

REGISTRATION REPORT
Part A

Risk Management

Product name: Roundup Gel Max
Product code: MON 76886
Active Substances: glyphosate 72 g/L

COUNTRY: Germany
All Zones
Zonal Rapporteur Member State: United Kingdom

NATIONAL ASSESSMENT

Applicant: Monsanto Agrar Deutschland
GmbH
Submission date: 15/01/2015
Finalisation date: 23/06/2017

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of MON 76829 containing glyphosate in Germany. This evaluation is required subsequent to the inclusion of glyphosate on Annex 1.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C and where appropriate the addendum for MON 76829. 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 MON 76829 where that data has not been considered in the EU review. Otherwise assessments for the safe use of *MON 76829* have been made using endpoints agreed in the EU review of glyphosate

This document describes the specific conditions of use and labelling required for Germany for the registration of MON 76829.

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

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

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

Appendix 4 of this document provides a copy of the final product authorisation Germany. It will be inserted in the final version.

1 Details of the application

1.1 Application background

This application was submitted by Monsanto Europe SA on 15 January 2015.

MON 76829 is a new herbicide formulation (AL) developed by Monsanto and containing the glyphosate active substance which was included into Annex I Directive for glyphosate 2001/99/EC. MON 76829 has not been previously evaluated in the EU according to Uniform Principles. A full Annex III dossier is submitted for evaluation. Where appropriate, this dossier refers to the conclusions of the EU review of glyphosate. MON 76829 is similar, but more concentrated (72 g/L versus 7.2g/L glyphosate) than Roundup Gel (MON 76258) and registered in many Member States UK, France, Belgium, Luxemburg, Sweden, Norway, Netherlands, Finland, Czech Republic, Denmark, Italy, Portugal, Spain under dir. 91/414. The commercial name for MON 76829 is Roundup Gel Max.

1.2 Annex I inclusion

Glyphosate was included on Annex I of Directive 91/414/EEC on 1 July 2002 under Inclusion Directive 2001/99/EC and implemented under Regulation (EU) No 540/2011.

The Annex I Inclusion Directive for glyphosate (**2001/99/EC**) 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 of Annex VI, the conclusions of the review report on the glyphosate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29/06/2001, shall be taken into account. In this overall assessment:

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

- Protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses

These concerns were all addressed in the submission.

1.3 Regulatory approach

To obtain authorisation the product MON 76829 must meet the conditions of Annex I inclusion/approval and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed/approved end-points.

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

1.4 Data protection claims

All study reports presented in doc K and the formulation composition of Roundup Gel Max available in Part C are confidential data owned by Monsanto Europe SA and protected.

1.5 Letters of Access

Not applicable.

2 Details of the authorisation

2.1 Product identity

Product Name	Roundup Gel Max MON 76886
Authorization Number (for re-registration)	008375-00/00
Function	herbicide
Applicant	Monsanto Europe SA
Composition	72 g/L glyphosate
Formulation type	Gel for direct application [Code: GD]
Packaging	15 – 500 ml bottle with separate dosing feeder, PP

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:

<i>Hazard classes and categories:</i>	
Skin Sen. 1	
<i>Hazard pictograms:</i>	
GHS07	exclamation mark
<i>Signal word:</i>	
Warning	
<i>Hazard statements:</i>	
H317	May cause an allergic skin reaction.
<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.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P501	Dispose of contents/container to ...

<i>Special rule for labelling of PPP:</i>	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
<i>Further labelling statements under Regulation (EC) No 1272/2008:</i>	
EUH208-0196 Contains 5-chlor-2-methyl- 3(2H)isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone at the ratio of 3:1. May produce an allergic reaction.	
2,5 percent of the mixture consist of one or more substances of unknown toxicity.	

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

None

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

2.3.1 Restrictions linked to the PPP

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

Human health protection	
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
SB110	The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed.
SB166	Do not eat, drink or smoke when using this product.
SS202	Wear protective gloves when 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.
Integrated pest management (IPM)/sustainable use	
WMG	Mode of action (HRAC-group): G
NN2002	The product is classified as slightly harmful for populations of relevant beneficial predatory mites and spiders.
Ecosystem protection	
NW467	The product and its remains, empty containers and packaging and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

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

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

2.3.2 Specific restrictions linked to the intended uses

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

Integrated pest management (IPM)/sustainable use	
WH914 for uses 001-014	The instructions for use must include a summary of weeds, and if applicable woody plants, which can be controlled well, less well and insufficiently by the product.

Ecosystem protection	
NW642-1	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
NS660-1 00-003 and 00-004	The product may only be applied on field areas which are not used for agricultural, forestry or horticultural purposes with the approval of the competent national authority. Such areas include all areas which are not permanently covered by buildings or roofing, including all traffic areas such as railway tracks, roads, paths, yards and business sites and other pieces of land changed by civil engineering measures. Violations may be punished by fines of up to 50 000 EUR

2.4 Product uses

Reg.-No. 008375-00/00
PPP (product name/code): Roundup Gel Max
Active substance 1: Glyphosat
Applicant: Monsanto Agrar Deutschland GmbH
Zone(s): central (d)
Verified by MS: Yes

GAP rev.1, date: 2017-05-12
Formulation type: GD
Conc. of as 1: 72.00 g/L (c)
Professional use: No
Non-professional use: Yes
Field of use: Herbicide

1 Use- No. (e)	2 Member state(s)	3 Crop and/ or situation (crop destination / purpose of crop)	4 F, Fn, Fpn G, Gn, Gpn or I	5 Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	6 Application				10 Application rate			12 Water L/ha min / max	13 PHI (days)	14 Remarks: e.g. g safener/synergist per ha (f)
					6 Method / Kind	7 Timing / Growth stage of crop & season	8 Max. number a) per use b) per crop/ season	9 Min. interval between applications (days)	10 kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	11 g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season				
001	DE	fruit crops (NNNOO)	Fn	monocotyledonous weeds (TTTTMM), dicotyledonous weeds (TTTTDD)	wiping for selective single- plant treatment	After emergence of weeds, during growing season	a) 1 b) 2	28 days	a) 2.5 mL/m ² b) 5.0 mL/m ²	a) 1.80 kg/ha b) 3.60 kg/ha	-/	-	Amateur gardening Note on dose rate: 1 click = 0,3 ml to treat weeds with 1200 cm ² leaf area WH914 NW642-1	
002	DE	fruit crops (NNNOO)	Fn	woody plants (NNNVP), <i>Rubus fruticosus</i> (RUBFR), dicotyledonous weeds (TTTTDD), <i>Rubus fruticosus</i>	wiping for selective single- plant treatment	After emergence of weeds, during growing season	a) 1 b) 1		a) 5.0 mL/m ² b) 5.0 mL/m ²	a) 3.60 kg/ha b) 3.60 kg/ha	-/	-	Amateur gardening Note on dose rate: 2 clicks = 0,6 ml to treat weeds with 1200 cm ² leaf area WH914 NW642-1	
003	DE	non-cultivated land without woody plants (YNKOB)	Fn	monocotyledonous weeds (TTTTMM), dicotyledonous weeds (TTTTDD)	wiping for selective single- plant treatment	After emergence of weeds, during growing season	a) 1 b) 2	28 days	a) 2.5 mL/m ² b) 5.0 mL/m ²	a) 1.80 kg/ha b) 3.60 kg/ha	-/	-	Amateur gardening Note on dose rate: 1 click = 0,3 ml to treat weeds with 1200 cm ² leaf area WH914 NW642-1 NS660-1	

004	DE	non-cultivated land without woody plants (YNKOB)	Fn	woody plants (NNNVP), <i>Rubus fruticosus</i> (RUBFR), dicotyledonous weeds (TTTDD)	wiping for selective single-plant treatment	After emergence of weeds, during growing season	a) 1 b) 1		a) 5.0 mL/m ² b) 5.0 mL/m ²	a) 3.60 kg/ha b) 3.60 kg/ha	-/	-	Amateur gardening Note on dose rate: 2 clicks = 0,6 ml to treat weeds with 1200 cm ² leaf area WH914 NW642-1 NS660-1
005	DE	ornamentals (NNNZZ)	Fn	stock wood (NNNST)	wiping for selective single-plant treatment	During growing season	a) 1 b) 2	28 days	a) 2.5 mL/m ² b) 5.0 mL/m ²	a) 1.80 kg/ha b) 3.60 kg/ha	-/	-	Amateur gardening Note on dose rate: 1 click = 0,3 ml to treat stock wood with a diameter of 2-4 cm WH914 NW642-1
006	DE	vegetables (NNNVV)	Fn	monocotyledonous weeds (TTTMM), dicotyledonous weeds (TTTDD)	wiping for selective single-plant treatment	After emergence of weeds, during growing season	a) 1 b) 2	28 days	a) 2.5 mL/m ² b) 5.0 mL/m ²	a) 1.80 kg/ha b) 3.60 kg/ha	-/	-	Amateur gardening Note on dose rate: 1 click = 0,3 ml to treat weeds with 1200 cm ² leaf area WH914 NW642-1
007	DE	ornamentals (NNNZZ)	Fn	monocotyledonous weeds (TTTMM), dicotyledonous weeds (TTTDD)	wiping for selective single-plant treatment	After emergence of weeds, during growing season	a) 1 b) 2	28 days	a) 2.5 mL/m ² b) 5.0 mL/m ²	a) 1.80 kg/ha b) 3.60 kg/ha	-/	-	Amateur gardening Note on dose rate: 1 click = 0,3 ml to treat weeds with 1200 cm ² leaf area WH914 NW642-1
008	DE	vegetables (NNNVV)	Fn	woody plants (NNNVP), <i>Rubus fruticosus</i> (RUBFR), dicotyledonous weeds (TTTDD)	wiping for selective single-plant treatment	After emergence of weeds, during growing season	a) 1 b) 1		a) 5.0 mL/m ² b) 5.0 mL/m ²	a) 3.60 kg/ha b) 3.60 kg/ha	-/	-	Amateur gardening Note on dose rate: 2 clicks = 0,6 ml to treat weeds with 1200 cm ² leaf area WH914 NW642-1
009	DE	ornamentals (NNNZZ)	Fn	woody plants (NNNVP), <i>Rubus fruticosus</i> (RUBFR), dicotyledonous weeds (TTTDD)	wiping for selective single-plant treatment	After emergence of weeds, during growing season	a) 1 b) 1		a) 5.0 mL/m ² b) 5.0 mL/m ²	a) 3.60 kg/ha b) 3.60 kg/ha	-/	-	Amateur gardening Note on dose rate: 2 clicks = 0,6 ml to treat weeds with 1200 cm ² leaf area WH914 NW642-1
010	DE	lawn (NNNZW)	Fn	dicotyledonous weeds (TTTDD)	wiping for selective single-plant	After emergence of weeds, during growing	a) 1 b) 2	28 days	a) 2.5 mL/m ² b) 5.0 mL/m ²	a) 1.80 kg/ha b) 3.60 kg/ha	-/	-	Amateur gardening Note on dose rate: 1 click = 0,3 ml to treat weeds with 1200 cm ² leaf area

					treatment	season								WH914 NW642-1
011	DE	fruit crops (NNNOO)	Fn	stock wood (NNNST)	wiping for selective single- plant treatment	During growing season	a) 1 b) 2	28 days	a) 2.5 mL/m ² b) 5.0 mL/m ²	a) 1.80 kg/ha b) 3.60 kg/ha	-/	-	Amateur gardening Note on dose rate: 1 click = 0,3 ml to treat stock wood with a diameter of 2-4 cm WH914 NW642-1	
012	DE	vegetables (NNNVV)	Fn	stock wood (NNNST)	wiping for selective single- plant treatment	During growing season	a) 1 b) 2	28 days	a) 2.5 mL/m ² b) 5.0 mL/m ²	a) 1.80 kg/ha b) 3.60 kg/ha	-/	-	Amateur gardening Note on dose rate: 1 click = 0,3 ml to treat stock wood with a diameter of 2-4 cm WH914 NW642-1	
013	DE	lawn (NNNZW)	Fn	stock wood (NNNST)	wiping for selective single- plant treatment	During growing season	a) 1 b) 2	28 days	a) 2.5 mL/m ² b) 5.0 mL/m ²	a) 1.80 kg/ha b) 3.60 kg/ha	-/	-	Amateur gardening Note on dose rate: 1 click = 0,3 ml to treat stock wood with a diameter of 2-4 cm WH914 NW642-1	
014	DE	lawn (NNNZW)	Fn	woody plants (NNNVP), <i>Rubus fruticosus</i> (RUBFR), dicotyledonous weeds (TTTDD)	wiping for selective single- plant treatment	After emergence of weeds, during growing season	a) 1 b) 1		a) 5.0 mL/m ² b) 5.0 mL/m ²	a) 3.60 kg/ha b) 3.60 kg/ha	-/	-	Amateur gardening Note on dose rate: 2 clicks = 0,6 ml to treat weeds with 1200 cm ² leaf area WH914 NW642-1	

**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
g/kg or g/l
(c)

- (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)

- 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.

-
- | | |
|--|---|
| 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 | 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha). |
| 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. | 12 If water volume range depends on application equipment (e.g. ULVA or LVA) it should be mentioned under "application: method/kind". |
| 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. | 13 PHI - minimum pre-harvest interval |
| 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 | 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:

MON 76886 is a gel formulation type to be used undiluted and contains 6.72 % of glyphosate as active ingredient. It is not explosive or oxidising and not flammable. The pH value of the preparation is around 8.3 (based on a 1% aqueous dilution). Its stability has been confirmed under cold conditions, accelerated ageing at 54°C and storage for one year at ambient temperature. No major changes were observed in any of the relevant parameters after storage for 14 days at 54 °C or after one year at ambient temperatures. Based on these results MON 76886 has an expected shelf life of at least 2 years.

Implications for labelling: none

Compliance with FAO specifications:

There is no FAO specification for glyphosate GD formulations.

The product Roundup-Gel Max complies with the general requirements for GD formulations according to the FAO/WHO manual (2016).

Compatibility of mixtures:

No mixtures are intended for the gel formulation.

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 Roundup Gel Max has been provided and is considered to be acceptable.

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

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

The analytical anion exchange HPLC method for the determination of active substance content in a ready-to-use formulation containing glyphosate and the analytical ion exclusion/ exchange HPLC method with post column reactions for the determination of relevant impurity content in a ready-to-use formulation containing glyphosate were sufficiently validated in accordance with SANCO 3030/99/rev.4.

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

The analytical methods for the determination of residues are active substance data and were provided in the EU review of glyphosate. The assessment according to the guidance document SANCO/825/00 rev. 8.1 has

shown that not all of the analytical methods for monitoring, which were found acceptable for the Annex I inclusion, are still in compliance with the current data requirements. However, taking the analytical methods into account that were evaluated within the renewal procedure of glyphosate, acceptably validated analytical methods are available to monitor residues in food of plant and animal origin, soil, water and air. Methods for body fluids and tissues are not required since glyphosate is not classified as toxic or highly toxic.

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

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

Roundup Gel Max, containing 72 g/L glyphosate has a low toxicity in respect to oral and dermal toxicity. Contrary to UK DE regards a classification as H317 as necessary.

Roundup Gel Max contains the following substances classified as skin sens. 1, H317:

5-chlor-2-methyl- 3(2H)isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone at the ratio of 3:1.

The concentration exceeds the limit set in regulation (EC) No 1272/2008 triggering a classification as H317 by ten times. The study concerning sensitising properties supplied by the applicant was conducted using a formulation that is not comparable to Roundup Gel Max. Roundup Gel Max also contains potassium hydroxide which may enhance absorption and sensitising properties.

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

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

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

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

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

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

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

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

See 2.2

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

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

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

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

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

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

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

An exposure assessment for the plant protection product Roundup Gel Max in its intended uses in home and garden use is documented in detail in the core assessment of the plant protection product Roundup Gel Max dated from February 2016 performed by UK.

The following chapters summarise specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of Roundup Gel Max in Germany according to its intended use in stored potatoes (Use No. 00-001 – 00-014).

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

Roundup Gel Max is a gel formulation that will be applied directly to leaves/stumps as a spot treatment. The dose rate for Roundup Gel Max has been calculated as 3600 g a.s/ha, but as it is a home garden spot treatment, the realistic use rate will be much lower. As such, exposure to environment will be minimised. Therefore, PEC_{soil} calculations are not provided.

3.1.5.2 Predicted Environmental Concentration in Ground Water (PECGW) (Part B, Section 5, Point 9.6)

Roundup Gel Max is a gel formulation that will be applied directly to leaves/stumps as a spot treatment. The dose rate for Roundup Gel Max has been calculated as 3600 g a.s/ha, but as it is a home garden spot treatment, the realistic use rate will be much lower. As such, exposure to environment will be minimised. Therefore, PEC_{gw} calculations are not provided.

3.1.5.3 Predicted Environmental Concentration in Surface Water (PECSW) (Part B, Section 5, Points 9.7 and 9.8)

Roundup Gel Max is a gel formulation that will be applied directly to leaves/stumps as a spot treatment. The dose rate for Roundup Gel Max has been calculated as 3600 g a.s/ha, but as it is a home garden spot treatment, the realistic use rate will be much lower. As such, exposure to environment will be minimised. Therefore, PEC_{sw} calculations are not provided.

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 glyphosate is $< 10^{-5}$ Pa. Hence the active substance glyphosate is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance glyphosate due to volatilization with subsequent deposition does not need to be considered.

Implications for labelling resulting from environmental fate assessment

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

A full risk assessment according to Uniform Principles for the plant protection product Roundup Gel Max for use in home gardening was performed by zRMS UK.

The following chapters summarise specific risk assessment for some annex points for authorization of the plant protection product Roundup Gel Max in Germany. The national addendum addresses national requirements differing from the standard EU modelling and risk assessment procedures. It refers moreover to specific management and risk mitigation practices that can be implemented in Germany.

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

Birds

Based on the screening step, the calculated TER-values for the acute and long-term risk resulting from an exposure of birds to the active substance glyphosate according to the GAP of the formulation Roundup Gel Max achieve the acceptability criteria $TER \geq 10$ resp. $TER \geq 5$, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for acute and long-term effects. The results of the assessment indicate an acceptable acute and long-term risk for birds.

Terrestrial vertebrates (other than birds)

Based on the screening step, the calculated TER-values for the acute and long-term risk resulting from an exposure of mammals to glyphosate according to the GAP of the formulation Roundup Gel Max do achieve the acceptability criteria $TER \geq 10$ resp. $TER \geq 5$ and modified ≥ 2 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. for acute and long-term effects. The results of the assessment indicate an acceptable acute and long-term risk for mammals.

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

Due to the intended use of Roundup Gel Max as gel formulation for spot treatment in private home and garden exposure to the environment will be minimized and calculations of surface water concentrations can be omitted. Especially no spray-drift has to be expected. Also exposure via run-off and drainage is assumed to be negligible. Even though no quantitative risk assessment is performed the acute and long-term risk for aquatic organisms resulting from an exposure to glyphosate according to the GAP of the formulation Roundup Gel Max is evaluated as acceptable.

For the authorization of the plant protection product Roundup Gel Max following conditions of use are mandatory:

Roundup Gel Max	NW 467
Roundup Gel Max	NW 642-1

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

Bees

Toxicity

Effects on bees of MON 76829 were not evaluated as part of the EU review of glyphosate acid. Therefore all relevant data and assessments are provided here and are considered adequate.

Table 3.1.6.3-1 EU Endpoints: Ecotoxicological endpoints for bees

Active substance	EU agreed endpoints (SANCO/ 6511/VI/99 – 21/01/2002)	Endpoints used in risk assessment ¹
Glyphosate acid	Oral LD ₅₀ = 100 µg a.s./bee Contact LD ₅₀ > 100 µg a.s./bee	
MON 76829		Oral LD ₅₀ > 102.5 µg a.s./bee ² Contact LD ₅₀ > 100 µg a.s./bee ³

¹ Since Annex I inclusion new studies on the active substance have been performed and as a result there are new end-points which are used in the risk assessment.

² KIIIA1 10.4.2.1/01, Vinall, S., 2013

³ KIIIA1 10.4.2.2/01, Vinall, S., 2013

Hazard quotients

The risks of MON 76829 to honey bees was assessed from hazard quotients between toxicity endpoints, estimated from acute oral and contact studies with active ingredient and formulated product, and the maximum single application rate of 3.6 kg formulation/ha (3600 g formulation/ha).

Table 3.1.6.3-2 Hazard quotients for honey bees exposed orally and by contact to MON 76829 at an application rate of 3.6 kg a.s./ha (3600 g a.s./ha)

Test substance	Exposure route	LD ₅₀ (µg a.i./bee)	Hazard quotient (HQ) ¹	HQ assessment trigger
MON 76829	Oral	> 102.5	< 35	50
	Contact	> 100	< 36	50

¹ HQ= MAR (in g a.s./ha)/LD₅₀.

Conclusions

All the hazard quotients are less than 50, indicating that the active ingredient poses a low risk to bees. Therefore a low risk to bees is expected from the application of MON76829 according to the recommended use pattern.

Label statement NB6641 is assigned to the product.

Other non-target arthropods

Please refer to the core assessment.

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

Due to the intended use of Roundup Gel Max as gel formulation for spot treatment in private home and garden exposure to the environment will be minimized and calculations of soil concentrations can be omitted. Even though no quantitative risk assessment is performed the risk for soil meso- and macro-organisms resulting from an exposure to glyphosate according to the GAP of the formulation Roundup Gel Max is evaluated as acceptable.

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

Since no risk was identified for soil fauna, soil micro-organisms and non-target arthropods from the use of Roundup Gel Max data on the effects on organic matter breakdown is not required.

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

Due to the intended use of Roundup Gel Max as gel formulation for spot treatment in private home and garden exposure to the environment will be minimized and calculations of soil concentrations can be omitted. Even though no quantitative risk assessment is performed the risk for soil microorganisms resulting from an exposure to glyphosate according to the GAP of the formulation Roundup Gel Max is evaluated as acceptable.

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

Roundup Gel Max is an herbicide formulation for home and garden use containing glyphosate as active substances. Roundup Gel Max will be applied through wiping directly on the leaves of the target weed. Consequently, non-target terrestrial plants will not be exposed to glyphosate by spray drift.

Implications for labelling resulting from ecotoxicological assessment:

Relevant toxicity	Glyphosate acid NOEC = 1 mg/L (<i>Brachydanio rerio</i>)
Classification and labelling according to Regulation 1272/2008	
Hazard symbol	no
Signal word	no
Hazard statement	no

R and S phrases under Directive 2003/82/EC (Annex IV and V)

None

Other labels /conditions for use

Labelling

NW467 The product and its remains, empty containers and packaging and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

Conditions of use:

NW 642-1 The product may not be applied in or in the immediate vicinity of surface or coastal
All uses waters. Irrespective of this, the minimum buffer zone from surface waters stipulated
by state law must be observed. Violations may be punished by fines of up to 50 000
EUR.

NS660-1 The product may only be applied on field areas which are not used for agricultural,
00-003 and 00- forestry or horticultural purposes with the approval of the competent national
004 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

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

Information on the active substance

Glyphosate (CAS: 1071-83-6, CIPAC: 284 and EINECS: 213-997-4) is a member of the chemical family glycines. Glyphosate is a non-selective herbicidal active substance, belonging to the chemical class of glycines, with no or low soil residual activity. Glyphosate is taken up by the leaves and other green parts of the plant and is translocated systemically (apoplastic and symplastic) in the whole plant, also in underground parts like roots, rhizomes or stolons.

In plants, glyphosate inhibits the shikimic acid pathway. Glyphosate binds to and blocks the activity of its target enzyme EPSPS (5-enolpyruvylshikimate-3-phosphate synthase), an enzyme of the aromatic amino acid biosynthetic pathway. The inhibition of the enzyme prevents the plant from synthesizing the essential aromatic amino acids needed for protein biosynthesis (HRAC-Group: G). EPSPS is present in all plants, bacteria, and fungi, but not animals.

Label statement WMG is assigned to the product.

Efficacy

MON 76829 will be used by a wiping application to control difficult to control weeds (ie foliar application) and to prevent regrowth of shoots by wiping the product on freshly cut trees or shrubs (ie tree stump treatment) in non-professional uses.

In total 12 trials to demonstrate weed control on non-cultivated land from 2012, 2013 and 2015 has been submitted. Additional seven trials were conducted to control stock wood. All trials were performed in the maritime EPPO climate zone in France, Belgium, Denmark, Germany and Ireland. Furthermore three trials demonstrating weed control and four trials controlling stock wood were submitted to prove a comparability of the formulations MON 76829 and MON 76886 (bridging studies). The trials were conducted in the maritime EPPO climate zone in Belgium, Germany, Ireland and the UK. The results showed that the efficacy of the formulations MON 76829 and MON 76886 are comparable. The formulations change is a minor change and can be accepted.

The instructions for use must include a summary of weeds, and if applicable woody plants, which can be controlled well, less well and insufficiently by the product.

Requirement WH914 is assigned to all uses.

Impact on other plants including adjacent crops

MON 76829 is a gel formulation that needs to be wiped on the tree stumps or individual weeds. There is no drift when MON 76829 is applied. However, secondary contamination especially of lawn, e.g. by walking across treated plants, should be avoided.

Adverse effects on beneficial arthropods

In the case of *Aphidius rhopalosiphi* only slight effects <25% were observed in the extended laboratory experiment, even at 6-fold of the intended field rate. These results indicate that the product should have no effects of $\geq 25\%$ on relevant beneficial arthropods if the product is used properly and according to its intended purpose.

For *Typhlodromus pyri* effects of > 50% were observed in an extended laboratory experiment at a 2.2-fold rate. Due to these results, adverse effects in the range of 25-50% to predatory mites and spiders might occur. Label phrases NN1001 and NN2002 are assigned to the product.

Conclusions

All the data regarding the efficacy of the product have been submitted. These data demonstrate that MON76829 fulfils all criteria for the authorization of preparations described in Directive 97/57/EC (Uniform Principles, Annex VI to Directive 91/414/EEC). No phytotoxicity, effects on neighbouring or following crops were observed, if the product is used properly and according to its intended purpose.

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.

Concerning efficacy/IPM and sustainable use incl. effects on honeybees and beneficial arthropods all uses of MON76829 applied for can be authorised.

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

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

An authorisation can be granted.

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 data required.

Appendix 1 – Copy of the product authorisation (see Appendix 4)

Appendix 2 – Copy of the product label

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 31 of Regulation (EU) No 1107/2009.

Appendix 3 – Letter of Access

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

Appendix 4 – Copy of the product authorisation

See below.



Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.008375-00/00.119584
(bitte bei Antwort angeben)

DATUM 3. Juli 2017

ZV3 008375-00/00

Roundup Gel Max

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit dem Wirkstoff: 72 g/l Glyphosat (als Kalium-Salz 88 g/l)

Zulassungsnummer: 008375-00

Versuchsbezeichnungen: MOT-76886-H-0-GD

Antrag vom: 15. Januar 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. Dezember 2018.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

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

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008375-00/00-006	Einkeimblättrige Unkräuter, Zwei- keimblättrige Unkräuter	Gemüsekulturen	
008375-00/00-003	Einkeimblättrige Unkräuter, Zwei- keimblättrige Unkräuter	Nichtkulturland ohne Holzgewächse	
008375-00/00-001	Einkeimblättrige Unkräuter, Zwei- keimblättrige Unkräuter	Obstkulturen	
008375-00/00-007	Einkeimblättrige Unkräuter, Zwei- keimblättrige Unkräuter	Zierpflanzen	
008375-00/00-008	Holzgewächse, Brombeere	Gemüsekulturen	
008375-00/00-004	Holzgewächse, Brombeere	Nichtkulturland ohne Holzgewächse	
008375-00/00-002	Holzgewächse, Brombeere	Obstkulturen	
008375-00/00-014	Holzgewächse, Brombeere	Rasen	
008375-00/00-009	Holzgewächse, Brombeere	Zierpflanzen	
008375-00/00-012	Stockholz	Gemüsekulturen	
008375-00/00-011	Stockholz	Obstkulturen	
008375-00/00-013	Stockholz	Rasen	
008375-00/00-005	Stockholz	Zierpflanzen	
008375-00/00-010	Zweikeimblättrige Unkräuter	Rasen	

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:

(NW467)

Mittel und dessen Reste, entleerte Behältnisse oder Packungen sowie Spülflüssigkeiten nicht in Gewässer gelangen lassen. Dies gilt auch für indirekte Einträge über die Kanalisation, Hof- und Straßenabläufe sowie Regen- und Abwasserkanäle.

Begründung:

Der im o.g. Pflanzenschutzmittel enthaltene Wirkstoff Glyphosat weist aufgrund seiner Toxizität ein hohes Gefährdungspotenzial für aquatische Organismen auf. Jeder Eintrag von Rückständen in Oberflächengewässer, der den Eintrag als Folge der bestimmungsgemäßen und sachgerechten Anwendung des Mittels entsprechend der guten fachlichen Praxis übersteigt, würde daher zu einer Gefährdung des Naturhaushaltes aufgrund von nicht akzeptablen Auswirkungen auf Gewässerorganismen führen. Da ein erheblicher Anteil der in Oberflächengewässern nachzuweisenden Pflanzenschutzmittelfrachten auf Einträge aus kommunalen Kläranlagen zurückzuführen ist, muss dieser Gefährdung durch die bußgeldbewehrte Anwendungsbestimmung durchsetzbar begegnet werden.

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

Verpackungen

Gemäß § 36 Abs. 1 S. 2 Nr. 1 und 2 PflSchG sind für das Pflanzenschutzmittel die nachfolgend näher beschriebenen Verpackungen für die Anwendung durch nichtberufliche Anwender zugelassen:

Verpackungsart	Verpackungsmaterial	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Flasche mit seperater Dosierereinheit	PP	1		15,00	500,00	ml

Die Verpackungen für den nichtberuflichen Anwender sind wie folgt zu kennzeichnen:
Anwendung durch nichtberufliche Anwender zulässig.

Auflagen

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

Kennzeichnungsaufgaben:

(NN2002)

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

(SB001)

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

(SB110)

Die Richtlinie für die Anforderungen an die persönliche Schutzausrüstung im Pflanzenschutz "Persönliche Schutzausrüstung beim Umgang mit Pflanzenschutzmitteln" des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit ist zu beachten.

(SB166)

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

(SS202)

Schutzhandschuhe tragen beim Umgang mit dem Mittel.

(SS205-1)

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

(WMG)

Wirkungsmechanismus (HRAC-Gruppe): G

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

Sonstige Auflagen:

(VH297)

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

(VH368)

Der Gehalt an N-Nitrosoglyphosat im technischen Konzentrat von Glyphosat oder Glyphosatsalzen darf 1mg/kg nicht überschreiten. Der Gehalt an Formaldehyd darf 1,3 g/kg bezogen auf die Äquivalenzmasse der Glyphosatsäure nicht überschreiten.

(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:

(S1) Achtung

Gefahrenpiktogramme:

(GHS07) Ausrufezeichen

Gefahrenhinweise (H-Sätze):

(H317)

Kann allergische Hautreaktionen verursachen.

(EUH 208-0196)

Enthält 5-Chlor-2-methyl- 3(2H)isothiazolon, Mischung mit 2-Methyl-3(2H)-isothiazolon im Verhältnis 3:1. Kann allergische Reaktionen hervorrufen.

(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.

(P302+P352)

BEI BERÜHRUNG MIT DER HAUT: Mit viel Wasser/... waschen.

(P333+P313)

Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

(P362+P364)

Kontaminierte Kleidung ausziehen und vor erneutem Tragen waschen.

(P501)

Inhalt/Behälter ... zuführen.

Abgelehnte Anwendungsgebiete bzw. Anwendungen

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

- keine -

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 bienen-gefährlich eingestuft (B4).

(NN1001)

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

Weitere Hinweise und Bemerkungen

Zu den Anwendungen 008375-00/00-002

In der Fassung der Anwendung wurden die Zweikeimblättrige Unkräuter gestrichen, da sie bereits in Anwendung -001 enthalten sind und mit einer Aufwandmenge von 2,5 ml/m² = 1 Klick bekämpft werden. Auch in der GAP des zRMS UK ist die Bekämpfung gegen zweikeimblättrige Unkräuter (TTTDD) mit 2,5 ml/m² = 1 Klick angeben.

Zu den Anwendungen 008375-00/00-004

In der Fassung der Anwendung wurden die Zweikeimblättrige Unkräuter gestrichen, da sie bereits in Anwendung -003 enthalten sind und mit einer Aufwandmenge von 2,5 ml/m² = 1 Klick bekämpft werden. Auch in der GAP des zRMS UK ist die Bekämpfung gegen zweikeimblättrige Unkräuter (TTTDD) mit 2,5 ml/m² = 1 Klick angeben.

Zu den Anwendungen 008375-00/00-008

In der Fassung der Anwendung wurden die Zweikeimblättrige Unkräuter gestrichen, da sie bereits in Anwendung -006 enthalten sind und mit einer Aufwandmenge von $2,5 \text{ ml/m}^2 = 1$ Klick bekämpft werden. Auch in der GAP des zRMS UK ist die Bekämpfung gegen zweikeimblättrige Unkräuter (TTTDD) mit $2,5 \text{ ml/m}^2 = 1$ Klick angeben.

Zu den Anwendungen 008375-00/00-009

In der Fassung der Anwendung wurden die Zweikeimblättrige Unkräuter gestrichen, da sie bereits in Anwendung -007 enthalten sind und mit einer Aufwandmenge von $2,5 \text{ ml/m}^2 = 1$ Klick bekämpft werden. Auch in der GAP des zRMS UK ist die Bekämpfung gegen zweikeimblättrige Unkräuter (TTTDD) mit $2,5 \text{ ml/m}^2 = 1$ Klick angeben.

Zu den Anwendungen 008375-00/00-014

In der Fassung der Anwendung wurden die Zweikeimblättrige Unkräuter gestrichen, da sie bereits in Anwendung -010 enthalten sind und mit einer Aufwandmenge von $2,5 \text{ ml/m}^2 = 1$ Klick bekämpft werden. Auch in der GAP des zRMS UK ist die Bekämpfung gegen zweikeimblättrige Unkräuter (TTTDD) mit $2,5 \text{ ml/m}^2 = 1$ Klick angeben.

2,5 Prozent des Gemisches bestehen aus einem oder mehreren Bestandteilen von unbekannter Toxizität.

KIIIA 3.9

In der Gebrauchsanleitung ist auf geeignete Weise auf die Gefahr einer sekundären Kontamination insbesondere von Rasenflächen, z.B. durch das Belaufen behandelter Pflanzen, hinzuweisen.

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

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

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

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

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Karsten Hohgardt
stellvertretender Abteilungsleiter

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

Anlage

Anlage 1 zugelassene Anwendung: 008375-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Einkeimblättrige Unkräuter, Zweikeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Obstkulturen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Obstbau

Anwendungsbereich: Freiland

Anwendung im Haus- und Kleingartenbereich: Ja

Anwendungszeitpunkt: Nach dem Auflaufen der Unkräuter, während der Vegetationsperiode

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 2

- Abstand: 28 Tage

Anwendungstechnik: streichen

- Erläuterungen: zur gezielten Einzelpflanzenbehandlung

Aufwand:

- 2,5 ml/m²

- Erläuterungen: 1 Klick zur Behandlung von Unkräutern mit einer Blattfläche von 1200 cm²

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

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

(WH914)

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

2.3 Wartezeiten

(F)

Freiland: Obstkulturen

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

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 008375-00/00-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Holzgewächse, Brombeere

Pflanzen/-erzeugnisse/Objekte: Obstkulturen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Obstbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Ja
Anwendungszeitpunkt:	Nach dem Auflaufen der Unkräuter, während der Vegetationsperiode
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	streichen
- Erläuterungen:	zur gezielten Einzelpflanzenbehandlung
Aufwand:	
-	5 ml/m ²
- Erläuterungen:	2 Klicks zur Behandlung von Unkräutern mit einer Blattfläche von 1200 cm ²

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

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

(WH914)

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

2.3 Wartezeiten

(F)

Freiland: Obstkulturen

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

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 008375-00/00-003

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Einkeimblättrige Unkräuter, Zweikeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Nichtkulturland ohne Holzgewächse

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Nichtkulturland

Anwendungsbereich: Freiland

Anwendung im Haus- und Kleingartenbereich: Ja

Anwendungszeitpunkt: Nach dem Auflaufen der Unkräuter, während der Vegetationsperiode

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 2

- Abstand: 28 Tage

Anwendungstechnik: streichen

- Erläuterungen: zur gezielten Einzelpflanzenbehandlung

Aufwand:

- 2,5 ml/m²

- Erläuterungen: 1 Klick zur Behandlung von Unkräutern mit einer Blattfläche von 1200 cm²

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.

(WH914)

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

2.3 Wartezeiten

(N)

Freiland: Nichtkulturland ohne Holzgewächse

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 008375-00/00-004

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Holzgewächse, Brombeere

Pflanzen/-erzeugnisse/Objekte: Nichtkulturland ohne Holzgewächse

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Nichtkulturland
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Ja
Anwendungszeitpunkt:	Nach dem Auflaufen der Unkräuter, während der Vegetationsperiode
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	streichen
- Erläuterungen:	zur gezielten Einzelpflanzenbehandlung
Aufwand:	
-	5 ml/m ²
- Erläuterungen:	2 Klicks zur Behandlung von Unkräutern mit einer Blattfläche von 1200 cm ²

2.2 Sonstige Kennzeichnungsauflagen

(NS660-1)

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

(NW642-1)

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

(WH914)

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

2.3 Wartezeiten

(N)

Freiland: Nichtkulturland ohne Holzgewächse

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 008375-00/00-005

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Stockholz

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Während der Vegetationsperiode, nach dem Schnitt

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 2

- Abstand: 28 Tage

Anwendungstechnik: streichen

- Erläuterungen: zur gezielten Einzelpflanzenbehandlung

Aufwand:

- 2,5 ml/m²

- Erläuterungen: 1 Klick zur Behandlung von Stockholz mit einem Durchmesser von 2-4 cm

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

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

(WH914)

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

2.3 Wartezeiten

(N) Freiland: Zierpflanzen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 008375-00/00-006

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Einkeimblättrige Unkräuter, Zweikeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Gemüsekulturen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Freiland

Anwendung im Haus- und Kleingartenbereich: Ja

Anwendungszeitpunkt: Nach dem Auflaufen der Unkräuter, während der Vegetationsperiode

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 2

- Abstand: 28 Tage

Anwendungstechnik: streichen

- Erläuterungen: zur gezielten Einzelpflanzenbehandlung

Aufwand:

- 2,5 ml/m²

- Erläuterungen: 1 Klick zur Behandlung von Unkräutern mit einer Blattfläche von 1200 cm²

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

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

(WH914)

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

2.3 Wartezeiten

(F)

Freiland: Gemüsekulturen

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

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 008375-00/00-007

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Einkeimblättrige Unkräuter, Zweikeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und Kleingartenbereich: Ja

Anwendungszeitpunkt: Nach dem Auflaufen der Unkräuter, während der Vegetationsperiode

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 2

- Abstand: 28 Tage

Anwendungstechnik: streichen

- Erläuterungen: zur gezielten Einzelpflanzenbehandlung

Aufwand:

- 2,5 ml/m²

- Erläuterungen: 1 Klick zur Behandlung von Unkräutern mit einer Blattfläche von 1200 cm²

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

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

(WH914)

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

2.3 Wartezeiten

(N)

Freiland: Zierpflanzen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 008375-00/00-008

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Holzgewächse, Brombeere

Pflanzen/-erzeugnisse/Objekte: Gemüsekulturen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Nach dem Auflaufen der Unkräuter, während der
Vegetationsperiode

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 1

Anwendungstechnik: streichen

- Erläuterungen: zur gezielten Einzelpflanzenbehandlung

Aufwand:

- 5 ml/m²

- Erläuterungen: 2 Klicks zur Behandlung von Unkräutern mit einer
Blattfläche von 1200 cm²

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

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

(WH914)

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

2.3 Wartezeiten

(F)

Freiland: Gemüsekulturen

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

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 008375-00/00-009

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Holzgewächse, Brombeere

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Nach dem Auflaufen der Unkräuter, während der
Vegetationsperiode

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 1

Anwendungstechnik: streichen

- Erläuterungen: zur gezielten Einzelpflanzenbehandlung

Aufwand:

- 5 ml/m²

- Erläuterungen: 2 Klicks zur Behandlung von Unkräutern mit einer
Blattfläche von 1200 cm²

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

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

(WH914)

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

2.3 Wartezeiten

(N)

Freiland: Zierpflanzen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 008375-00/00-010

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Zweikeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Rasen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Nach dem Auflaufen der Unkräuter, während der
Vegetationsperiode

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 2

- Abstand: 28 Tage

Anwendungstechnik: streichen

- Erläuterungen: zur gezielten Einzelpflanzenbehandlung

Aufwand:

- 2,5 ml/m²

- Erläuterungen: 1 Klick zur Behandlung von Unkräutern mit einer
Blattfläche von 1200 cm²

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

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

(WH914)

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

2.3 Wartezeiten

(N) Freiland: Rasen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 008375-00/00-011

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Stockholz

Pflanzen/-erzeugnisse/Objekte: Obstkulturen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Obstbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Ja
Anwendungszeitpunkt:	Während der Vegetationsperiode, nach dem Schnitt
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	2
- Abstand:	28 Tage
Anwendungstechnik:	streichen
- Erläuterungen:	zur gezielten Einzelpflanzenbehandlung
Aufwand:	
-	2,5 ml/m ²
- Erläuterungen:	1 Klick zur Behandlung von Stockholz mit einem Durchmesser von 2-4 cm

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

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

(WH914)

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

2.3 Wartezeiten

(F)

Freiland: Obstkulturen

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

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 008375-00/00-012

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Stockholz

Pflanzen/-erzeugnisse/Objekte: Gemüsekulturen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Gemüsebau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Ja
Anwendungszeitpunkt:	Während der Vegetationsperiode, nach dem Schnitt
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	2
- Abstand:	28 Tage
Anwendungstechnik:	streichen
- Erläuterungen:	zur gezielten Einzelpflanzenbehandlung
Aufwand:	
-	2,5 ml/m ²
- Erläuterungen:	1 Klick zur Behandlung von Stockholz mit einem Durchmesser von 2-4 cm

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

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

(WH914)

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

2.3 Wartezeiten

(F)

Freiland: Gemüsekulturen

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

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 008375-00/00-013

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Stockholz

Pflanzen/-erzeugnisse/Objekte: Rasen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Während der Vegetationsperiode, nach dem Schnitt

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 2

- Abstand: 28 Tage

Anwendungstechnik: streichen

- Erläuterungen: zur gezielten Einzelpflanzenbehandlung

Aufwand:

- 2,5 ml/m²

- Erläuterungen: 1 Klick zur Behandlung von Stockholz mit einem Durchmesser von 2-4 cm

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

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

(WH914)

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

2.3 Wartezeiten

(N) Freiland: Rasen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 008375-00/00-014

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Holzgewächse, Brombeere

Pflanzen/-erzeugnisse/Objekte: Rasen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Nach dem Auflaufen der Unkräuter, während der
Vegetationsperiode

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 1

Anwendungstechnik: streichen

- Erläuterungen: zur gezielten Einzelpflanzenbehandlung

Aufwand:

- 5 ml/m²

- Erläuterungen: 2 Klicks zur Behandlung von Unkräutern mit einer
Blattfläche von 1200 cm²

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

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

(WH914)

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

2.3 Wartezeiten

(N) Freiland: Rasen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

**REGISTRATION REPORT
Part B**

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

Product code: Roundup Gel Max
Active Substance: Glyphosate 72 g/L

**Central Zone
Zonal Rapporteur Member State: Germany**

NATIONAL ADDENDUM – Germany

**Applicant: Monsanto Europe SA
Date: 04/2017**

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

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for authorization of the plant protection product Roundup Gel Max in Germany.

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

5.1 Overall conclusion

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

Roundup Gel Max is a gel formulation that will be applied directly to leaves/stumps as a spot treatment. The dose rate for Roundup Gel Max has been calculated as 3600 g a.s/ha, but as it is a home garden spot treatment, the realistic use rate will be much lower. As such, exposure to environment will be minimised. Therefore, PEC_{soil} calculations are not provided.

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

Roundup Gel Max is a gel formulation that will be applied directly to leaves/stumps as a spot treatment. The dose rate for Roundup Gel Max has been calculated as 3600 g a.s/ha, but as it is a home garden spot treatment, the realistic use rate will be much lower. As such, exposure to environment will be minimised. Therefore, PEC_{gw} calculations are not provided.

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

Roundup Gel Max is a gel formulation that will be applied directly to leaves/stumps as a spot treatment. The dose rate for Roundup Gel Max has been calculated as 3600 g a.s/ha, but as it is a home garden spot treatment, the realistic use rate will be much lower. As such, exposure to environment will be minimised. Therefore, PEC_{sw} calculations are not provided.

5.1.4 Fate and behaviour in air

The vapour pressure at 20 °C of the active substance glyphosate is $< 10^{-5}$ Pa. Hence the active substance glyphosate is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance glyphosate due to volatilization with subsequent deposition does not need to be considered.

5.2 Metabolites considered in the assessment

Metabolites of glyphosate

The risk assessment for the metabolites of glyphosate has already been performed for EU approval (see EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302, 107 pp. doi:10.2903/j.efsa.2015.4302 and Renewal Assessment Report, Volume 3 Annex B.8).

5.3 General Information on the formulation

Table 5.3-1: General information on the formulation Roundup Gel Max

Code	Roundup Gel Max
Plant protection product	Roundup Gel Max
Applicant	Monsanto Europe SA
Date of application	15.01.2015
Formulation type (WP, EC, SC, ...; density)	
Active substances (as)	Glyphosate
Concentration of as (g/L)	72
Data pool/task force	
Letter of access/cross reference	

5.4 Proposed use pattern

The intended uses in Germany classified according the soil effective application rate (cumulative, disregarding degradation in soil) are presented in Table 5.4-1.

Table 5.4-1: Classification of intended uses in Germany for Roundup Gel Max

Group/ use No*	Crop/growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Application rate, cumulative	Soil effective application rate (g as/ha)
001	Home and garden uses, Pomiculture	Spreading wiping as single plant treatment, after emergence of weeds, during growing season	2 x, 28 d, 0 % interception	2 x 2,5 mL Roundup Gel Max /m ²	Glyphosate: 2 x 1800 g/ha

002	Home and garden uses, Pomiculture	Spreading wiping as single plant treatment, after emergence of weeds, during growing season	1 ×, 0 % interception	1 × 5 mL Roundup Gel Max /m ²	Glyphosate: 1 × 3600 g/ha
003	Home and garden uses, uncultivated areas without woody plants	Spreading wiping as single plant treatment, after emergence of weeds, during growing season	2 ×, 28 d, 0 % interception	2 × 2,5 mL Roundup Gel Max /m ²	Glyphosate: 2 × 1800 g/ha
004	Home and garden uses, uncultivated areas without woody plants	Spreading wiping as single plant treatment, after emergence of weeds, during growing season	1 ×, 0 % interception	1 × 5 mL Roundup Gel Max /m ²	Glyphosate: 1 × 3600 g/ha
005	Home and garden uses, Ornamentals	Spreading wiping as single plant treatment, during growing season	2 ×, 28 d, 0 % interception	2 × 2,5 mL Roundup Gel Max /m ²	Glyphosate: 2 × 1800 g/ha
006	Home and garden uses, vegetable gardening	Spreading wiping as single plant treatment, after emergence of weeds, during growing season	2 ×, 28 d, 0 % interception	2 × 2,5 mL Roundup Gel Max /m ²	Glyphosate: 2 × 1800 g/ha
007	Home and garden uses, Ornamentals	Spreading wiping as single plant treatment, after emergence of weeds, during growing season	2 ×, 28 d, 0 % interception	2 × 2,5 mL Roundup Gel Max /m ²	Glyphosate: 2 × 1800 g/ha

008	Home and garden uses, vegetable gardening	Spreading wiping as single plant treatment, after emergence of weeds, during growing season	1 ×, 0 % interception	1 × 5 mL Roundup Gel Max /m ²	Glyphosate: 1 × 3600 g/ha
009	Home and garden uses, Ornamentals	Spreading wiping as single plant treatment, after emergence of weeds, during growing season	1 ×, 0 % interception	1 × 5 mL Roundup Gel Max /m ²	Glyphosate: 1 × 3600 g/ha
010	Home and garden uses, Lawn	Spreading wiping as single plant treatment, after emergence of weeds, during growing season	2 ×, 28 d, 0 % interception	2 × 2,5 mL Roundup Gel Max /m ²	Glyphosate: 2 × 1800 g/ha
011	Home and garden uses, Pomiculture	Spreading wiping as single plant treatment, during growing season	2 ×, 28 d, 0 % interception	2 × 2,5 mL Roundup Gel Max /m ²	Glyphosate: 2 × 1800 g/ha
012	Home and garden uses, vegetable gardening	Spreading wiping as single plant treatment, during growing season	2 ×, 28 d, 0 % interception	2 × 2,5 mL Roundup Gel Max /m ²	Glyphosate: 2 × 1800 g/ha
013	Home and garden uses, Lawn	Spreading wiping as single plant treatment, during growing season	2 ×, 28 d, 0 % interception	2 × 2,5 mL Roundup Gel Max /m ²	Glyphosate: 2 × 1800 g/ha

014	Home and garden uses, Lawn	Spreading wiping as single plant treatment, after emergence of weeds, during growing season	1 ×, 0 % interception	1 × 5 mL Roundup Gel Max /m ²	Glyphosate: 1 × 3600 g/ha
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* For administrative purposes, each intended use of a plant protection product in Germany is assigned with an individual use number from the German Federal Office of Consumer Protection and Food Safety (BVL).

5.5 Information on the active substances

5.5.1 Glyphosate

5.5.1.1 Identity, further information of glyphosate

Table 5.5-1: Identity, further information on glyphosate

Active substance (ISO common name)	Glyphosate
IUPAC	N-(phosphonomethyl)-glycin
Function (e.g. fungicide)	Herbizide
Status under Reg. (EC) No 1107/2009	Approved
Date of approval	01/07/2002
Conditions of approval	<p>Member States must pay particular attention to the protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses (Review Report 6511/VI/99-final of 21 January 2002).</p> <p>Member States must pay particular attention to: – risks from the use in specific areas referred to in Article 12(a) of Directive 2009/128/EC; – compliance of pre-harvest uses with good agricultural practices. Member States shall ensure that plant protection products containing glyphosate do not contain the co-formulant POE-tallowamine (CAS No 61791-26-2) (Addendum to the Review report for the active substance glyphosate SANTE/11051/2016 rev 0 11 July 2016)</p>
Confirmatory data	None.
RMS	Germany
Minimum purity of the active substance as manufactured (g/kg)	950 g/kg
Molecular formula	C ₃ H ₈ NO ₅ P
Molecular mass	169.1 g/mol
Structural formula	$\text{HO}-\underset{\text{O}}{\underset{\parallel}{\text{C}}}-\text{CH}_2-\text{NH}-\text{CH}_2-\underset{\text{OH}}{\underset{\parallel}{\text{P}}}=\text{O}$

5.5.1.2 Physical and chemical properties of glyphosate

Physical and chemical properties of glyphosate as agreed at EU level (see EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302, 107 pp. doi:10.2903/j.efsa.2015.4302) and considered relevant for the exposure assessment are listed in Table 5.5-2.

Table 5.5-2: EU agreed physical chemical properties of glyphosate relevant for exposure assessment

	Value	Reference
Vapour pressure (at 20 °C) (Pa)	6.8· 10 ⁻⁶ Pa (calculated at 20°C) 1.31 x 10 ⁻⁵ Pa at 25 °C (98.6%)	1) 2)
Henry's law constant (Pa × m³ × mol⁻¹)	2.1 x 10 ⁻⁷ Pa m ³ mol ⁻¹ (25 °C)	2)
Solubility in water (at 25 °C in mg/L)	10.5 g/L at 20 °C (pH 1.90 – 1.98) (99.5 %)	2)
Partition co-efficient (at 25 °), log Pow	log P _{OW} = - 3.2 at 25 °C (pH buffer 5–9) (99.9 %)	2)
Dissociation constant, pKa	pKa1 = 2.34 pKa2 = 5.73 all at 20 °C (99 %)	2)
Hydrolytic degradation	Glyphosate: pH 5: stable (25°C) pH 7: stable (25°C) pH 9: stable (25°C)	2)
Photolytic degradation	DT50 (experimental): 33 d (at pH 5), 69 d (at pH 7), 77 d (at pH 9)	2)
Quantum yield of direct phototransformation in water > 290 nm	Not determined	2)
Photochemical oxidative degradation in air (calculation according to Atkinson)	DT ₅₀ of 1.6 hours derived by the Atkinson model (version 1.92). OH (12h) concentration assumed = 1.5x10 ⁶ cm ⁻³	2)

1) SANCO/6511/VI/99-final – 21/01/2002

2) EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302, 107 pp. doi:10.2903/j.efsa.2015.4302

5.5.1.3 Metabolites of glyphosate

Environmental occurring metabolites of glyphosate requiring further assessment according to the results of the assessment of glyphosate for EU approval (EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302, 107 pp. doi:10.2903/j.efsa.2015.4302) are summarized in Table 5.5-3.

No new study on the fate and behaviour of glyphosate or Roundup Gel Max has been performed. Hence no potentially new metabolites need to be considered.

Table 5.5-3: Metabolites of glyphosate potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolite	Structural formula/Molecular formula	occurrence in compartments (Max. at day)	Status of Relevance ¹⁾ according to Glyphosate LoEP 2015
Aminomethyl-phosphonic acid (AMPA) molar mass: 111.0 g/mol correction factor: 0.656	$\begin{array}{c} \text{O} \\ \\ \text{HO}-\text{P}-\text{CH}_2-\text{NH}_2 \\ \\ \text{OH} \end{array}$	Soil: aerob _{lab} : max. 50.1 % after 90 days aerob _{field} : max. 53.8 % after 271 days Water: max. 15.7 % after 14 days Sediment: max. 18.7 % after 58 days	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant
(Hydroxymethyl)-phosphonic acid molar mass: 112.0 g/mol correction factor: 0.662	$\begin{array}{c} \text{OH} \\ \\ \text{HO}-\text{P}-\text{C}-\text{OH} \\ \quad \\ \text{O} \quad \text{H}_2 \end{array}$	Water: max. 10.0 % after 61 days	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant

¹⁾ According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

5.6 Summary on input parameters for environmental exposure assessment

5.6.1 Rate of degradation in soil

5.6.1.1 Laboratory studies

Glyphosate and AMPA

No new studies have been submitted regarding route and rate of degradation in soil of glyphosate and AMPA. The environmental exposure assessment is based on the EU agreed DT₅₀ values from the laboratory (EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302, 107 pp. doi:10.2903/j.efsa.2015.4302 and Renewal Assessment Report, Volume 3 Annex B.8) as summarized in Table 5.6-1 and Table 5.6-2.

Table 5.6-1: Summary of aerobic degradation rates for glyphosate (modelling endpoints) - laboratory studies

Study	Soil	pH H ₂ O	Modelling endpoints				Model
			recalculated SFO DT ₅₀ actual (d)	Normalised SFO DT ₅₀ (d) 20 °C, pF2	f.f. AMPA	χ ² error (%)	
Glyphosate							
Ponte (2010), BVL no 2310242	Gartenacker, loam	7.1	17.79	16.0	0.1817	4.6	DT ₉₀ FOMC/ 3.32
Dean (1995), BVL no 2310244	Arrow, sandy loam	6.5*	186.6	159.6		3.52	DFOP slow phase
Goodyear (1996), BVL no 2310246	Soil B, sandy loam	6.7	6.2	6.6	0.2646	6.92	DT ₉₀ FOMC/ 3.32
Galicia & Morgenroth (1993) BVL no 1932059	Les Evouettes, silt loam	6.1 [§]	104.5	93.3	0.3618	6.17	DT ₉₀ FOMC/ 3.32
Matla & Vonk (1993) BVL no 2151389	Maasdjik, sandy loam	7.5*	17.05	15.2	n.m.	3.79	DT ₉₀ FOMC/ 3.32
Ponte (2010), BVL no 2310255	Drusenheim, loam	7.4	5.35	4.2	0.2578	3.5	DT ₉₀ FOMC/ 3.32
	Pappelacker, loamy sand	7.0	13.09	12.0	0.1835	4.1	DT ₉₀ FOMC/ 3.32
	18-Acres, clay loam	5.7	173.2	160.5	0.2169 ¹⁾	2.9	DFOP slow phase

Study	Soil	pH H ₂ O	Modelling endpoints				Model
			recalculated SFO DT ₅₀ actual (d)	Normalised SFO DT ₅₀ (d) 20 °C, pF2	f.f. AMPA	χ ² error (%)	
Glyphosate							
Galicia & Flückiger (1993), BVL no 1932046 / Mamouni, 2002, BVL no 2437068	Speyer 2.3, Lomay Sand	6.9	7.2	7.2	0.3435	3.84	DT ₉₀ FOMC/ 3.32
McLaughlin & Schanné (1996), BVL no 2310250	Speyer 2.1, sand	6.5*	19.5	19.5	0.520 ¹⁾	5.72	DT ₉₀ FOMC/ 3.32
	Speyer 2.2, loamy sand	6.2*	72.2	72.2	0.6076 ¹⁾	4.97	DFOP slow phase
	Speyer 2.3, loamy sand	6.9*	3.76	3.76	0.4283	7.67	DT ₉₀ FOMC/ 3.32
Kesterson & Atkins, 1991, BVL no 1932061 & add. Honegger, 1992, BVL no 2325652	Dupo, silt loam	7.3 [§]	2.80	3.70	0.3637	3.80	DT ₉₀ FOMC/ 3.32
Runnalls, 1991, BVL no 2154349	Speyer 2.2, loamy sand	6.0	43.53	40.6	n.m.	6.95	SFO
Lewis & Turnbull 1992, BVL no 1052659	Speyer 2.1 sand	6.9 [§]	43.06 [§]	43.06	0.5851 [§]	3.91 [§]	DT ₉₀ FOMC/ 3.32
Geometric mean (n = 15)				20.51	³⁾		
pH dependency				No	-		
Arithmetic mean (n = 12)				³⁾	0.3595		

- 1) Acceptable visual fit for formation phase of AMPA, however no statistically acceptable fit for the transformation rate of AMPA could be obtained in this pathway
- 2) no statistically reliable fit could be obtained (high chi² error and/ or t-test not passed at 0.05)
- 3) statistically not appropriate, according to FOCUS (2006, 2011) the geometric mean should be used for averaging degradation rates and half-lives while the arithmetic mean should be used for formation fractions
- n.m. not measured
- * converted from given pH value in CaCl₂ and KCl in order to allow pH dependency tests of the degradation
- § buffer solution unknown
- \$ labelled in the phosphonomethyl-glycine anion of glyphosate-trimesium

The DT₅₀ values of glyphosate do not show any pH dependency.

Table 5.6-2: Summary of aerobic degradation rates for AMPA (modelling endpoints) - laboratory studies

Study	Soil	pH H ₂ O	Modelling endpoints			Model Parent_Met.
			recalculated SFO DT ₅₀ actual (d)	Normalised SFO DT ₅₀ (days), 20 °C pF2	χ ² error (%)	
Metabolite AMPA						
Ponte (2010), BVL no 2310242	Gartenacker, loam	7.1	133.69	119.9	8.9	FOMC_SFO
Goodyear (1996), BVL no 2310246	Soil B, sandy loam	6.7	99.1	106.2	6.98	FOMC_SFO
Galicia & Morgenroth (1993) BVL no 1932059	Les Evouettes, silt loam	6.1	337	300.9	14.00	FOMC_SFO
Matla & Vonk (1993), BVL no 2151389	Maasdjik, sandy loam	7.5*	n.m.	n.m.	n.m.	n.m.
Ponte (2010), BVL no 2310255	Drusenheim, loam	7.4	47.04	36.8	2.1	FOMC_SFO
	Pappelacker, loamy sand	7.0	126.5	116.3	6.2	FOMC_SFO
	18-Acres, clay loam	5.7	_1)	_1)	_1)	DFOP_SFO
Galicia & Flückiger (1993), BVL no 1932046 / Mamouni (2002), BVL no 2437068	Speyer 2.2, sand	6.0	_2)	_2)	_2)	_2)
	Speyer 2.3, loamy sand	6.9	70.92	70.92	11.41	FOMC-SFO
McLaughlin & Schanné (1996), BVL no 2310250	Speyer 2.1, sand	6.5*	_1)	_1)	_1)	FOMC_SFO
	Speyer 2.2, loamy sand	6.2*	_1)	_1)	_1)	DFOP_SFO
	Speyer 2.3, loamy sand	6.9*	42.14	42.14	16.48	FOMC_SFO
Kesterson & Atkins, 1991, BVL no 1932061 & add. Honegger, 1992, BVL no 2325652	Dupo, silt loam	7.3 [§]	48.32	30.5	7.57	FOMC_SFO
Runnalls, 1991, BVL no 2154349	Speyer 2.2, loamy sand	6.0	n.m.	n.m.	n.m.	n.m.
Lewis & Turnbull, 1992, BVL no 1052659	Speyer 2.1, sand	6.9	230.7 [§]	230.7 [§]	4.29 [§]	FOMC_SFO
Minimum				30.5		
Maximum				300.9		
pH dependency				No		
Geometric mean (n = 9)				88.84		

¹⁾ No decline of AMPA was observed in parent study; thus, no acceptable fit for AMPA could be obtained

²⁾ no statistically reliable fit could be obtained (high chi² error and/ or t-test not passed at 0.05) for parent and metabolite

- n.m. not measured
* converted from given pH value in CaCl₂ and KCl in order to allow pH dependency tests of the degradation
§ buffer solution unknown
\$ labelled in the phosphonomethyl-glycine anion of glyphosate-trimesium

The DT₅₀ values of AMPA do not show any pH dependency.

5.6.1.2 Field studies

Glyphosate and AMPA

No new studies have been submitted on the soil dissipation of glyphosate and AMPA under field conditions. The environmental exposure assessment is based on the EU agreed DT₅₀ values under field conditions (EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302, 107 pp. doi:10.2903/j.efsa.2015.4302 and Renewal Assessment Report, Volume 3 Annex B.8) as summarized in Table 5.6-3 and Table 5.6-4.

Table 5.6-3: Field degradation studies of glyphosate

Soil / location	pH	DT ₅₀ (d)	DT ₉₀ (d)	Fit, Kinetic, Parameters	χ ² error (%)	SFO recalculated*	Parameter	Reference
Diegten, Switzerland, sandy clay	7.1	6.1	116.1	DFOP	4.96	210.0	k1 0.1437 k2 0.0033 g 0.854	Schulz, 1992a
Menslage, Germany, sandy loam	4.7	5.7	200.8	DFOP	9.4	169.1	k1 0.1786 k2 0.0041 g 0.771	Schulz, 1992d
Buchen, Germany, loamy sand	6.4	40.9	187.3	DFOP	6.6	3.0E13	k1 0.019 k2 2.3E-14 g 0.927	Hill, 1992
Kleinzecher, Germany, sandy loam	7.0	38.3	386.6	DFOP	11.7	187.3	k1 0.0384 k2 0.0037 g 0.575	Hill, 1992
Unzhurst, Germany, loam	6.7	27.7	122.3	DFOP	8.4	778.8	k1 0.0280 k2 8.9E-4 g 0.922	Hill, 1992
Rohrbach, Germany, silt loam	8.5	20.1	66.9	SFO Top down	3.8	-	k 0.0344	Hill, 1992
Herrngiersdorf, Germany, clay loam	8.0	33.7	111.9	SFO	10.6	-	k 0.0206	Hill, 1992
Wang-Inzkofen, Germany, silt loam	7.2	17.8	165.5	FOMC	8.7	49.8	alpha 0.975 beta 17.207	Hill, 1992

Table 5.6-4: Field degradation studies of AMPA (persistence endpoint and trigger for higher tier studies)

Soil / location	pH	DT ₅₀ (d)	DT ₉₀ (d)	ff	Fit, Kinetic, Parameters	χ ² error (%)	Parameter	Reference
Kleinzecher, Germany, sandy loam	7.0	514.9	>1000	0.508	DFOP-SFO	15.9	k 0.0013	Hill, 1992
Unzhurst, Germany, loam	6.7	633.1	>1000	0.332	DFOP-SFO	13.3	k 0.0011	Hill, 1992
Rohrbach, Germany, silt loam	8.5	374.9	>1000	n.d.	SFO Top down	8.6	k 0.0018	Hill, 1992
Herrngiersdor f, Germany, clay loam	8.0	288.4	958.1	n.d.	SFO Top down	10.9	k 0.0024	Hill, 1992
Wang- Inzkofen, Germany, silt loam	7.2	283.6	942.3	0.547	FOMC-SFO	15.6	k 0.0024	Hill, 1992

5.6.2 Adsorption/desorption

Glyphosate and AMPA

No new studies have been submitted regarding adsorption/desorption in soil of glyphosate and AMPA. The exposure modeling is based on the EU $K_{Foc/doc}$ values (EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302, 107 pp. doi:10.2903/j.efsa.2015.4302 and Renewal Assessment Report, Volume 3 Annex B.8) as summarized in Table 5.6-5 and Table 5.6-6.

Table 5.6-5: K_F , K_{Foc} and 1/n (Freundlich exponent) values for glyphosate

Soil Type	OC (%)	pH (-)	K_f (mL g ⁻¹)	K_{foc}/k_{doc} (mL g ⁻¹)	1/n (-)	Reference
Silty clay loam	1.45	6.5 ²⁾	324.0	22300	0.92	Livingston et al., 1986
Silt loam	0.87	7.4 ²⁾	33.0	3800	0.80	Livingston et al., 1986
Loamy sand	1.10	5.2 ²⁾	660.0	60000	1.16	Livingston et al., 1986
Sand	0.80	5.7 ²⁾	-	32838 ⁶⁾	1.00 ⁷⁾	Waring, 1992
Sand loam	1.60	7.1 ²⁾	-	50660 ⁶⁾	1.00 ⁷⁾	Waring, 1992
Sandy clay loam	1.40	7.8 ²⁾	-	3598 ⁶⁾	1.00 ⁷⁾	Waring, 1992

Loamy sand	0.60	8.3 ²⁾	-	884 ⁶⁾	1.00 ⁷⁾	Waring, 1992
Silt loam	1.40	6.1 ²⁾	-	3404 ⁶⁾	1.00 ⁷⁾	Waring, 1992
Loam	3.00	7.1 ²⁾	-	17010 ⁶⁾	1.00 ⁷⁾	Waring, 1992
Sand	0.29	5.7 ²⁾	64.0	22000	0.75	Thomas & Lane, 1996
Sandy loam	0.58	8.4 ²⁾	9.4	1600	0.72	Thomas & Lane, 1996
Silty clay loam	2.26	5.7 ²⁾	470.0	21000	0.93	Thomas & Lane, 1996
Silty clay loam	2.15	6.2 ²⁾	700.0	33000	0.94	Thomas & Lane, 1996
Sandy loam	1.80	7.4 ²⁾	90.0	5000	0.76	Thomas & Lane, 1996
sand	0.62	5.9 ³⁾	29.5 ⁵⁾	4762	0.84	Kolk, 1996
loamy sand	2.32	5.6 ³⁾	71.7 ⁵⁾	3091	0.84	Kolk, 1996
loamy sand	1.22	6.4 ³⁾	37.7 ⁵⁾	3092	0.84	Kolk, 1996
-	0.70	5.9	-	9486 ⁶⁾	1.00 ⁷⁾	Schneider, 1993
-	1.34	6.3	-	5709 ⁶⁾	1.00 ⁷⁾	Schneider, 1993
-	1.20	7.3	-	4533 ⁶⁾	1.00 ⁷⁾	Schneider, 1993
Arithmetic mean				15388	0.93	

- 1) BBA Soil Texture Parametrisation
- 2) Buffer Solution = H₂O
- 3) Buffer Solution = CaCl₂
- 4) For this study, the units of the K_f and K_{foc} values were converted from [102 cm³/g] and [103 cm³/g] to [mL/g].
- 5) For this study, the K_{foc} values were not rounded.
- 6) K_{doc} values determined for a single concentration.
- 7) default value, due to the fact that no investigations of the relationship between soil solution concentration and adsorption behaviour were conducted in the study

The K_{foc} and K_{doc} values (combined) of glyphosate do not show any pH dependency.

Table 5.6-6: K_F, K_{Foc} and 1/n (Freundlich exponent) values for AMPA

Soil Type	OC (%)	pH (-)	K _f (mL g ⁻¹)	K _{foc} (mL g ⁻¹)	1/n (-)	Reference
Clay loam	2.09	7.7 ¹⁾	77.1	3640	0.79	Weeden, 1992

Sand	18.68 ³⁾	4.7 ^{1,3)}	1570.0 ³⁾	8310 ³⁾	0.90 ³⁾	Weeden, 1992
Sand	1.33	7.4 ¹⁾	15.7	1160	0.75	Weeden, 1992
Clay loam	0.93	7.6 ¹⁾	53.9	5650	0.79	Weeden, 1992
Loamy sand	1.57	6.3 ¹⁾	110.0	6920	0.77	Weeden, 1992
Sand	0.29	4.6 ¹⁾	73.0	24800	0.79	Weeden, 1992
Sand	0.29	5.7 ¹⁾	133.0	45900	0.86	Mueller & Lane, 1996
Sandy loam	0.58	8.4 ¹⁾	10.0	1720	0.78	Mueller & Lane, 1996
Silty clay loam	2.26	5.7 ¹⁾	509.0	22500	0.91	Mueller & Lane, 1996
Silty clay loam	2.15	6.2 ¹⁾	237.0	11100	0.86	Mueller & Lane, 1996
Sandy loam	1.80	7.4 ¹⁾	74.2	4130	0.84	Mueller & Lane, 1996
Silt loam	1.59	6.1 ¹⁾	137.4	8642	0.98	Knoch, 2003b
Silt loam	1.24	6.1 ¹⁾	87.9	7089	0.92	Knoch, 2003b
Silty clay	2.25	8.3 ¹⁾	33.9	1507	0.91	Knoch, 2003b
Sand	0.90	5.2 ²⁾	16.7	1861	0.6650 ⁴⁾	Wittig & Bockholt, 2002
Loamy sand	2.30	5.6 ²⁾	189.7	8248	0.5506 ⁴⁾	Wittig & Bockholt, 2002
Sandy silty loam	2.60	7.1 ²⁾	29.1	1119	0.6710 ⁴⁾	Wittig & Bockholt, 2002
Arithmetic mean				9749	0.81	

1) buffer Solution = H₂O

2) buffer Solution = CaCl₂

3) not included for calculation of statistics (mean values, correlations) due to high OC content

4) the Pesticides Peer Review Meeting 126 concluded that the 1/n values associated with these K_{foc} values should be the agreed endpoints (and not a default of 0.9).

The K_{foc} values of AMPA do not show any pH dependency.

5.6.3 Rate of degradation in water/sediment

Glyphosate and AMPA

No new water/sediment study has been submitted. The environmental exposure assessment is based on the EU agreed DT₅₀ values (EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302, 107 pp. doi:10.2903/j.efsa.2015.4302 and Renewal Assessment Report, Volume 3 Annex B.8) as summarized in

Table 5.6-7 and Table 5.6-8.

Table 5.6-7: Degradation in water/sediment of glyphosate - Persistence and modelling endpoints

Reference	System	Persistence endpoints at Level P-I				Modelling endpoints at Level P-I	
		Model	DT ₅₀ ⁴⁾ (days)	DT ₉₀ ⁴⁾ (days)	SFO DT ₅₀ ⁴⁾ (days)	Model	SFO DT ₅₀ ⁴⁾ (days)
Glyphosate (total system)							
Bowler & Johnson (1999)	Cache	FOMC	8.47	45.89	13.82 ⁵⁾	FOMC	13.82 ¹⁾
	Putah	DFOP	210.66	976.54	294.14 ⁵⁾	DFOP	329.85 ²⁾
Möllerfeld & Römbke (1993)	Loamy Sediment	FOMC	70.48	∞	– ⁶⁾	– ³⁾	– ³⁾
	Sandy Sediment	HS	16.03	346.81	104.46 ⁵⁾	HS	154.19 ²⁾
Heintze (1996)	Creek	SFO	16.78	55.74	16.78	SFO	16.78
	Pond	HS	67.45	281.39	84.76 ⁵⁾	HS	92.42 ²⁾
Muttzall (1993)	TNO	FOMC	93.06	>1000	>301.20 ⁵⁾	– ³⁾	– ³⁾
	Kromme Rijn	DFOP	28.86	232.92	70.16 ⁵⁾	DFOP	88.67 ²⁾
Minimum			-	-	13.82		13.82
Maximum			-	-	301.20		329.85
Geometric mean (n = 7/6⁸⁾)			-	-	74.52		67.74
Glyphosate (water phase)							
Bowler & Johnson (1999)	Cache	HS	4.98	26.84	8.08 ⁵⁾	SFO	6.94
	Putah	FOMC	8.25	72.40	21.81 ⁵⁾	FOMC	21.81 ¹⁾
Möllerfeld & Römbke (1993)	Loamy Sediment	FOMC	1.06	24.11	7.26 ⁵⁾	FOMC	7.26 ¹⁾
	Sandy Sediment	DFOP	2.03	22.63	6.82 ⁵⁾	DFOP	6.82 ¹⁾
Heintze (1996)	Creek	SFO	13.15	43.67	13.15	SFO	13.15
	Pond	HS	1.00	26.89	8.10 ⁵⁾	HS	8.10 ¹⁾
Muttzall (1993)	TNO	– ³⁾	– ³⁾	– ³⁾	– ³⁾	– ³⁾	– ³⁾
	Kromme Rijn	– ³⁾	– ³⁾	– ³⁾	– ³⁾	– ³⁾	– ³⁾
Minimum			-	-	6.82		6.82
Maximum			-	-	21.81		21.81
Geometric mean (n = 6)			-	-	9.88		9.63
Glyphosate (sediment phase)							
Bowler & Johnson (1999)	Cache	SFO	34.05	113.10	34.05	SFO	34.05
	Putah	– ³⁾	– ³⁾	– ³⁾	– ³⁾	– ³⁾	– ³⁾
Möllerfeld & Römbke (1993)	Loamy Sediment	– ³⁾	– ³⁾	– ³⁾	– ³⁾	– ³⁾	– ³⁾
	Sandy Sediment	FOMC	383.86	∞	– ⁶⁾	– ³⁾	– ³⁾
Heintze (1996)	Creek	– ³⁾	– ³⁾	– ³⁾	– ³⁾	– ³⁾	– ³⁾
	Pond	– ³⁾	– ³⁾	– ³⁾	– ³⁾	– ³⁾	– ³⁾
Muttzall (1993)	TNO	– ³⁾	– ³⁾	– ³⁾	– ³⁾	– ³⁾	– ³⁾
	Kromme Rijn	SFO	75.61	251.16	75.61	SFO	75.61
Minimum			-	-	34.05		34.05

Maximum	-	-	75.61		75.61
Geometric mean (n = 2)	-	-	- ⁷⁾		- ⁷⁾

- 1) Back-calculated from DT₉₀ of bi-phasic model (DT₉₀/3.32)
- 2) Calculated from slower k-rate
- 3) no reliable fit achieved
- 4) DT₅₀ = degradation DT₅₀ for total system, Dissipation DT₅₀ for water and sediment phase
- 5) Back-calculated SFO to derive endpoints for P criteria (SFO DT₅₀ = DT₉₀/3.32)
- 6) Back-calculation of SFO DT₅₀ not possible
- 7) Not calculated, since a sufficient number of DT₅₀ values were not available
- 8) Number of values for deriving persistence endpoint (SFO DT₅₀) and the modelling endpoint

Table 5.6-8: Degradation in water/sediment of AMPA - Persistence and modelling endpoints

Reference	System	Persistence endpoints at Level P-I				Modelling endpoints at Level P-I	
		Model	DT ₅₀ ⁴⁾ (days)	DT ₉₀ ⁴⁾ (days)	SFO DT ₅₀ ⁴⁾ (days)	Model	SFO DT ₅₀ ⁴⁾ (days)
AMPA (total system)							
Feser-Zügner (2002)	Rückhaltebecken	FOMC	13.80	1513.00	455.72 ⁵⁾	DFOP	102.87 ²⁾
	Schäphysen	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾
Knoch (2003)	Bickenbach	HS	10.54	191.25	57.61 ⁵⁾	HS	77.83 ²⁾
	Unter-Widdersheim	HS	77.36	307.19	92.53 ⁵⁾	HS	98.98 ²⁾
Knoch & Spirlet (1999)	Bickenbach	HS	44.53	205.21	61.81 ⁵⁾	HS	69.31 ²⁾
	Unter-Widdersheim	FOMC	20.13	885.03	266.58 ⁵⁾	_ ³⁾	_ ³⁾
McEwen (2004b)	A	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾
	B	_ ⁶⁾	_ ⁶⁾	_ ⁶⁾	_ ⁶⁾	_ ⁶⁾	_ ⁶⁾
Minimum			-	-	57.61		69.31
Maximum			-	-	455.72		102.87
Geometric mean (n = 5/4⁷⁾)			-	-	131.97		86.09
AMPA (water phase)							
Feser-Zügner (2002)	Rückhaltebecken	FOMC	2.20	22.50	6.78 ⁵⁾	FOMC	6.78 ¹⁾
	Schäphysen	FOMC	1.00	7.80	2.35 ⁵⁾	FOMC	2.35 ¹⁾
Knoch (2003)	Bickenbach	DFOP	2.54	47.57	14.33 ⁵⁾	DFOP	14.33 ¹⁾
	Unter-Widdersheim	FOMC	2.13	26.31	7.92 ⁵⁾	FOMC	7.92 ¹⁾
Knoch & Spirlet (1999)	Bickenbach	DFOP	6.59	51.47	15.50 ⁵⁾	DFOP	15.50 ¹⁾
	Unter-Widdersheim	HS	2.02	17.15	5.17 ⁵⁾	HS	5.17 ¹⁾
McEwen (2004b)	A	FOMC	0.69	8.87	2.67 ⁵⁾	FOMC	2.67 ¹⁾
	B	DFOP	1.28	6.87	2.07 ⁵⁾	DFOP	2.07 ¹⁾
Minimum			-	-	2.07		2.07
Maximum			-	-	15.50		15.50
Geometric mean (n = 8)			-	-	5.47		5.47
AMPA (sediment phase)							
Feser-Zügner (2002)	Rückhaltebecken	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾
	Schäphysen	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾
Knoch (2003)	Bickenbach	_ ⁸⁾	_ ⁸⁾	_ ⁸⁾	_ ⁸⁾	_ ⁸⁾	_ ⁸⁾
	Unter-Widdersheim	_ ⁸⁾	_ ⁸⁾	_ ⁸⁾	_ ⁸⁾	_ ⁸⁾	_ ⁸⁾
Knoch & Spirlet (1999)	Bickenbach	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾
	Unter-Widdersheim	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾
McEwen (2004b)	A	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾	_ ³⁾
	B	_ ⁶⁾	_ ⁶⁾	_ ⁶⁾	_ ⁶⁾	_ ⁶⁾	_ ⁶⁾

- 1) Back-calculated from DT₉₀ of bi-phasic model (DT₉₀/3.32)
- 2) Calculated from slower k-rate
- 3) no reliable fit achieved
- 4) DT₅₀ = degradation DT₅₀ for total system, Dissipation DT₅₀ for water and sediment phase
- 5) Back-calculated SFO to derive endpoints for P criteria (SFO DT₅₀ = DT₉₀/3.32)

- 6) excluded from kinetic evaluation due to analytical problems
- 7) Number of values for deriving persistence endpoint (SFO DT50) and the modelling endpoint
- 8) excluded from kinetic evaluation due to different amounts of AMPA in the sediment reported in the study

Accumulation of active substance and relevant metabolites in the sediment

active substance	Glyphosate
accumulation potential in sediment	yes ($DT_{90, \text{whole system}} > 1$ year, persistence endpoint at Level P-I, maximum, see chapter 5.6.3)
accumulation factor (SFO) $f_{\text{accu}} = e^{-kt}/(1 - e^{-kt})$	0.76 based on $DT_{50, \text{whole system}} = 301.20$ d (recalculated (SFO) persistence endpoint at Level P-I, maximum, see chapter 5.6.3), $t = 365$ d

5.7 Estimation of concentrations in soil (KIIIA1 9.4)

Roundup Gel Max is a gel formulation that will be applied directly to leaves/stumps as a spot treatment. The dose rate for Roundup Gel Max has been calculated as 3600 g a.s/ha, but as it is a home garden spot treatment, the realistic use rate will be much lower. As such, exposure to environment will be minimised. Therefore, PEC_{soil} calculations are not provided in this document.

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

Roundup Gel Max is a gel formulation that will be applied directly to leaves/stumps as a spot treatment. The dose rate for Roundup Gel Max has been calculated as 3600 g a.s/ha, but as it is a home garden spot treatment, the realistic use rate will be much lower. As such, exposure to environment will be minimised. Therefore, PEC_{sw} calculations are not provided in this document.

5.9 Risk assessment for groundwater (KIIIA1 9.6)

Roundup Gel Max is a gel formulation that will be applied directly to leaves/stumps as a spot treatment. The dose rate for Roundup Gel Max has been calculated as 3600 g a.s/ha, but as it is a home garden spot treatment, the realistic use rate will be much lower. As such, exposure to environment will be minimised. Therefore, PEC_{gw} calculations are not provided in this document.

Appendix 1 List of data submitted in support of the evaluation

No additional data for national assessment submitted.

Appendix 2 Detailed evaluation of studies relied upon

No additional data for national assessment submitted.

**REGISTRATION REPORT
Part B**

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

Product code: Roundup Gel Max

Active Substance: Glyphosate 72 g/L

**Central Zone
Zonal Rapporteur Member State: UK**

NATIONAL ADDENDUM Germany

Applicant: Monsanto Deutschland GmbH

Date: 04/2017

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Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

A full risk assessment according to Uniform Principles for the plant protection product Roundup Gel Max for use in home gardening was performed by zRMS UK.

This document comprises specific risk assessment for some annex points for authorization of the plant protection product Roundup Gel Max in Germany. The national addendum addresses national requirements differing from the standard EU modelling and risk assessment procedures. It refers moreover to specific management and risk mitigation practices that can be implemented in Germany.

Currently, the active substance glyphosate is in the Renewal Assessment (AIR2) with Germany as RMS. In the course of this, the environmental endpoints were re-evaluated and new relevant endpoints are proposed.

- Article 36 of Regulation (EC) No 1107/2009 states that „the Member State examining the application shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application“, an assessment based on updated data taking into account the latest knowledge from the LoEP 2015 is included.
- Considering the legal requirement resulting from Article 29(1)-e of the Regulation (EC) No 1107/2009 the risk regulation for product authorization has to be based on an assessment in the light of current scientific and technical knowledge as also mentioned in chapter 4 of the proposal for revision 9 of the SANCO/10328/2004 guidance document. The compliance with this objective requires an immediate evaluation (prior to a renewal according to Art. 14) for those new active substance data for which the consideration in the product risk assessment would either result in a non-authorization or to the necessity to derive stricter risk mitigation measures to ensure that the plant protection product under realistic conditions of use meets the requirements set up in Art. 4 (3) of the Regulation (EC) No 1107/2009 with respect to acceptability of risk to human health and environment. According to the proposal of the current version of the guidance document (as also in previous revisions) new annex II data would only have to be immediately evaluated if they are considered as ‘adverse data’ in the sense of Art. 56 (chapter 4.4, not covered in detail in the guidance document) or if they are (presumably) in support of the authorization of the applied uses (chapter 4.1 to 4.3).

The updated endpoints for glyphosate according to LoEP 2015 are presented and a risk assessment on updated data according to dRAR (Red draft, November 2013) and the LoEP 2015 is performed.

6.1 Overall conclusion

6.1.1 Effects on birds (MIIIA 10.1, KPC 10.1, KPC 10.1.1)

Based on the screening step, the calculated TER-values for the acute and long-term risk resulting from an exposure of birds to the active substance glyphosate according to the GAP of the formulation Roundup Gel Max achieve the acceptability criteria $TER \geq 10$ resp. $TER \geq 5$, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for acute and long-term effects. The results of the assessment indicate an acceptable acute and long-term risk for birds.

Consequences for authorization:

None

6.1.2 Effects on terrestrial vertebrates other than birds (MIIIA 10.3, KPC 10.1, KPC 10.1.2)

Based on the screening step, the calculated TER-values for the acute and long-term risk resulting from an exposure of mammals to glyphosate according to the GAP of the formulation Roundup Gel Max do achieve the acceptability criteria $TER \geq 10$ resp. $TER \geq 5$ and modified ≥ 2 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for acute and long-term effects. The results of the assessment indicate an acceptable acute and long-term risk for mammals.

Consequences for authorization:

None

6.1.3 Effects on aquatic organisms (MIIIA 10.2, KPC 10.2, KPC 10.2.1)

Due to the intended use of Roundup Gel Max as gel formulation for spot treatment in private home and garden exposure to the environment will be minimized and calculations of surface water concentrations can be omitted. Especially no spray-drift has to be expected. Also exposure via run-off and drainage is assumed to be negligible. Even though no quantitative risk assessment is performed the acute and long-term risk for aquatic organisms resulting from an exposure to glyphosate according to the GAP of the formulation Roundup Gel Max is evaluated as acceptable.

Consequences for authorization:

For the authorization of the plant protection product Roundup Gel Max following conditions of use are mandatory:

Roundup Gel Max	NW 467
Roundup Gel Max	NW 642-1

6.1.4 Effects on bees (MIIIA 10.4, KPC 10.3.1)

See relevant point in overall conclusion and the relevant summary, respectively.

Consequences for authorization:

None

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

Please refer to the core assessment.

Consequences for authorization:

None

6.1.6 Effects on non-target soil meso-, macro- and microfauna (MIIIA 10.6 and 10.7, KPC 10.4, KPC 10.4.1, KPC 10.4.2 and KPC 10.5)

Due to the intended use of Roundup Gel Max as gel formulation for spot treatment in private home and garden exposure to the environment will be minimized and calculations of soil concentrations can be omitted. Even though no quantitative risk assessment is performed the risk for soil meso-, macro- and micro-organisms resulting from an exposure to glyphosate according to the GAP of the formulation Roundup Gel Max is evaluated as acceptable

Consequences for authorization:

None

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

Please refer to the core assessment.

Consequences for authorization:

None

6.2 Proposed use pattern and considered metabolites

6.2.1 Grouping of intended uses for risk assessment

Roundup Gel Max is a herbicide intended for non-professional use in private home and garden for weed control in cultivated and uncultivated areas, for lawn renovation and control of stumps. Full details of the proposed use pattern of the formulation Roundup Gel Max that will be assessed are presented in the German National Addendum (NA) section 5 and summarized in the table below.

Table 6.2-1: Critical use pattern of Roundup Gel Max

Use No.*	Crop/growth stage/interception	Application method/drift scenario	Application rate, cumulative
1	Home and garden uses Pomiculture	Spreading, wiping as single plant treatment	2 × 2.5 mL/m ² = 2 × 1800 g glyphosate/ha
2	Home and garden uses Pomiculture	Spreading, wiping as single plant treatment	1 × 5 mL/m ² = 1 × 3600 g glyphosate/ha
3	Home and garden uses uncultivated areas without woody plants	Spreading, wiping as single plant treatment	2 × 2.5 mL/m ² = 2 × 1800 g glyphosate/ha
4	Home and garden uses uncultivated areas without woody plants	Spreading, wiping as single plant treatment	1 × 5 mL/m ² = 1 × 3600 g glyphosate/ha
5	Home and garden uses Ornamentals	Spreading, wiping as single plant treatment	2 × 2.5 mL/m ² = 2 × 1800 g glyphosate/ha
6	Home and garden uses Vegetable gardening	Spreading, wiping as single plant treatment	2 × 2.5 mL/m ² = 2 × 1800 g glyphosate/ha
7	Home and garden uses Ornamentals	Spreading, wiping as single plant treatment	2 × 2.5 mL/m ² = 2 × 1800 g glyphosate/ha
8	Home and garden uses Vegetable gardening	Spreading, wiping as single plant treatment	1 × 5 mL/m ² = 1 × 3600 g glyphosate/ha
9	Home and garden uses Ornamentals	Spreading, wiping as single plant treatment	1 × 5 mL/m ² = 1 × 3600 g glyphosate/ha
10	Home and garden uses Lawn	Spreading, wiping as single plant treatment	2 × 2.5 mL/m ² = 2 × 1800 g glyphosate/ha
11	Home and garden uses Pomiculture	Spreading, wiping as single plant treatment	2 × 2.5 mL/m ² = 2 × 1800 g glyphosate/ha
12	Home and garden uses Vegetable gardening	Spreading, wiping as single plant treatment	2 × 2.5 mL/m ² = 2 × 1800 g glyphosate/ha
13	Home and garden uses Lawn	Spreading, wiping as single plant treatment	2 × 2.5 mL/m ² = 2 × 1800 g glyphosate/ha

14	Home and garden uses Lawn	Spreading, wiping as single plant treatment	$1 \times 5 \text{ mL/m}^2$ $= 1 \times 3600 \text{ g glyphosate/ha}$
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* For administrative purposes, each intended use of a plant protection product in Germany is assigned with an individual use number from the German Federal Office of Consumer Protection and Food Safety (BVL).

6.2.2 Consideration of metabolites

The following metabolites of glyphosate are potentially relevant for exposure assessment (> 10 % or > 5 % in 2 sequential measurements or > 5 % and maximum of formation not yet reached at the end of the study).

Metabolite	Structural formula/Molecular formula	Occurrence in compartments (Max. at day)	Status of Relevance ¹⁾ according to Glyphosate LoEP 2015
Aminomethyl-phosphonic acid (AMPA) molar mass: 111.0 g/mol correction factor: 0.656	$\begin{array}{c} \text{O} \\ \\ \text{HO}-\text{P}-\text{CH}_2-\text{NH}_2 \\ \\ \text{OH} \end{array}$	Soil: aerob _{lab} : max. 50.1 % after 90 days aerob _{field} : max. 53.8 % after 271 days Water: Max. 15.7 % after 14 days Sediment: Max. 18.7 % after 58 days	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: not relevant
(Hydroxymethyl)-phosphonic acid molar mass: 112.0 g/mol correction factor: 0.662	$\begin{array}{c} \text{OH} \\ \\ \text{HO}-\text{P}-\text{C}-\text{OH} \\ \quad \\ \text{O} \quad \text{H}_2 \end{array}$	Water: Max. 10.0% after 61 days	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: not relevant

¹⁾ According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

6.3 Effects on birds (MIIIA 10.1, KPC 10.1, KPC 10.1.1)

The risk assessment for effects on birds and other terrestrial vertebrates is carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438).

If the Tier 2 assessment in the Core Assessment (CA) indicated an unacceptable risk using all acceptable refinement options except of the generic PT-refinement used in Germany according to the announcement BVL 10/02/14 in Bundesanzeiger, then these refinement options are used here on top of the Tier 2 refinement presented in the CA. The refinement corresponds to PT = 0.5 for birds in the chronic scenario.

Currently, the active substance glyphosate is in the Renewal Assessment (AIR2) with Germany as RMS. In the course of this, the environmental endpoints were re-evaluated and new relevant endpoints are proposed. **The updated endpoints according to LoEP 2015 are presented in tables presenting toxicity data, and a risk assessment on updated data according to LoEP 2015 is performed.**

6.3.1 Toxicity

Birds are exposed to residues of glyphosate on their food items following spraying of the formulated product. According to current data requirements in Commission Regulation 1107/2009 of 21 October 2009 amending Council Directive 91/414/EEC the acute oral toxicity of an active substance to a quail species (Japanese quail, *Coturnix coturnix japonica* or bobwhite quail, *Colinus virginianus*) or to mallard duck (*Anas platyrhynchos*) must be determined.

For the current Renewal Assessment (AIR2) a large number of acute studies in birds without any mortality at limit doses were submitted. EFSA guidance document 1438/2009 indicates that “it is permissible to extrapolate an LD₅₀ value in cases where there is no mortality or a single mortality at a limit dose in an acute avian toxicity study”. Using the study with the bobwhite quail with a limit dose of 2000 mg/kg bw, the extrapolation factor for no mortalities at the limit dose and 20 birds per dose group (the actual number of birds tested at this limit dose exceeded 20), the acute LD₅₀ to be used in a bird risk assessment according to EFSA guidance document 1438/2009 is proposed to be 2000 x 2.167 = 4334 mg/kg bw.

Concerning the effects of glyphosate on bird reproduction, studies have been conducted with bobwhite quail (Beavers and Fink 1978/ WI 78-52 and Frey, L.T. et al., 1999; 123-186) and mallard duck (Beavers and Fink 1978/ WI 78-53, Frey, L.T. et al., 1999; 123-187) for the active substance glyphosate. All studies have been reevaluated according to current guidelines.

Table 6.3-1: Toxicity of glyphosate to birds with reference to agreed endpoints

Species	Substance	System	Results	Reference	ICS-No.
<i>Colinus virginianus</i>	Glyphosate	1 d	LD ₅₀ = 4334 mg/kg bw (extrapolated according to EFSA GD 1438/2009) ¹⁾	dRAR (Red draft, November 2013)	
<i>Colinus virginianus</i>	Glyphosate	119 d	NOEC = 200 mg/kg food or NOEL = 18.1 mg/kg	Beavers and Fink, 1978,	35159/37256

Species	Substance	System	Results	Reference	ICS-No.
			bw/d ¹⁾ NOAEL = 96.3 mg/kg bw/d	Report No.: WI-78-52,	
<i>Colinus virginianus</i>	Glyphosate	140 d	<i>The study is not considered to be acceptable and valid</i> ¹⁾	Frey, L.T. et al., 1999; 123-186	44176
<i>Anas platyrhynchos</i>	Glyphosate	147 d	NOEL/NOAEL = 117 mg a.s./kg bw/day ¹⁾	Frey, L.T. et al., 1999; 123-187	44174

¹⁾ Updated endpoints according to dRAR (Red draft, November 2013)

6.3.2 Exposure

Roundup Gel Max is a garden formulation containing 72 g a.s./L glyphosate. It is a herbicide for control of difficult to control perennials and cut stumps in non-professional use (private sector: home and garden use). The product is a ready to use formulation which is applied by direct wiping onto weeds/stumps.

1 click of the applicator releases 0.3 ml product.

- One click (0.3ml) is applied to weeds with a leaf surface area over approximately 1200 cm².
- Two clicks (0.6ml) is applied to difficult/tall weeds over approximately 1200 cm².

Wiping over such a large surface (0.3 ml over 1200 cm²) is not practically possible, so the label instructs 'starting with the largest leaves first, apply to every third leaf'.

A theoretical dose rate in g/ha can be calculated as follows:

On 1 ha: 180 mg x 10 000 = 1 800 000 mg a.s/ha = 1800 g a.s/ha

For 2 clicks (0.6 ml) the dose rate is 3600 g a.s/ha

However, the home garden user will never be able to treat a full hectare of weeds with the gel in a single day. In practice the user will apply the product as a spot treatment. For the purposes of risk evaluation, this is considered to be 10% of a hectare, leading to a maximum dose rate of 360 g a.s/ha. While the 10% figure is somewhat arbitrary, it is reasonable to assume that amateur home garden use will be much more localised and on a smaller scale than professional uses. The total area that can be treated on a single day is also limited by the maximum pack size of 500 ml (based on the maximum rate of 0.6 ml (2 clicks) per 0.12 m², a 500 ml container can treat a maximum of 100 m²).

Birds could be exposed to the formulation via consumption of glyphosate acid (a.s.) residues on food items. Exposure to standard generic focal species was estimated according to the Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438):

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

Where:

DDD = Daily dietary dose (mg/kg bw/day)

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

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

The risk assessment procedure follows a stepwise approach. A first screening step involves standard scenarios and default values for the exposure estimate, representing a “reasonable worst case”. If a potential risk is indicated in the screening step, then one or several refinement steps (Tier 1, Tier 2) may follow. According to the Guidance Document, no further assessment is required if all uses are safe in the screening step.

Drinking water risk assessment

In case of home and garden uses birds might be exposed via drinking water from puddles. According to the new Guidance Document (EFSA, 2009), no specific calculations of drinking water exposure and TER are necessary when the ratio of effective application rate (in g/ha) to the relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg). This is due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by birds. The puddle scenario has been taken into account to calculate the exposure concentration of glyphosate formed on a field after rainfall. The ratios do not exceed the value of 3000 for glyphosate ($K_{oc} = 15388$ L/kg) thus it is not necessary to conduct a drinking water risk assessment for birds.

Food chain behavior

An assessment of the risk from secondary poisoning is not required due to $\log P_{ow}$ values of glyphosate being below the trigger. The primary metabolite of glyphosate is aminomethylphosphonic acid (AMPA). According to Sanco 6511/VI/99-final, 21 January 2002 the toxicologically significant compound is the parent glyphosate. Glyphosate is nearly completely excreted (approx. 30% via urine) and glyphosate is poorly metabolized to AMPA (< 0.5 %). Furthermore $\log K_{ow}$ was estimated via EpisuiteProgramm and SMILES code (C(N)P(=O)(O)O) to be -2.47 for AMPA and therefore indicates not the potential for bioaccumulation.

6.3.3 Toxicity to exposure ratio for birds (K III A 10.2.1)

6.3.3.1 Acute toxicity to exposure ratio (TER_A)

Screening step

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

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

Daily dietary dose (DDD):

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

* see section 4.1 of EFSA/2009/1438

Toxicity exposure ratio (acute):

$$TER_A = \frac{LD_{50} \text{ (mg/kgbw/day)}}{\text{AcuteDDD (mg/kgbw/day)}}$$

The resulting TER_A-values for the worst case application rate of 1 x 0.36 kg a.s./ha are summarized in the following table, along with the indicator species and the respective shortcut values.

Table 6.3-2: Acute screening risk assessment (TER_A) for birds

Scenario	Indicator species	Applic. rate (kg a.s./ha)	Shortcut value	MAF	DDD (mg/kg bw)	LD ₅₀ (mg/kg bw)	TER _A
Bare soil	Small graniv. bird	Max. 0.36	24.7	1	8.9	4334 (LoEP 2015)	487
Grassland	Large herbiv. bird		30.5		11.0		394
Orchards	Small insectivorous bird		46.8	16.9	257		
Leafy crops	Small omnivorous bird		158.8	57	76		

TERs shown in bold fall below the relevant trigger.

Based on the highly conservative presumptions of the screening step, the calculated TER-values for the acute risk resulting from an exposure of birds to the active substance glyphosate according to the GAP of the formulation Roundup Gel Max achieve the acceptability criterion $TER \geq 10$, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable acute risk for birds.

6.3.3.2 *Short-term toxicity exposure ratio (TER_{ST})*

There is no requirement for the calculation of TER_{ST} for birds under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) and, consequently, a risk assessment for short-term toxicity will not be conducted.

6.3.3.3 *Long-term toxicity exposure ratio (TER_{LT})*

Screening step

For the reproductive risk assessment, the calculation of the long-term toxicity exposure ratio (TER_{LT}) in principle follows the same procedure as for the acute risk assessment. However, the defined daily dose is obtained by multiplying the application rate with the mean short-cut values (based on mean RUD according to the new Guidance Document (EFSA, 2009)) as summarized in the following table.

Table 6.3-3: Avian generic focal species for the intended uses of Roundup Gel Max and relevant shortcut values for long-term exposure

Crop	Indicator species	Shortcut value (mean RUD)
Bare soils	Small granivorous bird	11.4
Grassland	Large herbivorous bird	16.2
Orchards	Small insectivorous bird	18.2
Leafy crops	Small omnivorous bird	64.8

As stated in the guidance document, it is justified to apply a time-weighted average (TWA) factor of 0.53 based on a default observation interval of 21 days and a default DT₅₀ of 10 days for the calculation of the DDD (daily dietary dose):

$$DDD_{\text{single application}} = \text{application rate [kg/ha]} \times \text{shortcut value} \times \text{TWA} \times \text{MAF}^*$$

* see section 4.3 of EFSA/2009/1438

Toxicity exposure ratio (Long-term):

$$TER_{LT} = \frac{\text{NOEL(mg/kgbw/day)}}{\text{Long-term DDD(mg/kgbw/day)}}$$

The relevant lowest NOAEL for the reproduction exposure scenario for glyphosate is 96.3 mg a.s./kg bw/d. Conversion of endpoints from ppm to mg a.s./kg bw/d was performed according to EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009). A recalculated value of 96.3 mg a.s./kg bw/d instead of 102.23 mg a.s./kg bw/d has been used. The relevant long-term endpoint is provided in the following table as well as calculated long-term toxicity exposure ratios (TER_{LT}) for birds exposed to glyphosate following applications of Roundup Gel Max at a worst case application rate of 1 x 0.36 kg a.s./ha.

Table 6.3-4: Long-term screening risk assessment (TER_{LT}) for birds exposed to Roundup Gel Max according to the intended uses

Scenario	Indicator species	Applic. rate (kg a.s./ha)	Shortcut value	MAF× f _{TWA}	DDD (mg/kg bw)	NOAEL (mg/kg bw)	TER _{LT}
Bare soil	Small graniv. bird	Max. 0.36	11.4	0.53	2.2	96.3 (LoEP 2015)	44
Grassland	Large herbiv. bird		16.2		3.1		31
Orchards	Small insectivorous bird		18.2		3.5		26
Leafy crops	Small omnivorous bird		64.8		12.4		7.8

Based on the conservative presumptions of the screening step, the calculated TER-values for the long-term risk resulting from an exposure of birds to the active substance glyphosate according to the GAP of the formulation Roundup Gel Max do achieve the acceptability criterion $TER \geq 5$, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable long-term risk for birds.

Consequences for authorization:

None

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

The risk assessment for effects on mammals is carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438). **The assessment for the active substance glyphosate is based on the updated data taking into account the latest knowledge from the LoEP 2015 .**

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

6.4.1 Toxicity

Table 6.4-1: Toxicity of glyphosate to mammals with reference to updated endpoints (dRAR, Nov. 2013) and LoEP 2015

Species	System	Results	Reference
Rat	Acute oral toxicity	LD ₅₀ > 2000 mg/kg bw	AIR2 dRAR (Red draft, November 2013) and LoEP 2015
Rabbit	Teratogenic study, toxicity to mother animals	NOAEL = 50 mg/kg bw/day; Maternal: bw gain ↓, Developmental: post-implantation loss	1996, ASB2012-11499; Renewal Assessment Report, Volume 3 Annex B.9.3.3, Red Draft and LoEP 2015

In the Renewal Assessment Report for glyphosate (Volume 3 Annex B.9, Red Draft and LoEP 2015), an overall LD₅₀ of > 2000 mg/kg bw was determined.

In the Renewal Assessment Report for Glyphosate (Volume 3 Annex B.9, Red Draft) an overall NOAEL of 50 mg/kg bw/day is proposed for risk assessment. The lowest NOAEL for developmental effects is 50 mg/kg bw/day, based on post-implantation loss in the rabbit at 200 mg/kg bw/day in the study ASB2012-11499. Due to dose spacing, the NOAELs in other studies were higher (TOX2552390, TOX9552391; TOX2000-2002) but consistently below 200 mg/kg bw/day. Beside post-implantation losses and late embryonic death (TOX9551960; TOX9552391), developmental findings at higher dose levels included a lower foetal weight and delayed ossification (please refer to RAR, Vol. 1, chapter 2.6.7.2.2.).

6.4.2 Exposure

Roundup Gel Max is a gel formulation that will be applied directly to leaves/stumps as a spot treatment. The maximum dose rate for Roundup Gel Max has been calculated as 3600 g a.s/ha (for calculation see chapter 6.3.2). However, the home garden user will never be able to treat a full hectare of weeds with the gel in a single day. In practice the user will apply the product as a spot treatment. For the purposes of risk evaluation, this is considered to be 10% of a hectare, leading to a maximum dose rate of 360 g a.s/ha. While the 10% figure is somewhat arbitrary, it is reasonable to assume that amateur home garden use will be much more localised and on a smaller scale than professional uses. The total area that can be treated on a single day is also limited by the maximum pack size of 500 ml (based on the maximum rate of 0.6 ml (2 clicks) per 0.12 m², a 500 ml container can treat a maximum of 100 m²).

Mammals could be exposed to the formulation via consumption of glyphosate acid (a.s.) residues on food items. Exposure to standard generic focal species was estimated according to the Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438).

6.4.3 Risk assessment

6.4.3.1 Acute toxicity exposure ratio (TER_A)

Screening step

In the screening step, indicator species are used. These indicators are considered to have highest exposure in a specific crop at a particular time due to their size and feeding habits and represent a worst case scenario. The indicator mammal species for the intended uses are listed in the following table.

Table 6.4-2: Indicator species for mammals according to intended uses of Roundup Gel Max and shortcut values

Crop	Indicator species	Shortcut value (90th percentile RUD)
Bare soils	Small granivorous mammal	14.4
Grassland Leafy vegetables Orchards	Small herbivorous mammal	136.4

For the estimation of daily dietary doses (DDD) and the calculation of TER-values please refer to 6.3.3.1.

Table 6.4-3: Acute screening risk assessment (TER_A) for mammals

Indicator species	Application rate (kg a.s./ha)	Shortcut value, acute	MAF	DDD (mg/kg bw)	LD ₅₀ (mg/kg bw)	TER _A
Small granivorous mammal	Max. 0.36	14.4	1	5.2	> 2000	> 385
Small herbivorous mammal		136.4	1	49	> 2000	> 41

Based on the screening step, the calculated TER-values for the acute risk resulting from an exposure of mammals to glyphosate according to the GAP of the formulation Roundup Gel Max do achieve the acceptability criterion $TER \geq 10$ according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable acute risk for mammals due to the intended uses of Roundup Gel Max according to the label.

6.4.3.2 Short-term toxicity exposure ratio (TER_{ST})

There is no requirement for the calculation of TER_{ST} for mammals under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) and, consequently, a risk assessment for short-term toxicity has not been performed.

6.4.3.3 Long-term toxicity exposure ratio (TER_{LT})

In the Renewal Assessment Report for Glyphosate (Volume 3 Annex B.9, Red Draft and LoEP 2015), an overall NOAEL of 50 mg/kg bw/day is proposed for risk assessment. The lowest NOAEL for developmental effects is 50 mg/kg bw/day, based post-implantation loss in the rabbit at 200 mg/kg bw/day in the study ASB2012-11499. See information above. This endpoint is considered in the risk assessment. Full details of the toxicity studies are provided in the respective EU DAR.

Screening step

For the reproductive risk assessment, the calculation of the long-term toxicity exposure ratio (TER_{LT}) follows in principle the same procedure as for the acute risk assessment.

The defined daily dietary dose is obtained by multiplying the application rate with the mean short-cut value (based on the mean RUD according to the new Guidance Document (EFSA, 2009)) as summarized in the following table.

Table 6.4-4: Mammal generic focal species for the intended uses of Roundup Gel Max and relevant shortcut values for long-term exposure

Crop	Indicator species	Shortcut value (mean RUD)
Bare soils	Small granivorous mammal	6.6
Grassland Leafy vegetables Orchards	Small herbivorous mammal	72.3

Please refer to chapter 6.3.3.3 for the equation employed in the estimation of the daily dietary doses and the calculation of TER-values.

Table 6.4-5: Long-term screening risk assessment (TER_{LT}) for mammals exposed to Roundup Gel Max according to the updated endpoints (dRAR, Nov. 2013)

	Indicator species	Applic. rate (kg/ha)	Shortcut value (long-term)	f _{TWA}	MAF	DDD (mg/kg bw/day)	NOAEL (mg/kg bw/day)	TER _{LT}
Renewal Assessment (AIR2), dRAR (Red draft, November 2013) and LoEP 2015	Small graniv. mammal	Max. 0.36	6.6	0.53	1	1.3	50	39
	Small herbiv. mammal		72.3			13.8		3.6*
TERs shown in bold fall below the relevant trigger.								

* In cases where the relevant model species for assessment of the risk from the intended uses is a wood mouse (*Apodemus sylvaticus* L.) or a common vole (*Microtus arvalis*), the TER acceptability criterion may be modified (TER ≥ 5 in the acute exposure scenario and TER ≥ 2 in the long-term exposure scenario).

Based on the conservative assumptions of the screening assessment, the calculated TER-values for the long-term risk resulting from an exposure mammals to the active substance glyphosate according to the GAP of the formulation Roundup Gel Max do achieve the acceptability criterion TER ≥ 5 resp. modified ≥ 2, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects with a max. application rate of 0.36 kg a.s./ha. The results of the assessment indicate an acceptable long-term risk for mammals due to the intended uses of Roundup Gel Max according to the label.

Consequences for authorization:

none

6.5 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KPC 10.1.3)

Roundup Gel Max is a gel formulation that will be applied directly to leaves/stumps as a spot treatment. The maximum dose rate for Roundup Gel Max has been calculated as 3600 g a.s/ha, but as it is a home and garden spot treatment, the realistic use rate will be much lower (for calculation see chapter 6.3.2). As such, exposure to the environment will be minimized and a risk assessment für terrestrial vertebrate wildlife (here reptiles and amphibians) can be omitted.

6.6 Effects on aquatic organisms (MIIIA 10.2, KPC 10.2, KPC 10.2.1)

6.6.1 Overview

Roundup Gel Max is a gel formulation that will be applied directly to leaves/stumps as a spot treatment. The maximum dose rate for Roundup Gel Max has been calculated as 3600 g a.s/ha, but as it is a home and garden spot treatment, the realistic use rate will be much lower (for calculation see chapter 6.3.2). As such, exposure to the environment will be minimized and calculations of surface water concentrations can be omitted. Especially no spraydrift has to be expected. Also exposure via run-off and drainage is assumed to be negligible as the gel will stick to the leaves, which reduces the potential of wash-off.

New acute aquatic studies with Roundup Gel Max were submitted by the applicant (study summaries see core assessment UK). They show no greater toxicity than already known for glyphosate or other glyphosate formulations.

Even though no quantitative risk assessment is performed the acute and long-term risk for aquatic organisms resulting from an exposure to glyphosate according to the GAP of the formulation Roundup Gel Max is evaluated as acceptable.

Consequences for authorization:

none

6.7 Effects on bees (MIIIA 10.4, KPC 10.3.1)

The impact of glyphosate / Roundup Gel Max respectively on bees is assessed by the Julius-Kühn Institute and will be added here accordingly.

Consequences for authorization:

none

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

According to the herbicidal effect of the formulation these effect values are substantially higher than those effects determined for non-target terrestrial plants, which are therefore relevant for the risk assessment for terrestrial biocoenoses. For that reason a quantitative risk assessment for non-target arthropods is not conducted in this national addendum .

6.9 Effects on non-target soil meso- and macrofauna (MIIIA 10.6, KPC 10.4, KPC 10.4.1, KPC 10.4.2)

Roundup Gel Max is a gel formulation that will be applied directly to leaves/stumps as a spot treatment. The dose rate for Roundup Gel Max has been calculated as 3600 g a.s/ha, but as it is a home garden spot treatment, the realistic use rate will be much lower. As such, exposure to the environment will be minimized and the calculations of soil concentrations can be omitted.

In support of the evaluation of Roundup Gel Max the applicant submitted a study on sublethal effects for earthworms, which does not show greater toxicity than already known for glyphosate or other glyphosate formulations (study summary see core assessment UK).

Even though no quantitative risk assessment is performed the acute and long-term risk for soil meso- and macro-organisms resulting from an exposure to glyphosate according to the GAP of the formulation Roundup Gel Max is evaluated as acceptable.

Consequences for authorization:

none

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

Roundup Gel Max is a gel formulation that will be applied directly to leaves/stumps as a spot treatment. The dose rate for Roundup Gel Max has been calculated as 3600 g a.s/ha, but as it is a home garden spot treatment, the realistic use rate will be much lower. As such, exposure to environment will be minimized and the calculations of soil concentrations can be omitted.

In support of the evaluation of Roundup Gel Max the applicant submitted a study on C/N-mineralisation, which does not show greater toxicity than already known for glyphosate or other glyphosate formulations (study summary see core assessment UK).

Even though no quantitative risk assessment is performed the risk for soil micro-organisms resulting from an exposure to glyphosate according to the GAP of the formulation Roundup Gel Max is evaluated as acceptable.

Consequences for authorization:

none

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

6.11.1 Risk assessment

The applicant did not submit a new study with the formulation Roundup Gel Max on non-target terrestrial plants in support of the evaluation. However, as no exposure in off-field areas has to be assumed no quantitative risk assessment is performed. Even though the risk for non-targeted terrestrial plants resulting from an exposure to glyphosate according to the GAP of the formulation Roundup Gel Max is evaluated as acceptable.

Consequences for authorization:

None

6.12 Classification and proposed labelling with regard to fate and behaviour and ecotoxicological data

Because of the toxicity of the active ingredient following label has to be given:

NW 467:	The product and its remains, empty containers and packaging and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.
NW 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.

Classification and labelling of the formulation Roundup Gel Max:

Relevant toxicity data	Glyphosate acid NOEC = 1 mg/L (<i>Brachydanio rerio</i>)	
Classification & Labelling according directives 67/548/EEC, 78/631/EEC and 1999/45/EEC		
Danger Symbol	none	
Risk Phrases	none	
C&L according directive 1272/2008		
Danger Symbol	none	
Hazard Statements	none	

Hazard symbol(s):	none	
Identification of danger:	none	none
R and S phrases under Directive 2003/82/EC (Annex IV and V)		
Risk Phrases:	none	
Safety Phrases:	none	