposure HQ_O values for bees are calculated (Table 3.8.3-2).

Table 3.8.3-2: HQ_O value for *Apis mellifera* exposed to pelargonic acid

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

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

The hazard quotient for contact exposure (HQ_C) is calculated by dividing the single dose (application rate, g a.s./ha) by the contact LD₅₀ value (µg a.s./bee). Using the maximum recommended application rate and the results of the acute contact toxicity study to bees (Table 3.8.3-1) the contact exposure HQ_C value for bees is calculated (Table 3.8.3-3).

Table 3.8.3-3: HQ_C value for *Apis mellifera* exposed to pelargonic acid

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

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

Overall conclusion

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

Label NB6641 is assigned to the product.

3.8.4 Effects on other arthropod species other than bees

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

3.8.5 Effects on soil organisms

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

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

3.8.6 Effects on non-target terrestrial plants

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

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Please refer to core assessment.

3.9 Relevance of metabolites (Part B, Section 10)

Not relevant.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Pelargonic acid is not a Candidate for Substitution and therefore a national comparative assessment has not been performed.

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

None.

Appendix 1 Copy of the product authorization (see Appendix 5)

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 (EU) No 1107/2009.

Appendix 3 Letter of Access

No LoA was submitted by the applicant.

Appendix 4 Lists of data considered for national authorization

Please refer to the Austrian final RR Part B Section 3 Core Assessment of the extension of use application and the different Sections of Part B of the final RR for the original product application of Austria.

Appendix 5 Copy of the product authorization



Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.008529-00/01.194440
(bitte bei Antwort angeben)

DATUM 26. März 2018

ZV3 008529-00/01

BELOUKHA GARDEN

Zulassungsverfahren für Pflanzenschutzmittel

Ergänzungsbescheid

Die Zulassung des oben genannten Pflanzenschutzmittels

mit dem Wirkstoff: 500 g/l Pelargonsäure

Zulassungsnummer: 008529-00

Versuchsbezeichnungen: BBL-86087-H-0-EC

Antrag vom: 9. Juni 2017

ändere ich wie folgt:

Zusätzliche Anwendungsgebiete bzw. Anwendungen

Die Zulassung wird um folgende Anwendungsgebiete bzw. Anwendungen erweitert (siehe Anlage 1):

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008529-00/01-001	Einjährige zweikeimblättrige Unkräuter, Einjährige einkeimblättrige Unkräuter	Wege und Plätze, Wege und Plätze mit Holzgewächsen	

Festgesetzte Anwendungsbestimmungen

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

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

Auflagen

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

Siehe Anlage 1, jeweils unter Nr. 2.

Vorbehalt

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

Abgelehnte Anwendungsgebiete bzw. Anwendungen

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

- keine -

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

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

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Karsten Hohgardt
stellvertretender Abteilungsleiter

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

Anlage

Anlage 1 zugelassene Anwendung: 008529-00/01-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Einjährige zweikeimblättrige Unkräuter, Einjährige einkeimblättrige Unkräuter

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

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Nichtkulturland

Anwendungsbereich: Freiland

Anwendung im Haus- und

Kleingartenbereich: Ja

Anwendungszeitpunkt: Frühjahr bis Herbst, nach dem Auflaufen der Unkräuter

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 2 bis 4 Woche(n)

Anwendungstechnik: spritzen

Aufwand:

- 2,25 ml/m² in 20 bis 50 ml Wasser/m²

2.2 Sonstige Kennzeichnungsauflagen

(NS660-1)

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

(NW642-1)

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

(WH9161)

In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden, sowie eine Arten- und/oder Sortenliste der Kulturpflanzen, für die der vorgesehene Mittelaufwand verträglich oder unverträglich ist.

(WW730)

Das Mittel besitzt keine nachhaltige Wirkung.

2.3 Wartezeiten

(N) Freiland: Wege und Plätze mit Holzgewächsen
Die Festsetzung einer Wartezeit ist ohne Bedeutung.

(N) Freiland: Nichtkulturland ohne Holzgewächse
Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -