

REGISTRATION REPORT
Part A

Risk Management

Product name: BARRACUDA
Product code: AE-036-1
Active Substance: Mesotrione 100 g/L

COUNTRY: Germany
Central Zone
Zonal Rapporteur Member State: UK

NATIONAL ASSESSMENT

Applicant: AlbaughUK Ltd
Submission date: 08/12/2014
Finalisation date: 22/05/2017

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PART A – Risk Management

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

The risk assessment conclusions are based on the information, data and assessments provided in “Barracuda” Registration Report, Part B Sections 1-8 and Part C from UK and where appropriate the addendum for Germany. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national re-registration/registration by the EU review. It also includes assessment of data and information relating to Barracuda where that data has not been considered in the EU review. Otherwise assessments for the safe use of Barracuda have been made using endpoints agreed in the EU review of mesotrione.

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

Appendix 1 include the authorisation (copy) of the final product in Germany.

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

1 Details of the application

1.1 Application background

This application was submitted by Albaugh UK Ltd on 08/12/2014.

The application was for approval of AE-036-1 which is an herbicide formulation containing 100 g as/L mesotrione. AE-036-1 is applied for registration as an herbicide in Maize for early post emergence applications for the control of annual monocotyledonous and dicotyledonous weeds.

1.2 Annex I inclusion

Mesotrione was included on Annex I of Directive 91/414/EEC on 1 October 2003 under Inclusion Directive 2003/68/EC and approved under Regulation 1107/2009 by the Regulations n°540/2011 and 823/2012.

The Annex I Inclusion Directive for mesotrione (2003/68/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 mesotrione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account.

1.3 Regulatory approach

To obtain registration the product Barracuda must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed/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

Where data protection is being claimed regarding information supporting registration of Barracuda, it is indicated in the reference list in Appendix 1 of the respective documents of the Registration Report.

1.5 Letters of Access

The data not provided by the applicant and necessary to conduct the evaluation is out of protection, no access authorization is needed.

2 Details of the authorisation

2.1 Product identity

Product Name	Barracuda (AE-036-1)
Authorization Number (for re-registration)	008357-00/00
Function	Herbicide
Applicant	Albaugh
Composition	100 g/L mesotrione
Formulation type	suspension concentrate [Code: SC]
Packaging	0.5 – 1 L bottle HDPE; 3 - 20 L jerry can HDPE

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not proposed anymore.

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

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

<i>Hazard classes and categories:</i>	
Skin Sens. 1, Eye Dam. 1	
<i>Hazard pictograms:</i>	
GHS05	corrosion
GHS07	exclamation mark
GHS09	environment
<i>Signal word:</i>	
Danger	
<i>Hazard statements:</i>	
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
<i>Precautionary statements:</i>	
P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P310	IF exposed or concerned: Immediately call a POISON CENTER or a doctor/physician.
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>	
46 percent of the mixture consist of one or more ingredients 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.
SB199	When applying the product with tractor-mounted, trailed or self-propelled application equipment, only vehicles with closed pressurized cabins (e.g. cabin category 3, if no respiratory protective equipment or particle-filtering masks are necessary or category 4, if gas-tight respiratory protective equipment is needed acc. to EN 15695-1 and -2) are suited to replace personal protective equipment during application. During all other activities outside of the cabin the prescribed personal protective equipment must be worn. In order to avoid contamination of the cabin, it is not permitted to enter the cabin with contaminated personal protective equipment (it should be deposited e.g. in an appropriate storage facility). Contaminated gloves should be washed before removing the gloves and hands should be washed before entering the cabin with pure water, respectively.
SE110	Wear tight fitting eye protection when handling the undiluted product.
SF1891	Re-entering the treated areas/crops are only possible on the day of application wearing personal protective equipment which is specified for applying the particular product. Successive work on/in treated areas/crops may fundamentally not be carried out until 24 hours after applying the product. Within the first 48 hours, protective suits against pesticides and standard protective gloves (plant protection) are to be worn.
SS110	Wear standard protective gloves (plant protection) when handling the undiluted product.
SS120	Wear standard protective gloves (plant protection) when handling/applying the product ready for application.
SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.
SS2202	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when applying/handling the product ready for application.
SS610	Wear a rubber apron when handling the undiluted product.
Integrated pest management (IPM)/sustainable use	
WMF2	Mode of action (HRAC-group): F2
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)
NN3002	The product is classified as harmful for populations of relevant beneficial predatory mites and spiders.
Ecosystem protection	

NW265	The product is toxic for higher aquatic plants.
NW468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

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

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

2.3.2 Specific restrictions linked to the intended uses

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

Integrated pest management (IPM)/sustainable use	
WH9161	The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.
WP734	Damage is possible to the crop.
WP713	Damage is possible to replanted dicotyledonous crops.
Ecosystem protection	
NW609-1	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water-bearing surface waters - the product must be applied observing the minimum buffer zone stated below. It is not necessary to observe this buffer zone if the product is applied using equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended. Irrespective of this, in addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times. Violations may be punished by fines of up to 50 000 EUR. 5 m.
NW705	Between treated areas which have an incline of more than 2 % and surface waters - including periodically but excluding occasionally water-bearing surface waters - there must be a buffer zone under complete plant cover. The buffer zone's protective function must not be impaired by the use of implements. It must be at least 5 m wide. This buffer zone is not necessary if: -sufficient catching systems are available for the water and soil transported by run-off, which do not flow into surface water or are not connected with the urban drainage system or -the product is used for conservation or no-tillage methods.
NT108	A buffer zone of at least 5 m must be kept from adjacent areas (except agriculturally or horticulturally used areas, roads, paths and public places). In addition, in an adjoining strip of at least 20 m, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette

	<p>No 205, p. 9780) as amended, and be registered in at least drift reducing class 75 %. Neither loss reducing equipment nor a buffer zone of at least 5 m are required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide. A buffer zone of at least 5 m is also unnecessary if the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures, or if evidence can be shown that adjacent areas (e.g. field boundaries, hedges, groups of woody plants) were planted on agriculturally or horticulturally used areas.</p>
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2.4 Product uses

Reg.-No. 008357-00/00
PPP (product name/code): Barracuda
Active substance: Mesotrione
Applicant: Albaugh UK Limited
Zone(s): central
Verified by MS: Yes

GAP rev.1, Date: 2016-11-11
Formulation type: SC ^(a, b)
Conc. of as: 100.00 g/L ^(c)
Professional use: Yes
Non-professional use: No
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			13 PHI (days)	14 Remarks: e.g. g safener / synergist per ha (f)	15 Conclusion (efficacy)
					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	12 Water L/ha min / max			
001	DE	Maize (ZEAMX) (grain maize and fodder maize) except for seedling production	F	annual dicotyledonous weeds (TTDS)	spraying	after emergence BBCH 12 to 18	a) 1 b) 1		a) 1.5 L/ha b) 1.5 L/ha	a) 0.15 kg/ha b) 0.15 kg/ha	200 - 300	F	WH9161 WP734 WP713 NW609-1, NW705, NT108	positive

Remarks table heading:

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

(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPS in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)

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.

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- | | |
|--|--|
| 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 |
| | 15 A: Acceptable
R: Acceptable with further restriction
C: To be confirmed by cMS
N: Not acceptable / evaluation not possible
n.r.: Not relevant for section 3 |

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)

Overall Summary:

The product Barracuda is a SC formulation. All studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable. The appearance of the product is that of dark cream, uniform liquid, with an odour similar to octanol. It is not explosive, has no oxidising properties. It has a self-ignition temperature superior to 400°C. In aqueous solution, it has a pH value around 3.09. A storage stability study was done, due to the higher amount of rinsed residue an addition labelling on the package has to be made. Its technical characteristics are acceptable for a SC formulation.

Implications for labelling: *None.*

Compliance with FAO guidelines:

The product Barracuda complies with FAO specifications, as far as could be assessed. No specific FAO specifications are available for mesotrione.

Compatibility of mixtures:

No tank mixture is recommended.

Nature and characteristics of the packaging:

Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment:

Information regarding the required protective clothing and equipment for the safe handling of Barracuda has been provided and is considered to be acceptable.

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

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

The method of analysis for the total active substance in the formulation was validated in accordance with SANCO/3030/99 rev 4. Analytical methods for determination of mesotrione, impurities and relevance of CIPAC methods in Barracuda were not evaluated as part of the EU review of mesotrione. Therefore all relevant data are provided and are considered adequate.

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

The analytical methods are active substance data and were provided in the EU review of mesotrione and were considered adequate for food of plant and animal origin, soil, water, air and body fluids and tissues. Since these studies are out of data protection, they are used in support of this application. New analytical methods for residues were not supplied with this application.

However, taking the data requirement in SANCO/825/00 rev 8.1 into account, the following data gaps have been noticed:

- A primary method, an independent laboratory validation (ILV) and a confirmatory method for the determination of mesotrione in commodities with high acid content and high oil content is required.
- A primary method, an independent laboratory validation (ILV) and a confirmatory method for the determination of mesotrione in food of animal origin is required.
- A confirmatory method for the determination of mesotrione, AMBA and MNBA in soil on the EC₁₀ level of the most sensitive crop is required.
- A confirmatory method for the determination of mesotrione tap and surface water is required.

These data gaps can be addressed in the context of the next renewal of the approval of mesotrione according to Reg. (EC) No 1107/2009 or in the context of the assessment of existing MRLs of mesotrione according to Reg. (EC) No 396/2005. The applicant will be informed about the data gaps.

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

Germany agrees with the risk assessment carried out by the zRMS UK. For details please see the dRR by the zRMS UK.

However the active substance mesotrione is currently being reassessed in the renewal process. At this point in time the process is still ongoing. A new AOEL of 0.005 mg/kg bw/d (currently AOEL of 0.015 mg/kg bw/d) is being proposed within the peer review process. If this AOEL is confirmed the risk assessment for the worker will show a consumption of the AOEL of more than 100 % even with the restriction of SF1891 (see 2.3).

Furthermore it is proposed to classify the active substance mesotrione with H361d (Repro. 2) and H373 (STOT RE 2). The P-Phrases P201 and P405 would be proposed additionally.

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

For details please see the dRR by the zRMS UK.

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

For details please see the dRR by the zRMS UK.

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

For details please see the dRR by the zRMS UK.

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

For details please see the dRR by the zRMS UK.

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

See 2.2

3.1.3.5 Groundwater Metabolites

For the mesotrione-metabolites MNBA and AMBA concentrations of $\geq 0.1\mu\text{g/L}$ in groundwater can be excluded. For details see Part B, National Addendum Germany, Section 5, chapter 5.7.1.

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

Germany agrees with the risk assessment carried out by the zRMS UK. For details please see the dRR by the zRMS UK. Currently the MRL for mesotrione in maize is set at 0.01 mg/kg (Reg (EU) No 2016/53). The residue data shows that this MRL will not be exceeded by the intended use.

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

For details please see the dRR by the zRMS UK.

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

For details please see the dRR by the zRMS UK.

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

A full exposure assessment for the plant protection product Barracuda (AE-036-1) in its intended use in maize is documented in detail in the core assessment of the plant protection product Barracuda (AE-036-1) dated from 03/2016 performed by UK.

The following chapters summarize specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of Barracuda in Germany according to its intended use in maize (Use No. 00-001).

Due to the date of application, endpoints from the Renewal Assessment Report (RAR, February 2015) were taken. Updated endpoints were published in the EFSA Conclusion (03/2016), but they underlined only slight changes that do not influence the overall results and authorization.

Metabolites

New studies on the fate and behaviour of Mesotrione have been performed in the context of the renewal of the approval (please refer to RAR, February 2015). A new potentially relevant metabolite has been identified in a new water/sediment-study (SYN546974).

The risk assessment for these metabolites has already been performed for the renewal of the EU approval. MNBA and AMBA are relevant for the risk to aquatic water organisms as well as terrestrial organisms. Hence a national assessment of the metabolites is required (see core assessment). However, for the soil metabolites of Mesotrione occurring in relevant concentrations, national groundwater risk assessment was performed.

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

For the intended use of the plant protection product Barracuda in maize according to use No 00-001 PEC_{soil} was calculated for the active substance Mesotrione considering a soil depth of 2.5 cm.

Due to the fast degradation of the active substance mesotrione in soil (DT₉₀ < 365 d, SFO, laboratory data) the accumulation potential of mesotrione does not need to be considered. No short-term and long-term PEC_{soil} were calculated since PEC_{soil,act} is considered sufficient for German risk assessment.

The results for PEC_{soil} for the active substance and the metabolites were used for the ecotoxicological risk assessment.

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

1. Direct leaching into groundwater

Results of modelling with FOCUS PELMO 5.5.3 show that the active substance Mesotrione is not expected to penetrate into groundwater at concentrations of $\geq 0.1 \mu\text{g/L}$ in the intended use of Barracuda in maize according to use No. 00-001.

For the metabolites MNBA and AMBA concentrations of $\geq 0.1 \mu\text{g/L}$ in groundwater can be excluded.

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

According to modelling with EXPOSIT 3.0.1, groundwater contamination at concentrations $\geq 0.1 \mu\text{g/L}$ by the active substance Mesotrione and its soil metabolites MNBA and AMBA of Mesotrione due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

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

For the intended use of the plant protection product Barracuda in maize according to use No. 00-001 PEC_{sw} was calculated for the active substance Mesotrione considering the two routes of entry separately: (i)

spraydrift and volatilization with subsequent deposition and (ii) run-off and drainage.

The calculation of concentrations in surface water was based on spray drift data by Ganzelmeier, Rautmann et al. 1995 (Studies on the spray drift of plant protection products. Mitteilungen aus der BBA für Land- und Forstwirtschaft Berlin-Dahlem, Heft 305, 113).

The vapour pressure at 20 °C of the active substance Mesotrione is $< 10^{-5}$ Pa. Hence the active substance Mesotrione is regarded as non-volatile. Therefore, exposure of surface water by the active substance Mesotrione due to deposition following volatilization was not considered.

The concentrations of the active substance Mesotrione in adjacent ditch due to surface run-off and drainage were calculated using the model EXPOSIT 3.0.1.

The results for PEC_{sw} and PEC_{sed} for the active substance and its metabolites were used for the ecotoxicological risk assessment.

3.1.5.4 Predicted Environmental Concentration in Air (PECAir) (Part B, Section 5, Point 9.9)

The fate and behaviour in air of mesotrione was evaluated during the Annex I Inclusion. The atmospheric half-life was found to be 1.5 days which means that no long-term transportation would be expected for mesotrione.

The vapour pressure at 20 °C of the active substance mesotrione is $< 10^{-5}$ Pa ($< 5.7 \times 10^{-6}$). Hence the active substance mesotrione is regarded as non-volatile. Therefore exposure of non-target areas by the active substance mesotrione due to volatilization with subsequent deposition does not need to be considered.

Implications for labelling resulting from environmental fate assessment: (Phrase **Rxx** should be added to the label)

For the authorization of the plant protection product Barracuda following labelling and conditions of use are mandatory.

Classification and labelling

Based on the data on the active substance Mesotrione the plant protection product Barracuda is considered to be not readily degradable in the sense of the CLP regulation.

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

A full risk assessment according to Uniform Principles for the plant protection product Barracuda (AE-036-1) in its intended uses in maize is documented in detail in the core assessment of the plant protection product Barracuda (AE-036-1) dated from January 2016 performed by UK. The intended use of Barracuda (AE-036-1) in Germany is generally covered by the uses evaluated in the course of the core assessment by UK.

The authorization in UK is linked with risk mitigation measures regarding effects on non-target organisms (see Part A, National Assessment – UK).

The following chapters summarise specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of Barracuda (AE-036-1) in Germany according to its intended use in maize (use No. 00-001).

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

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

Birds

The results of the risk assessment by zRMS UK indicate an acceptable acute and long-term risk for birds due to the intended use of Barracuda (AE-036-1) in maize that is also transferable to the intended use of Barracuda (AE-036-1) in Germany.

Terrestrial vertebrates (other than birds)

The results of the risk assessment by zRMS UK indicate an acceptable acute and long-term risk for mammals due to the intended use of Barracuda (AE-036-1) in maize that is also transferable to the intended use of Barracuda (AE-036-1) in Germany.

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

Results of aquatic risk assessment for the intended uses of Barracuda (AE-036-1) in maize based on FOCUS Surface Water PEC values is presented in the core assessment, Part B, Section 6, chapter IIIA 10.2.

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

No additional entries as those according to the evaluated use pattern and good agricultural practice are acceptable, therefore condition of use NW468 is assigned. Based on the intrinsic property of the PPP (*Lemna gibba* $E_bC_{50} = 0.0077$ mg a.s./L), the national labelling NW265 is assigned.

1. Exposure by spraydrift and deposition following volatilization

Based on the relevant toxicity of the Mesotrione, the calculated TER values for the risk to aquatic organism resulting from an exposure of surface water by spraydrift according to Barracuda according to the use No 00-001 only achieve the acceptability criteria of $TER \geq 10$, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2 if appropriate risk mitigation measures (5 m buffer strip or drift reducing technique) are applied.

Risk assessment for mesotrione for aquatic organisms for the entry route via spraydrift and deposition following volatilization under the implementation of different risk mitigation measures

Compound:	Mesotrione
Crop/Application rate:	Maize, 1 x 150 g a.s./ha
Growth stage and season	BBCH 12 – 18, spring
Intended use:	00-001

DT₅₀ water (SFO):			6 d					
PEC-selection:			actual					
Drift-Percentile:			90th					
Buffer zone [m]	Entry via spraydrift		Entry via deposition following volatilization		PEC _{sw} ; conventional and drift reducing technique			
	[%]	[µg/ha]	[%]	[µg/L]	0% conv.	50% red.	75% red.	90% red.
					[µg/L]			
1	2.77	1.385	-	-	1.385	0.693	0.346	0.139
5	0.57	0.285	-	-	0.285	0.143	0.071	0.029
Relevant toxicity endpoint: E _b C ₅₀ = 7.7 µg a.s./L (<i>Lemna gibba</i>) Relevant TER: 10								
Buffer zone [m]					TER			
1					5.6	11.1	22.2	55.6
5					27	54.0	108.1	270.2
Risk mitigation measures			NW 609-1, 5 m					

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

2. Exposure by surface run-off and drainage

The concentrations of Mesotrione in adjacent ditch due to surface runoff and drainage was calculated using the model EXPOSIT.

The calculated TER values for the risk to aquatic organisms resulting from an exposure of surface water by Mesotrione due to run-off and drainage according to the use No 00-001 achieve the acceptability criteria of TER ≥ 100 or 10 respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. if risk mitigation measures are applied (5 m buffer stripe).

Risk assessment for mesotrione for aquatic organisms for the entry route via run-off and drainage under the implementation of different risk mitigation measures

Compound:	Mesotrione	
Application rate:	1 x 150 g ai/ha	
Intended use	00-001 maize	
Relevant toxicity endpoint:	E _b C ₅₀ = 7.7 µg a.s./L (<i>Lemna gibba</i>)	
Relevant TER:	10	
Run-off		
Buffer zone	PEC	TER
[m]	[µg/L]	
0	0.79	9.79
5	0.68	11.29
Drainage		
Time of application	PEC	TER
	[µg/L]	
Autumn/winter/early spring	Not relevant	-
Spring/summer	0.26	29.87

Risk mitigation measures	NW 705 (5 m vegetated buffer strip)
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PEC: predicted environmental concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

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

Bees

EU Endpoints

Table 3.1.6.3-1 presents the EU-endpoints of the active substance mesotrione for bees.

Table 3.1.6.3-1: Ecotoxicological endpoints for bees (SANCO/1416/2001 – Final – 2003/04/14)

Active substance	EU agreed endpoints
Mesotrione	Oral LD ₅₀ > 11 µg a.s./bee based on a study using the technical active substance Contact LD ₅₀ > 9.1 µg a.s./bee based on a study using the formulation 'ZA 1296 SC 10' containing 100 g a.s./L

Toxicity

Table 3.1.6.3-2 presents the results of bee toxicity studies.

Table 3.1.6.3-2: Toxicity to bees of AE-036-1

Substance	Endpoint	Value (µg a.s./bee)	Reference
Mesotrione	48 h oral LD ₅₀	> 11	<i>SANCO/1416/2001 – Final – 2003/04/14</i>
	48 h contact LD ₅₀	> 9.1	
AE-036-1	48 h oral LD ₅₀	> 163.3	<i>KHIA 10.4.2.1/01</i>
	96 h contact LD ₅₀	72.7	

Exposure

Applications of pesticides can potentially result in exposure of honeybees either through direct over-spray, or by contact with residues on plants whilst bees are foraging for food.

Hazard quotients for bees

The acute risk to honeybees from use of AE-036-1 was assessed using the maximum single application rate and the LD₅₀ values to calculate hazard quotients (EPPO 2003)¹ as follows:

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

Hazard quotients were calculated for oral exposure (Q_{HO}) and contact exposure (Q_{HC}) to AE-036-1. A hazard quotient of less than 50 indicates a low risk to bees in the field. Table 3.1.6.3-3 presents the hazard quotients for mesotrione and the formulated product AE-036-1.

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

Table 3.1.6.3-3: Risk to bees from exposure to AE-036-1

Test substance	Application rate (g a.s./ha)	LD ₅₀ (µg a.s./bee)	Hazard quotient
Mesotrione	150	48 h oral LD ₅₀ > 11	< 13.6
		48 h contact LD ₅₀ > 9.1	< 16.5
AE-036-1	150	48 h oral LD ₅₀ > 163.3	< 0.919
		96 h contact LD ₅₀ = 72.7	2.06

Conclusion

All the hazard quotients are considerably less than 50, indicating that the active substances pose a low risk to bees. Therefore a low risk to bees is expected from the application of AE-036-1.

Label NB6641 is assigned to the product.

Other non-target arthropods

The results of the risk assessment by zRMS UK indicate an acceptable for arthropods in the intended use of the formulation Barracuda (AE-036-1) in maize according to the label. That is also applicable to the intended use of the product Barracuda (AE-036-1) in Germany according to use No. 00-001.

For details please refer to the core assessment Part B, section 6, chapter IIIA.10.5.

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

The evaluation of the risk for earthworms and other soil macro-organisms was performed by zRMS in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002). The risk assessment is based on maximum PEC_{soil} concentrations at a soil depth of 5 cm.

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

The calculated TER values achieve the acceptability criterion $TER \geq 10$ and 5 respectively, for acute and chronic effects on earthworms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5. The results of the assessment indicate an acceptable risk for earthworms due to the intended use of Barracuda in maize according to the label.

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

No tests are required considering the persistence trigger in accordance with the EU Guidance Document, since the field DT₉₀ is < 365 days for Mesotrione and only a single application is recommended per year, indicating that there will be no long-term exposure or accumulation of residues.

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

The results of the risk assessment by zRMS UK indicate an acceptable for arthropods in the intended use of the formulation Barracuda (AE-036-1) in maize according to the label. That is also applicable to the intended use of the product Barracuda (AE-036-1) in Germany according to use No. 00-001.

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

Based on the predicted rates of the Barracuda in off-field areas, the TER values describing the risk for non-target plants following exposure to Barracuda according to the GAP of the formulation barracuda achieves the acceptability criteria $TER \geq 5$ according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of Barracuda in maize according to the label.

Risk assessment for mesotrione for non-target plants for the entry route via spraydrift and deposition following volatilization under the implementation of different risk mitigation measures

Compound:			Mesotrione					
Intended use group:			00-001					
Drift-Percentile:			Arable crop/90th					
Buffer zone [m]	Entry via spraydrift		Entry via deposition following volatilization		PER _{off-field} ; conventional and drift reducing technique			
	[%]	[g/ha]	[%]	[g/ha]	0% conv.	90% red.	75% red.	50% red.
							[g/ha]	
1	2.77	4.16	-	-	4.16	0.42	1.04	2.08
5	0.57	0.86	-	-	0.86	0.09	0.21	0.43
Relevant toxicity endpoint: ER ₅₀ = 1.11 g a.s./ha (<i>Beta vulgaris</i>)								
Buffer zone [m]					TER			
1					0.26	2.62	1.06	0.53
5					1.27	12.2	5.24	2.56
Risk mitigation measures			NT 108					

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

Implications for labelling resulting from ecotoxicological assessment:

For the authorization of the plant protection product Barracuda (AE-036-1) the following labelling and conditions of use are mandatory:

Classification and labelling

Relevant toxicity	Active substance: Mesotrione (content 10 %) EbC50 = 0.0077 mg/L (<i>Lemna gibba</i>) M-factor = 100
Classification and labelling according to Regulation 1272/2008	
Hazard symbol	GHS09
Signal word	No signal word used
Hazard statement	H400, H410

National phrases notified under Regulation (EC) No 547/2011

NW265	The product is toxic for higher aquatic plants.
NW468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water.

	This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.
NW 609-1	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water-bearing surface waters - the product must be applied observing the minimum buffer zone stated below. It is not necessary to observe this buffer zone if the product is applied using equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended. Irrespective of this, in addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times. Violations may be punished by fines of up to 50 000 EUR. Buffer zone: 5 m
NW 705	Between treated areas which have an incline of more than 2 % and surface waters - including periodically but excluding occasionally water-bearing surface waters - there must be a buffer zone under complete plant cover. The buffer zone's protective function must not be impaired by the use of implements. It must be at least 5 m wide. This buffer zone is not necessary if: -sufficient catching systems are available for the water and soil transported by run-off, which do not flow into surface water or are not connected with the urban drainage system or -the product is used for conservation or no-tillage methods.
NT108	A buffer zone of at least 5 m must be kept from adjacent areas (except agriculturally or horticulturally used areas, roads, paths and public places). In addition, in an adjoining strip of at least 20 m, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 75 %. Neither loss reducing equipment nor a buffer zone of at least 5 m are required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide. A buffer zone of at least 5 m is also unnecessary if the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures, or if evidence can be shown that adjacent areas (e.g. field boundaries, hedges, groups of woody plants) were planted on agriculturally or horticulturally used areas

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

Information on the active substance

AE-036-1 is an herbicide formulation containing 100 g as/L mesotrione. AE-036-1 is applied for registration as an herbicide in Maize for early post emergence applications. Mesotrione is taken up by leaves and roots and translocated as well in xylem as in phloem. In germinating plants it hinders seedlings from emergence. It is a selective systemic herbicide, absorbed by foliage and roots with foliage efficacy being predominant. It acts as a bleaching herbicide. Site of Action (HRAC): F2.

Minimum Effective Dose

Data were submitted covering a range of weeds, and compared control at 0.5, 0.75, 1.0 and 1.5 l/ha. Dose responses were seen in ECHCG, which supports the proposed dose of 1.5 l/ha for this weed. Results on CHEAL showed no dose response from the final assessment of effectiveness, however the 0.75 l/ha dose (the target dose) does show a quicker and more consistent level of early control compared to the 0.5 l/ha dose. This improved early control can be important in supporting early establishment for maize. The other

tested weed species show a range of responses with POLCO, POLPE and VERPE showing a dose response between 0.5 and 0.75 l/ha.

Effectiveness

Data have been submitted on a range of weeds from trials conducted in all three relevant EPPO climatic zones. However, the zRMS notes that the range of weed data presented is very limited and it is not possible to make a direct assessment of comparability of control across all three EPPO zones as only 1 weed was common across all three zones in the data. The data set as whole indicates that there is no significant difference in control between the three zones and that data from the maritime zone could be used to support effectiveness claims in the NE and SE zones. However, concerned member States will need to draw their own conclusion based on their local knowledge of the weeds, Member State agronomic and environmental conditions and access to any available data from comparable products. Finally, as data on major monocotyledonous weeds in Maize such as ECHCG are deficient (According to the EPPO Standard PP1/226, a major target in a major crop must be supported by 10 trials (range 6-15 trials required depending on factors such as range of environmental and climatic conditions, levels of target pressure and consistency of results).) annual monocotyledonous weeds are not covered in the GAP.

The applicant is requested to give relevant informations on the species controlled (WH9161).

Effects on yield and quality

Yield trials were conducted on crops in three EPPO zones and treated crops between GS13-17. Trials in the maritime zone were conducted over two years, but only one year's trials were conducted in SE and NE. These data mostly show that Barracuda has no impact on yield across a range of tested varieties. No phytotoxicity was seen in the trials submitted. Taking all the data together, the results show no consistent significant yield reductions. Only three trials were conducted in the EPPO NE and SE zones, covering one year, which is less than that recommended by EPPO PP1/226. However, no significant phytotoxicity was seen. Data on quality of yield showed no adverse effects and residue data showed no concerns.

In accordance with the experience of national conditions the label warning WP734 is assigned to the particular use.

Plant parts for propagation

EPPO PP1/135 (4) indicates that germination testing is only required for post-emergence herbicides when application is made at or after inflorescence initiation e.g. for cereals when the first node is detectable (BBCH GS 30) or where detectable residues occur in harvested seed. Neither is the case for this product. However, the use applied for is on crops that are not being grown for seed.

Succeeding crops

The applicant has submitted data and a case, using EPPO PP1/207. However, the applicant has not tested all the proposed succeeding crops, with only ryegrass tested and oat selected as a second grass species. However, the two grass species show a low sensitivity and oat is a suitable indicator for cereals as it is often the most sensitive. Oilseed rape is not supported by the data as the TER >1 is after 250 days (using *Brassica oleracea* as an indicator), compared to the application to harvest interval for maize of around 150 days; so in accordance with the experience of national conditions the label warning WP713 is assigned to the particular use.

Adjacent crops

The applicant has submitted satisfactory tests and a suitable assessment on the risk to adjacent crops using EPPO PP 1/256 and concluded that as Barracuda is an herbicide particular care is needed to avoid drift.

Resistance

Barracuda contains mesotrione which is from a group of herbicides referred to as 4-HPPD inhibitors. This class of compounds act by disrupting the synthesis of certain plant pigments involved in photosynthesis. The applicant has presented a suitable assessment of the resistance risk and correctly identified that at the current time there are no known cases of resistance outside of the USA to mesotrione. In addition, at the present time there is no known cross-resistance to mesotrione in weeds that exhibit resistance or reduced sensitivity to other herbicides with different modes of action. Crop rotation with the use of herbicides with a different mode of action will help to reduce the development of resistance. Label WMF2 is assigned to the product.

Effects on beneficial arthropods

The toxicity of the comparable formulation ZA 1296 SC 100 was tested in laboratory tests or extended laboratory tests with the standard test organisms *Typhlodromus pyri* and *Aphidius rhopalosiphi*, in laboratory tests with *Poecilus cupreus*, *Aleochara bilineata* and *Chrysoperla carnea* as well as in laboratory tests, aged-residue and / or field tests with spiders of the genus *Pardosa*.

The laboratory experiments with the formulation ZA 1296 SC showed that *Typhlodromus pyri* was very sensitive with an LR50 of 8.6 g AS / ha, whereas in *Aphidius rhopalosiphi* only marginal effects <30% occurred even with 200 g AS / ha. For *Typhlodromus pyri* effects in the range of 25 to 50% were observed in the extended laboratory test. Spiders of the genus *Pardosa* reacted much more strongly than *T. pyri*, and re-colonization very limited even after 12 days. For *Aphidius rhopalosiphi* a reduction in reproduction of 25 to 50% was observed in an extended laboratory experiment with an application rate of up to 25% of the maximum field rate, whereas in the case of higher quantities only marginal effects of <25% occurred. Likewise, the results presented for *Poecilus cupreus*, *Aleochara bilineata* and *Chrysoperla carnea* show effects of <25%.

Labels NN1001 and NN3002 are assigned to the product.

3.2 Conclusions

With regard to efficacy/IPM and sustainable use incl. protection of honeybees an authorisation can be granted for the product BARRACUDA in accordance with the intended and evaluated GAP.

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

Concerning 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 information is required.

Appendix 1 – Copy of the product authorisation

See below.

Appendix 2 – Copy of the product label

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

Appendix 3 – Letter of Access

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



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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.008357-00/00.117350
(bitte bei Antwort angeben)

DATUM 29. Mai 2017

ZV3 008357-00/00

Barracuda

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit dem Wirkstoff: 100 g/l Mesotrione

Zulassungsnummer: 008357-00

Versuchsbezeichnungen: ALB-15566-H-0-SC

Antrag vom: 8. Dezember 2014

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. Mai 2018.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

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

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008357-00/00-001	Einjährige zweikeimblättrige Unkräuter	Mais	Körner- und Futtermais, ausgenommen zur Saatguterzeugung

Festgesetzte Anwendungsbestimmungen

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

(NW468)

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

Begründung:

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

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

Verpackungen

Gemäß § 36 Abs. 1 S. 2 Nr. 1 PflSchG sind für das Pflanzenschutzmittel die nachfolgend näher beschriebenen Verpackungen für den beruflichen Anwender zugelassen:

Verpackungsart	Verpackungsmaterial	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Flasche	HDPE	1		0,50	1,00	l
Kanister	HDPE	1		3,00	20,00	l

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

Anwendung nur durch berufliche Anwender zulässig.

Auflagen

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

Kennzeichnungsaufgaben:

(NN3002)

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

(NW265)

Das Mittel ist giftig für höhere Wasserpflanzen.

(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.

(SB199)

Wenn das Produkt mittels an den Traktor angebauten, gezogenen oder selbstfahrenden Anwendungsgeräten ausgebracht wird, dann sind nur Fahrzeuge, die mit geschlossenen Überdruckkabinen (z. B. Kabinenkategorie 3, wenn keine Atemschutzgeräte oder partikelfiltrierenden Masken benötigt werden oder Kabinenkategorie 4, wenn gasdichter Atemschutz erforderlich ist (gemäß EN 15695-1 und -2)) ausgestattet sind, geeignet, um die persönliche Schutzausrüstung bei der Ausbringung zu ersetzen. Während aller anderen Tätigkeiten außerhalb der Kabine ist die vorgeschriebene persönliche Schutzausrüstung zu tragen. Um die Kontamination des Kabineninnenraumes zu vermeiden, ist es nicht erlaubt, die Kabine mit kontaminierter persönlicher Schutzausrüstung zu betreten (diese sollte in einer entsprechenden Vorrichtung aufbewahrt werden). Kontaminierte Handschuhe sollten vor dem Ausziehen abgewaschen werden, beziehungsweise sollten die Hände vor Wiederbetreten der Kabine mit klarem Wasser gereinigt werden.

(SE110)

Dicht abschließende Schutzbrille tragen beim Umgang mit dem unverdünnten Mittel.

(SF1891)

Das Wiederbetreten der behandelten Flächen/Kulturen ist am Tage der Applikation nur mit der persönlichen Schutzausrüstung möglich, die für das Ausbringen des Mittels vorgegeben ist. Nachfolgearbeiten auf/in behandelten Flächen/Kulturen dürfen grundsätzlich erst 24 Stunden nach der Ausbringung des Mittels durchgeführt werden. Innerhalb 48 Stunden sind dabei der Schutzanzug gegen Pflanzenschutzmittel und Universal-Schutzhandschuhe (Pflanzenschutz) zu tragen.

(SS110)

Universal-Schutzhandschuhe (Pflanzenschutz) tragen beim Umgang mit dem unverdünnten Mittel.

(SS120)

Universal-Schutzhandschuhe (Pflanzenschutz) tragen bei Ausbringung/Handhabung des anwendungsfertigen Mittels.

(SS2101)

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

(SS2202)

Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung des anwendungsfertigen Mittels.

(SS610)

Gummischürze tragen beim Umgang mit dem unverdünnten Mittel.

(WMF2)

Wirkungsmechanismus (HRAC-Gruppe): F2

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

Sonstige Auflagen:

(WH952)

Auf der Verpackung und in der Gebrauchsanleitung ist die Angabe zur Kennzeichnung des

Wirkungsmechanismus als zusätzliche Information direkt jedem entsprechenden Wirkstoff-namen zuzuordnen.

Vorbehalt

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

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

Signalwort:

(S2) Gefahr

Gefahrenpiktogramme:

(GHS05) Ätzwirkung

(GHS07) Ausrufezeichen

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(H317)

Kann allergische Hautreaktionen verursachen.

(H318)

Verursacht schwere Augenschäden.

(H400)

Sehr giftig für Wasserorganismen.

(H410)

Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

(EUH 401)

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

Sicherheitshinweise (P-Sätze):

(P101)

Ist ärztlicher Rat erforderlich, Verpackung oder Kennzeichnungsetikett bereithalten.

(P102)

Darf nicht in die Hände von Kindern gelangen.

(P280)

Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.

(P302+P352)

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

(P305+P351+P338)

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

(P308+P310)

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

(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 bienengefährlich eingestuft (B4).

(NN1001)

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

Weitere Hinweise und Bemerkungen

Zum Etikett:

Auf dem Etikett ist zusätzlich zum Wirkstoffgehalt anzugeben:

"Enthält ca. 15 g/L Phosphorsäure zur Regulierung des pH-Wertes".

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

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

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

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

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Martin Streloke
Abteilungsleiter

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

Anlage

Anlage 1 zugelassene Anwendung: 008357-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Einjährige zweikeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Mais

Verwendungszweck: Körner- und Futtermais
ausgenommen zur Saatguterzeugung

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	12 bis 18
Anwendungszeitpunkt:	Nach dem Auflaufen
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	1,5 l/ha in 200 bis 300 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(WH9161)

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

(WP713)

Schäden an nachgebauten zweikeimblättrigen Kulturen möglich.

(WP734)

Schäden an der Kulturpflanze möglich.

2.3 Wartezeiten

- (F) Freiland: Mais
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

(NT108)

Bei der Anwendung des Mittels muss ein Abstand von mindestens 5 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) eingehalten werden. Zusätzlich muss die Anwendung in einer darauf folgenden Breite von mindestens 20 m mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungskategorie 75 % eingetragen ist.

Bei der Anwendung des Mittels ist weder der Einsatz verlustmindernder Technik noch die Einhaltung eines Abstandes von mindestens 5 m erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind. Bei der Anwendung des Mittels ist ferner die Einhaltung eines Abstandes von mindestens 5 m nicht erforderlich, wenn die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) nachweislich auf landwirtschaftlich oder gärtnerisch genutzten Flächen angelegt worden sind.

Begründung:

Das o.g. Pflanzenschutzmittel bzw. der darin enthaltene Wirkstoff Mesotrione weist ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 1,11 g a.s./ha. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 5 ist nach dem Stand der wissenschaftlichen Erkenntnisse die o.g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen zu gewährleisten.

(NW609-1)

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

beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu 50.000 Euro geahndet werden.

5 m

Begründung:

Das o.g. Pflanzenschutzmittel bzw. der darin enthaltene Wirkstoff Mesotrione weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere höhere Wasserpflanzen auf. Bewertungsbestimmend ist hier die EbC50 von 7,7 µg a.i./L für Lemna gibba. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die o.g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von Gewässerorganismen zu gewährleisten.

(NW705)

Zwischen behandelten Flächen mit einer Hangneigung von über 2 % und Oberflächengewässern - ausgenommen nur gelegentlich wasserführender, aber einschließlich periodisch wasserführender - muss ein mit einer geschlossenen Pflanzendecke bewachsener Randstreifen vorhanden sein. Dessen Schutzfunktion darf durch den Einsatz von Arbeitsgeräten nicht beeinträchtigt werden. Er muss eine Mindestbreite von 5 m haben. Dieser Randstreifen ist nicht erforderlich, wenn:

- ausreichende Auffangsysteme für das abgeschwemmte Wasser bzw. den abgeschwemmten Boden vorhanden sind, die nicht in ein Oberflächengewässer münden, bzw. mit der Kanalisation verbunden sind oder
- die Anwendung im Mulch- oder Direktsaatverfahren erfolgt.

Begründung:

Der im o.g. Pflanzenschutzmittel enthaltene Wirkstoff Mesotrione weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere höhere Wasserpflanzen auf. Bewertungsbestimmend ist hier die EbC50 von 7,7 µg a.i./L für Lemna gibba. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 160 mg/L; DT50 Boden = 31,7 d; KFoc = 83), einer Berechnung der über den Pfad Oberflächenabfluss (Run-off) zu erwartenden Einträge mit dem Modell Exposit 3.01 und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die o.g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von Gewässerorganismen zu gewährleisten.