REGISTRATION REPORT
Part A

Risk Management

Product code: **A14203B**

Active Substance: **Mesotrione 500 g/kg**

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: Hungary

NATIONAL ASSESSMENT

Applicant: **Syngenta Agro GmbH**

Date: **29/05/2017**

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of A14203B containing mesotrione in Germany. This evaluation is required subsequent to the inclusion of mesotrione on Annex 1.

The risk assessment conclusions are based on the information, data and assessments provided in "A14203B" Registration Report, Part B Sections 1-7 and Part C from Hungary 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 registration by the EU review. It also includes assessment of data and information relating to A14203B where that data has not been considered in the EU review. Otherwise assessments for the safe use of A14203B 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 A14203B.

Appendix 1 of this document provides a copy of the final product authorisation 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 of this document contains copies of the letters of access to the protected data / third party data that was needed for evaluation of the formulation.
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 Syngenta Agro GmbH on 12/04/2013.

The application was for approval of A14203B formulated as a water dispersible granule (WG) containing 500 grams per kg (g/kg) mesotrione for the control of annual broad-leaved weeds and *Echinochloa crus-galli* in maize.

1.2 Annex I inclusion

Mesotrione

Mesotrione which was included into Annex I of Council Directive 91/414/EEC (Commission Directive 03/68/EC of 11 July 2003). This active substance is an approved active substance under Regulation (EC) 1107/2009 (repealing Commission Directive 91/414/EEC) as specified in Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011.

The Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011 does not stipulate any specific provisions for Mesotrione which need to be considered by the applicant in the preparation of their submission or by the MS prior to granting an authorisation.

1.3 Regulatory approach

To obtain approval the product A14203B must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of A14203B, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letters of Access

Where Syngenta has provided the supporting data in Dokument K, the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation

2.1 Product identity

Product Name	A14203B
Authorization Number (for re-registration)	007938-00/00
Function	Herbicide
Applicant	Syngenta
Composition	500 g/kg mesotrione
Formulation type	Water dispersible granule [Code: WG]
Packaging	1-5 L jerry can, HDPE 0.4-10 kg folding box, composite material

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

The following labelling is proposed in accordance with Directive 1999/45/EC:

Symbol(s)/Indication(s) of danger:	
Risk phrases:	
Safety phrases:	
S2	Keep out of the reach of children
S24	Avoid contact with skin
S36/S37	Wear suitable protective clothing and gloves.
S46	If swallowed, seek medical advice immediately and show this container or label
Specific labelling requirement:	
To avoid risks to man and the environment, comply with the instructions for use.	
Contains urea, polymer with formaldehyde. May produce allergic reactions.	

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

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

Hazard classes and categories:	
None	
Hazard pictograms:	
GHS09	environment
GHS 02	Flame
Signal word:	
Danger	
Hazard statements:	
H251	Self-heating: may catch fire.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Precautionary statemtents:	
P501	Dispose of contents/container to ...

Special rule for labelling of PPP:	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208 - Contains urea, polymer with formaldehyde. May produce allergic reactions.	

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

None

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

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.
SF245-01	Treated areas/crops may not be entered until the spray coating has dried.
SS110	Wear standard protective gloves (plant protection) when handling the undiluted product.
SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.
SS530	Wear face protection when handling the undiluted product.
SS610	Wear a rubber apron when handling the undiluted product.
Integrated pest management (IPM)/sustainable use	
WMF2	Mode of action (HRAC-group): F2
NN2002	The product is classified as slightly 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.
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)

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	
NW 605-1	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 with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*". 50 %: 5 m, 75 %: *, 90 %: *
NW606	The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters - except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro. 5 m.
NW701	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 10 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

2.3 Product uses

Reg.-No. **007938-00/00** **GAP rev. (No), date: 2016-10-24**

PPP (product name/code): **A14203B** **Formulation type:** **WG**
Active substance: **Mesotrione** **Conc. of as:** **500 g/kg**

Applicant: **Syngenta Agro GmbH** **Professional use:** ☒
Zone(s): **central** **Non-professional use:** ☐

Verified by MS: **yes**

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	g, kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	maize (ZEAMX)	F	annual dicotyledonous weeds (TTTDS), Echinochloa crus-galli (ECHCG), ~~Digitaria sanguinalis (DIGSA)~~ (BBCH -21)	spraying	Spring, after emergence 12 to 19	a) 1 b) 1	a) 300 g/ha b) 300 g/ha	a) 150 kg/ha b) 150 kg/ha	~~80~~200 - 400	F*	Mandatory tank mixture: „in combination with a non-ionic or oil-based surfactant“ WH9161, WP734, WP713 NW605-1, NW606, NW701, NT108 *The PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product and the use of the product (e. g.

												harvest) or the setting of a PHI in days is not required resp.

Remarks:
(1) Numeration of uses in accordance with the application/as verified by MS
(2) Member State(s) or zone for which use is applied for
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage of treatment(s) (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
Min. interval between applications (days) where relevant
(9) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
(10) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
(11) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
(12) PHI - minimum pre-harvest interval
(13) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

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 A14203B is a water dispersible granule. 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 beige solid, with an uncharacteristic odour. It is not explosive, has no oxidising properties, but according to the submitted study it is classified as a self-heating substance. In aqueous solution, it has a pH value around 4.8. The stability data indicate a shelf life of at least two years at ambient temperature in HDPE and other packages. The technical characteristics of A14203B are acceptable for a water dispersible granule formulation.
Regarding the storage stability for two years at ambient temperature following properties, which should be determined according to the FAO/WHO manual (2010), were not determined: pH, wettability, persistence of foam and flowability.

Implications for labelling:

GHS pictogram: 

Hazard Category:	1.	
Signal word:	Danger	
Hazard Statement:	H251	Self-heating: may catch fire.
Precautionary statem.:	P235+P410	Keep cool. Protect from sunlight.
	P280	Wear protective glove /eye protection / face protection.
	P407	Maintain air gap between stacks/pallets.
	P420	Store away from other materials.

Compliance with FAO guidelines:
The product A14203B complies with FAO specifications, as far as could be assessed.

Compatibility of mixtures:
No tank mixtures are foreseen.

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 and handling, resistance to and 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 A14203B 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)

In the analytical method SF-67/1 HPLC/UV is used for the determination of mesotrione in the product A14203B. The method is fully validated according to SANCO/3030/99.
The CIPAC method 625 for the determination of mesotrione in water dispersible granule formulations is applicable to A14203B.
Regarding the relevant impurity R287431 (1-cyano-6-(methylsulfonyl)-7-nitro-9H-xanthen-9-one) a LC/MS method was submitted. The method is fully validated for specificity, linearity, accuracy and precision.

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. 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 and MNBA in commodities with high acid content and high oil content 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.

Taking the data requirement in SANCO/825/00 rev 8.1 into account data gaps were also identified for soil, drinking water and surface water. However, in the context of an application for Callisto the applicant provided new studies for these matrices. Germany as zRMS considered these studies as acceptably validated.

3.1.3 Mammalian Toxicology

Germany agrees with the assessment of the zRMS Hungary in terms of classification and labelling of the product. No national addendum was deemed necessary. Please refer to the RR of the zRMS Hungary.

3.1.3.1 Acute Toxicity

Please refer to the RR of the zRMS Hungary

3.1.3.2 Operator Exposure

Please refer to the RR of the zRMS Hungary

3.1.3.3 Bystander Exposure

Please refer to the RR of the zRMS Hungary

3.1.3.4 Worker Exposure

Please refer to the RR of the zRMS Hungary

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

See 2.2

3.1.4 Residues and Consumer Exposure

Germany agrees with the assessment of the zRMS Hungary in terms of residues and consumer exposure. No national addendum was deemed necessary. Please refer to the RR of the zRMS Hungary.

3.1.4.1 Residues

Please refer to the RR of the zRMS Hungary

3.1.4.2 Consumer exposure

Please refer to the RR of the zRMS Hungary

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

A full exposure assessment for the plant protection product A14203B in its intended uses in maize is documented in detail in the core assessment of the plant protection product A14203B dated from 17. Sept.2014 performed by Hungary.
The following chapters summarize specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of A14203B in Germany according to its intended use in maize (Use No. 00-001).

3.1.5.1 Predicted Environmental Concentration in Soil (PECsoil) (Part B, Section 5, Points 9.4 and 9.5)

For the intended use of the plant protection product A14203B 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 the accumulation potential of Mesotrione was not considered.
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 (PEC_{GW}) (Part B, Section 5, Point 9.6)

No new study on the fate and behaviour of Mesotrione or A14203B has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.
The risk assessment for the metabolites of Mesotrione has already been performed for EU approval (SANCO / 1416/2001).
However, in the specific groundwater risk assessment for Germany considering the entry path surface run-off and drainage with subsequent bank filtration the soil metabolites of Mesotrione are included.

1. Direct leaching into groundwater
According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3, a groundwater contamination of the active substance Mesotrione in concentrations ≥ 0.1µg/L cannot be excluded for the intended use in maize (using labor DT50 values).
For the metabolites MNBA and AMBA of Mesotrione a groundwater concentrations ≥ 0.1 µg/L cannot be excluded for the application in maize according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3 when using labor DT50 values.
In addition to the PECgw modelling with laboratory DT50 values a max field DT50 value as higher tier option was used. The simulation results for the Szenario Kremsmuenster show that concentrations for the active substance and its metabolites ≥ 0.1µg/L can be excluded. Furthermore, in the core assessment

(Sept. 2014) scenario specific DT_{50} values has been calculated using the pH of each scenario and the regression equations detailed in the modelling report. The following equations describe the variation of DT_{50} with pH for mesotrione:Log10(half-life) = (-0.2285 * soil pH) + 2.5479 The DT50 value for Kremsmuenster is 6.1d.

2. Ground water contamination by bank filtration due to surface water exposure via run-off and drainage
According modelling with EXPOSIT 3.01 a groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Mesotrione due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.
According to modelling with EXPOSIT 3.01 a groundwater contamination at concentrations ≥ 0.1 µg/L by the 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 (PEC_{SW}) (Part B, Section 5, Points 9.7 and 9.8)

For the intended use of the plant protection product A14203B in maize according to use No 00-001 PECsw was calculated for the active substance Mesotrione considering the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately.
The calculation of concentrations in surface water was based on spray drift data by Rautmann and Ganzelmeier.
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 EXPOSIT3.01.
The results for PEC surface water for the active substance and its metabolites were used for the eco-toxicological risk assessment.

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

Mesotrione has low volatility (vapour pressure < 5.7 x 10^{-6} Pa at 20ºC, Henry's law constant <5.1 x 10^{-7} Pa m^3/mol at 20ºC) and is shown to have insignificant volatilisation from soil and plants.
The photochemical oxidative degradation of mesotrione in air is rapid (half-life 1.5 days calculated using Atkinson method) and therefore long-range transport is not considered to be of relevance.
The predicted environmental concentration in air (PEC_{AIR}) is therefore predicted to be negligible.

Implications for labelling resulting from environmental fate assessment: (Phrase **Rxx** should be added to the label): none

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

A full risk assessment according to Uniform Principles for the plant protection product A14203B in its intended uses in maize is documented in detail in the core assessment of the plant protection product A14203B dated from September 2014 performed by Hungary. The intended use of A14203B in Germany is generally covered by the uses evaluated in the course of the core assessment by Hungary.
The authorization in Hungary is linked with risk mitigation measures regarding effects on non-target organisms (see Part A, National Assessment – Hungary).
The following chapters summarise specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of A14203B 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)

Birds

The results of the risk assessment by zRMS Hungary indicate an acceptable acute and long-term risk for birds due to the intended use of A14203B in maize that is also transferable to the intended use of A14203B in Germany.

Terrestrial vertebrates (other than birds)

The results of the risk assessment by zRMS Hungary indicate an acceptable acute and long-term risk for mammals due to the intended use of A14203B in maize that is also transferable to the intended use of A14203B 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 for uses of A14203B in maize based on FOCUS Surface Water PEC values is presented in the core assessment, Part B, Section 6, chapter 6.4.
For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spray drift and volatilization with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.
Based on the intrinsic property of the active substance MCPA to *Lemna gibba* EC_{50} (14 d): 152 µg PPP/L), the national labelling NW265 is assigned. No additional entries as those according to the evaluated use pattern and good agricultural practice are acceptable (NW468)

1. Exposure by spray drift 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 spray drift to A14203B according to the use No 00-001 only achieve the acceptability criteria of TER ≥ 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 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.i./ha
Growth stage and season	BBCH 12 – 19, spring
Intended use:	00-001
DT_{50} water (SFO):	6 d
PEC-selection:	actual

Drift-Percentile:			90th					
Buffer zone	**Entry via spraydrift**		**Entry via deposition following volatilization**		**PECsw; conventional and drift reducing technique**			
					0% conv.	**50% red.**	**75% red.**	**90% red.**
[m]	**[%]**	**[µg/ha]**	**[%]**	**[µg/L]**	**[µg /L]**			
1	2.77	1.385	n.a.	n.a.	1.385	0.693	0.346	0.139
5	0.57	0.285	n.a.	n.a.	0.285	0.143	0.071	0.029
Relevant toxicity endpoint: E_bC_{50} = 12 µg product/L, **corresponding to 6 µg a.i./L (*Lemna gibba*)** Relevant TER: 10								
Buffer zone [m]					**TER**			
1					**4.3**	**8.7**	17.3	43.3
5					21.1	42.1	84.2	210.5
Risk mitigation measures			**NW 605-1/606**					

PEC: predicted environmenral 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 vegetated buffer strip).

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_yC_{50} = 6.0 µg a.s./L (*Lemna gibba*)	
Relevant TER:	10	
Run-off		
Buffer zone	**PEC**	**TER**
[m]	**[µg/L]**	
0	0.79	**7.63**
5	0.68	**8.80**
10	0.58	10.26
Drainage		
Time of application	**PEC**	**TER**
	[µg/L]	
Autumn/winter/early spring	Not relevant	**-**
Spring/summer	0.26	23.27
Risk mitigation measures	**NW701**	

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

Bees

Effects on bees for A14203B have not been evaluated as part of an EU review. The toxicity of mesotrione to bees is given in the Table 3.1.6.3-1.

Table 3.1.6.3-1: EU Conclusions - Toxicity to bees of mesotrione

Test substance	EU agreed endpoints (mesotrione; SANCO/1416/2001)
Mesotrione	Oral (48 h) LD_{50} = >11 µg a.s/bee Contact (48 h) LD_{50} = >9.1 µg a.s/bee[1]

[1] based on a study using the formulation 'ZA 1296 SC 100' containing 100 g a.s./l

Risk Assessment

Data on A14203B are evaluated here, and these risk assessments for A14203B with the proposed use pattern are considered adequate.

Toxicity

The results of bee toxicity studies carried out with A14203B and mesotrione are presented in Table 10.4-2. Further details regarding the tests with the formulation are provided in Annex Point IIIA 10.4.2.

Table 3.1.6.3-2: Summary of toxicity endpoints for bees

Substance	Endpoint	Value	Reference
A14203B + A12127R	48 h contact LD_{50}	91.3 µg A14203B/bee	*Kling, 2012*
	48 h oral LD_{50}	128 µg A14203B/bee	
A14203B + DPX-KG691	72 h contact LD_{50}	160 µg A14203B/bee	*Kling, 2009*
	48 h oral LD_{50}	>525 µg A14203B/bee	
Mesotrione	48 h contact LD_{50}	>100 µg a.s/bee	*Jackson & Gough, 1995*
	48 h oral LD_{50}	>11 µg a.s/bee	*Jackson & Gough, 1995*

Exposure

Applications of pesticides in the field may potentially result in exposure of bees either through direct over-spray (contact exposure) or via residues on plants while bees are foraging for food (contact or oral exposure). The likelihood of bees being in pre-emergence or early post-emergence maize fields is extremely low. Early post-and pre-emergence maize fields are not attractive to bees, since they do not offer any food sources. However, in accordance with the conservative approach adopted in this assessment the highest proposed single application rate for A14203B applied at the maximum recommended rate of 150 g a.s/ha (equivalent to 300 g A14203B/ha) will be used in a preliminary risk evaluation.

Hazard quotients for bees

The risk to honey bees is evaluated following the Hazard Quotient approach. The Hazard Quotient for oral (Q_{HO}) and contact (Q_{HC}) exposure are calculated based on the maximum application rate divided by the corresponding LD_{50} value, according to the following formula:

Hazard Quotient = Single application rate (g a.s/ha)/LD_{50} (µg a.s/bee)

A hazard quotient of less than 50 indicates a low risk to bees in the field (EPPO, 2003)1.

Oral exposure QHO

The hazard quotient for oral exposure of honeybees is given in the Table 3.1.6.3-3.

Table 3.1.6.3-3: Acute QHO values for A14203B and mesotrione

Substance	Single application rate	Endpoint LD_{50} (µg a.s/bee)	QHO	Trigger
A14203B + A12127R	300 g A14203B/ha	128	2.3	50
A14203B + DPX-KG691	300 g A14203B/ha	>525	<0.57	
Mesotrione	150 g a.s/ha	>11	<14	

The oral hazard quotients are below the Annex VI trigger of 50, indicating a low acute oral risk to bees from the use of A14203B at the proposed use rate of 150 g a.s/ha.

Contact exposure QHC

The hazard quotient for contact exposure of honeybees is given in the Table 3.1.6.3-4.

Table 3.1.6.3-4: Acute QHC values for A14203B and mesotrione

Substance	Single application rate	Endpoint LD_{50} (µg a.s/bee)	QHO	Trigger
A14203B + A12127R	300 g A14203B/ha	91.3	3.3	50
A14203B + DPX-KG691	300 g A14203B/ha	160	1.9	
Mesotrione	150 g a.s/ha	>100	<1.5	

The contact hazard quotients are below the Annex VI trigger of 50, indicating that the use of A14203B at the proposed label rate poses low acute contact risk to bees.

Summary

The risk of A14203B to honey-bees was assessed from hazard quotients, estimated from acute oral and contact studies with mesotrione and A14203B, and the maximum single application rate of 150 g mesotrione/ha.

All the hazard quotients for A14203B and mesotrione are less than 50, indicating that the risk to bees is acceptable following use of A14203B according to the proposed use pattern.

Label NB6641 is assigned to the product.

[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

Other non-target arthropods

The in-field predicted environmental rates of the test substance are below the lethal and sublethal toxicity endpoints indicating that the risk to in-field non-target arthropods is acceptable following use of A14203B according to the proposed use pattern.
The off-crop predicted environmental rates of the test substance are below the lethal and sublethal toxicity endpoints indicating that the risk to in-field non-target arthropods is acceptable following use of A14203B according to the proposed use pattern.

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

The acute and chronic TER values for mesotrione are greater than the Annex IV triggers of 10 and 5, respectively, indicating that the risk to earthworms is acceptable following use of A14203B according to the proposed use pattern.
No risk assessment is required considering the persistence trigger in accordance with the EU Guidance Document, since the field DT90 is <365 days for both active substances and only a single application is recommended per year, indicating that there will be no long-term exposure or accumulation of residues.
No risk assessment is required considering the persistence trigger in accordance with the EU Guidance Document, since the field DT90 is <365 days for both active substances and only a single application is recommended per year, indicating that there will be no long-term exposure or accumulation of residues.

3.1.6.5 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 no effect levels exceed the relevant PEC_S values by a factor of at least 2.5 indicating that A14203B does not pose an unacceptable risk to soil micro-organisms.

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 A14203B in off-field areas, the TER values describing the risk for non-target plants following exposure to A14203B according to the GAP of the formulation A14203B achieves the acceptability criteria TER ≥ 3 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 A14203B 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:		A14203B (1 x 300 g product/ha)	
Intended use group:		00-001	
Drift-Percentile:		90th, agriculture	
Buffer zone	**Entry via spraydrift**	**Entry via deposition following**	**$PER_{off\text{-}field}$; conventional and drift reducing technique**

[m]	[%]	[g/ha]	[%]	[L/ha]	0% conv.	50% red.	75% red.	90% red.
					[L/ha]			
1	2.77	8.31	-/-	-/-	8.31	4.16	2.08	0.83
5	0.57	1.71	-/-	-/-	1.71	0.86	0.43	0.17
Relevant toxicity ER50 = 2.24 g product/ha (vegetative vigour) Relevant TER: 5								
Buffer zone [m]					**TER**			
1					**0.3**	**0.5**	**1.1**	**2.7**
5					**1.3**	**2.6**	5.2	13.1
Risk mitigation measures			**NT 108**					

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

Implications for labelling resulting from ecotoxicological assessment:

Classification and labelling

Relevant toxicity	Active substance: Mesotrione (Test with the formulation+adjuvant; content: 50 % a.i.) ErC50 = 0.034 mg a.i./L (*Lemna gibba*); M-factor = 10
Classification and labelling according to Regulation 1272/2008	
Hazard sysmbol	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.
NW605-1	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 with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*". 50 %: 5 m, 75 %: *, 90 %: *
NW606	The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters - except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro. 5 m.

NW701	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 10 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)

Further information to the active substance

Mesotrione is a systemic herbicide, taken up via roots, shoots and leaves and translocated rapidly in both the xylem and phloem into all plant parts. In sensitive plants symptoms of white chlorosis become visible within a few days after application in actively growing tissues being in the cell elongation phase. Complete death of sensitive plants may occur up to 2 weeks after application.

Mesotrione belongs to the chemical group of callistemones or triketones (2-benzylcyclohexane-1,3-diones), which acts by blocking the function of the essential plant enzyme 4-hydroxy-phenyl-pyruvate-dioxygenase (4-HPPD) in the cytosol of sensitive plants. The target enzyme 4-HPPD catalyses an important metabolic step in the biosynthesis of plastoquinone and α-tocopherol (vitamin E) in plants. Mesotrione is a competitive inhibitor of 4-HPPD, and by binding very tightly to the enzyme's active site it prevents the normal substrate (4-hydroxyphenyl-pyruvate) from binding and rendering the enzyme inactive. The direct result of blocking the function of 4-HPPD is that the compounds plastoquinone and α-tocopherol are not synthesized. Without these compounds, the formation of carotenoid pigments is stopped. Since plastoquinone as redox component (enzyme cofactor) is interacting with both photosynthesis and carotenoid biosynthesis, the HPPD inhibition also leads to an inhibition of the phytoene-desaturase enzyme (PDS), interrupting the biosynthesis of carotenoids. This interruption is lethal on its own. Without protecting functions of α-tocopherol and carotenoids, light and by-products of photosynthesis (oxidative radicals) destroy chlorophyll and cell membranes, resulting in bleaching of the plants leaves within 3 to 5 days after application. Complete weed death occurs within 2 to 3 weeks after application. The white chlorosis symptoms caused by indirect PDS inhibition and photo-oxidative destruction of chlorophyll are faster visible than the indirect inhibition of synthesis of carotenoids.

Maize has a natural tolerance against mesotrione as it can detoxify the herbicide into inactive compounds. This detoxification is mediated by cytochrome-P450-oxygenase and is so rapid in maize that mesotrione is not translocated away from the treated zone to the point of action. Sensitive weed species cannot detoxify mesotrione in this way.
Site of action (HRAC): F2. Label phrase "Mode of action (HRAC-group): F2" is assigned to the product.

Efficacy

Data regarding the efficacy of the product demonstrate that A14203B fulfils all criteria for the authorization of preparations as required by Commission Regulation (EU) No. 546/2011.
However, all efficacy trials in the RR were carried out with an adjuvant. This issue is not addressed in the description of the application. The product should be handled as a required TM „in combination with a non-ionic or oil-based surfactant".
It is also questioned if a sufficient efficacy can be achieved with a water application rate of 80 L/ha. In the RR no results with this water amount are shown. Consequently the amount of water is fixed to 200 up to 400 L/ha. Finally, as there are no efficacy results for DIGSA, DIGSA is deleted.
In the instructions for use is to include a list stating which weeds the product is effective, less effective and insufficiently effective against as well as a list of the species and/or varieties of the crops the respective product is compatible or incompatible with the product (WH9161).

Phytotoxicity

A14203B did not show any long term adverse phytotoxicity or negative effects on any quality parameters of grain or whole maize plants at the proposed label rate of 0.3 kg/ha. However, damage to the maize crop cannot be excluded. The label warning WP734 (Damage is possible to the crop.) is assigned to the GAP.

Succeeding crops

Under usual climatic conditions of the maize growing regions in Europe, all rotational field crops can be grown after regular harvest of maize. In case of unfavourable soil and/or weather conditions a deep mingling tillage prior to sowing is recommended for susceptible crops such as sugar beet or peas. For precocious replanting due to a crop failure the safety margin might become close for highly sensitive crops such as cabbage, mustard and peas (sugar beet should be avoided as a replacement crop in this situation). Due to the persistence in soil and the biological activity of the active substances the label warning WH713 (Damage is possible to succeeding dicotyledonous crops) is assigned to the GAP.

Resistance

The resistance assessment led to the conclusion that the risk for the use of A14203B in Europe is low.

Adverse effects on beneficial organisms

On the basis of the results of laboratory tests, the test product is to be considered as slightly harmful for the predatory mite *Typhlodromus pyri*, indicating that the product can be slightly harmful for other, relevant predatory mites and spiders. On the basis of the results of higher tier tests, the test product can be classified as not harmful for populations of relevant beneficial insect species.
Labels NN2002 and NN1001 are assigned to the product.

3.2 Conclusions

With respect to identity, physical, chemical and technical properties, packaging and further information as well as analytical methods (formulation and residues) an authorisation can be granted.

Regarding efficacy/IPM and sustainable use incl. protection of honeybees an authorisation can be granted, if the GAP is fixed as prescribed under point 2.4.

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.

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.007938-00/00.81737
(bitte bei Antwort angeben)

DATUM 29. Mai 2017

ZV3 007938-00/00

A14203B

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit dem Wirkstoff:	500 g/kg	Mesotrione
Zulassungsnummer:	007938-00	
Versuchsbezeichnungen:	SYD-11560-H-0-WG	
Antrag vom:	12. April 2013	

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):

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
007938-00/00-001	Einjährige zweikeim-blättrige Unkräuter, Hühnerhirse	Mais	

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:

Verpackungs-art	Verpackungs-material	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Faltschachtel	Karton, beschichtet	1		0,40	10,00	kg
Kanister	HDPE	1		1,00	5,00	l

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

Auflagen

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

Kennzeichnungsauflagen:

(NN2002)
Das Mittel wird als schwach 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.

(SF245-01)
Behandelte Flächen/Kulturen erst nach dem Abtrocknen des Spritzbelages wieder betreten.

(SS110)
Universal-Schutzhandschuhe (Pflanzenschutz) tragen beim Umgang mit dem unverdünnten Mittel.

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

(SS530)
Gesichtsschutz tragen beim Umgang mit dem unverdünnten Mittel.

(SS610)
Gummischürze tragen beim Umgang mit dem unverdünnten Mittel.

(WMF2)
Wirkungsmechanismus (HRAC-Gruppe): F2

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

Sonstige Auflagen:

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

Vorbehalt

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

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

Signalwort:

(S2) Gefahr

Gefahrenpiktogramme:

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):
(H251)
Selbsterhitzungsfähig; kann in Brand geraten.

(H400)
Sehr giftig für Wasserorganismen.

(H410)
Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

(EUH 208-0137)
Enthält Harnstoff-Formaldehyd-Kondensat. Kann allergische Reaktionen hervorrufen.

(EUH 401)

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

Sicherheitshinweise (P-Sätze):
(P235+P410)
Kühl halten. Vor Sonnenbestrahlung schützen.

(P280)
Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.

(P407)
Luftspalt zwischen Stapeln oder Paletten lassen.

(P420)
Getrennt aufbewahren.

(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
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: 007938-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Einjährige zweikeimblättrige Unkräuter, Hühnerhirse

Pflanzen/-erzeugnisse/Objekte: Mais

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium des Schadorganismus:	bis 21
Stadium der Kultur:	12 bis 19
Anwendungszeitpunkt:	Frühjahr, nach dem Auflaufen
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Mischungspartner:	vorgeschriebene Mischung mit: 006355-00 ADIGOR (1,5 l/ha)
Anwendungstechnik:	spritzen
Aufwand:	
-	300 g/ha in 200 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(WH9161)
In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden, sowie eine Arten- und/oder Sortenliste der Kulturpflanzen, für die der vorgesehene Mittelaufwand verträglich oder unverträglich ist.

(WP713)
Schäden an nachgebauten zweikeimblättrigen Kulturen möglich.

(WP734)
Schäden an der Kulturpflanze möglich.

2.3 Wartezeiten

(F) Freiland, Pflanzkultur: Mais (Frühjahrsanwendung)
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 Abdriftminderungsklasse 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 2,24 g A14203B /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.

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu

Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
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 6 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.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
Begründung:
Siehe unter NW605-1.

(NW701)
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 10 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 6 µg a.i./L für Lemna gibba. Ausgehend von einem Datensatz charakteristischer Eigenschaften des Wirkstoffs (Wasserlöslichkeit = 160 mg/L; DT50 Boden = 34,3 d; KFoc = 53,2), 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.

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product Code: A142038

Reg. No.: 007938-00/00

Active Substance: 500 g/kg mesotrione

Central Zone

Zonal Rapporteur Member State: HU

National Addendum Germany

Applicant: Syngenta Agro GmbH

Evaluator: Julius Kühn-Institut

Date: 2014-12-04

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IIIA1 6 Efficacy Data and Information on the Plant Protection Product

General information

This application was not submitted to the JKI for commenting.
Therefore it was not possible to point out that all efficacy trials in the RR were carried out with an adjuvant. This issue is not addressed in the description of the application. Concerning the BVL guidance document about tank mixtures (TM) (BVL 2012) the product should be handled as a required TM.
It is also questioned if a sufficient efficacy can be achieved with a water application rate of 80 L/ha. In the RR no results with this water amount are shown.
Furthermore there are no efficacy results for DIGSA.

Refer to Registration Report for further information.

Recent registration situation/history of the PPP

Refer to Registration Report for further information.

Information on the active ingredients (Uptake and mode of action)

Refer to Registration Report for further information.

Information on crops and pests

Refer to Registration Report for further information.

Information on the intended uses

Date: 2014-10-30	**Product: A14203B**
Use No.	**007938-00/00-001**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	maize (ZEAMX)
Crop stage(s) (BBCH)	12 to 19
Pest(s)/target(s)	annual dicotyledonous weeds (TTTDS), *Echinochloa crus-galli* (ECHCG), ~~*Digitaria sanguinalis* (DIGSA)~~
Pest stage(s) (BBCH)	to 21
Area of application	Outdoors
Timing of application	Spring, after emergence
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application method/kind of treatment	spraying
Application rate(s)	300 g/ha in ~~80~~200 to 400 L water/ha

It should be added: „in combination with a non-ionic or oil-based surfactant“

IIIA1 6.1 Efficacy data

Refer to Registration Report for further information.

IIIA1 6.1.1 Preliminary range-finding tests

Refer to Registration Report for further information.

IIIA1 6.1.2 Minimum effective dose tests

Refer to Registration Report for further information.

IIIA1 6.1.3 Efficacy tests

The instructions for use is to include a list stating which weeds the product is effective, less effective and insufficiently effective against as well as a list of the species and/or varieties of the crops the respective product is compatible or incompatible with the product.
Therefore the label warning 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.) is proposed.
Refer to Registration Report for further information.

IIIA1 6.1.4 Effects on yield and quality

Refer to Registration Report for further information.

IIIA1 6.1.4.1 Impact on the quality of plants and plant products

Refer to Registration Report for further information.

IIIA1 6.1.4.2 Effects on the processing procedure

Refer to Registration Report for further information.

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

Refer to Registration Report for further information.

IIIA1 6.2 Adverse effects

Refer to Registration Report for further information.

IIIA1 6.2.1 Phytotoxicity to host crop

Damage to the maize crop cannot be excluded. The label warning WP734 (Damage is possible to the crop.) is proposed.
Refer to Registration Report for further information.

IIIA1 6.2.2 Adverse effects on health of host animals

Refer to Registration Report for further information.

IIIA1 6.2.3 Adverse effects on site of application

Refer to Registration Report for further information.

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

The herbicide A14203B (500 g/kg mesotrione, WG) is proposed for one post emergence treatment in maize with a field rate of 0.3 kg/ha.

During the field tests on the efficacy of A14203B no adverse effects on beneficials and other non-target organisms were observed.
Appropriate studies on the potential adverse effects of the test product on beneficial arthropods were available from Registration Report Part B, Section 6, Annex Point IIIA 10.5 (Effects on Arthropods Other Than Bees), Core Assessment.

The toxicity to beneficial arthropods has been investigated by carrying out laboratory tests and extended laboratory tests with *Typhlodromus pyri*, *Aphidius rhopalosiphi* and *Aleochara bilineata* using the test product in mixture with the adjuvant A12127R (Table 6.2.4-1) and with *Typhlodromus pyri*, *Aphidius rhopalosiphi* and *Chrysoperla carnea* using the test product in mixture with the surfactant DPX-KG691 (Table 6.2.4-2).

Table 6.2.4-1: Effects of Mesotrione WG (50) (A14203B) (475 g/kg mesotrione) + A12127R (Adigor, adjuvant), ratio 1:5

Species (Exposed Stage)	Substrate	Rate Product [kg/ha]	Corrected Mortality [%]	Sublethal Effect (Re) [%]	Reference
T. pyri (PN)	Glass	0.6	73		SYN-12-6
		0.3	50	58	
		0.15	36	43	
		0.075	9	39	
		0.0375	13	18	
		0.01875	11	26	
A. rhopalosiphi (A)	Glass	0.6	100		SYN-12-7
		0.3	100		
		0.15	100		
		0.075	87		
		0.0375	50	28	
		0.01875	37	12	
	Barley	0.45	6.7	-11	SYN-12-25
		0.3	3.3	-10	
		0.2	3.3	-6	
		0.1333	0		
		0.0888	0		
		0.06	0		
A. bilineata (EC)	Lufa 2.1	0.6	0	23	SYN-12-24
		0.3	1.7	-20	
		0.15	0	-11	
		0.075	0	-10	
		0.0375	0	15	

PN = protonymphs, A = adults, EC = Environmental cycle, Re = reproduction

Table 6.2.4-2: Effects of Mesotrione WG (50) (A14203B) (485 g/kg mesotrione) + DPX-KG691 (surfactant), ratio 1:1

Species (Exposed Stage)	Substrate	Rate Product [kg/ha]	Corrected Mortality [%]	Sublethal Effect (Re) [%]	Reference
T. pyri (PN)	Glass	0.3	20	26	SYN-09-7
		0.15	8	17	
		0.075	23	22	
		0.00831	3		
		0.000416	11		
A. rhopalosiphi (A)	Glass	0.3	86		SYN-09-8
		0.15	69		
		0.075	33	0.5	
		0.00831	19	0.3	
		0.000416	11	13	
	Barley	0.3	0	22	SYN-09-27
		0.24	0	5	
		0.0831	0	-13	
		0.0416	0		
		0.00416	0		
C. carnea (La)	Bean leaves	0.3	0	-4	SYN-09-28
		0.24	0	-21	
		0.0831	0	-18	
		0.00831	0		
		0.000416	0		

PN = protonymphs, A = adults, La = larvae, Re = reproduction

In laboratory tests with the predatory mite *Typhlodromus pyri,* the proposed rate of the test product caused single effects up to 58% when mixed with the adjuvant Adigor and 26% when mixed with the surfactant DPX-KG691. The lowest LR_{50} was calculated to be 0.3055 kg/ha.
This result could give rise to the assumption that the effects were possibly driven by the mixture partners, although it cannot be excluded that the test product itself can cause effects > 30%.

The parasitic wasp *Aphidius rhopalosiphi* reacted with mortality rates up to 100% in laboratory tests at the proposed rate. The lowest LR_{50} was calculated to be 0.0299 kg/ha.
Aphidius rhopalosiphi as well as the lacewing *Chrysoperla carnea* and the rove beetle *Aleochara bilineata* showed only effects < 25% in extended laboratory tests at the proposed rate on natural substrates.

Conclusion
On the basis of the results of laboratory tests, the test product is to be considered as slightly harmful for the predatory mite *Typhlodromus pyri.* As this sensitive indicator species is not a relevant antagonist for the proposed crop, no classification is proposed for it. However, the results for this species indicate that the test product can be slightly harmful for other, relevant predatory mites and spiders.

On the basis of the results of higher tier tests, the test product can be classified as not harmful for populations of the parasitic wasp *Aphidius rhopalosiphi,* the lacewing *Chrysoperla carnea* and the rove beetle *Aleochara bilineata*.

Classification:

Laboratory tests on artificial substrates

< 30%	= not harmful
30 – 79%	= slightly harmful
≥ 80%	= harmful

Extended laboratory tests on natural substrates

< 25%	= not harmful
25 - 50%	= slightly harmful
> 50%	= harmful

Adverse effects on soil quality indicators (e. g. microorganisms, earthworms) are considered in Section 6 Ecotoxicological Studies in the Registration Report.

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

Refer to Registration Report for further information.

IIIA1 6.2.6 Impact on succeeding crops

Due to the persistence in soil and the biological activity of the active substances the label warning WH713 (Damage is possible to succeeding dicotyledonous crops) is proposed.
Refer to Registration Report for further information.

IIIA1 6.2.7 Impact on other plants including adjacent crops

Refer to Registration Report for further information.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

Refer to Registration Report for further information.

IIIA1 6.3 Economics

Refer to Registration Report for further information.

IIIA1 6.4 Benefits

Refer to Registration Report for further information.

IIIA1 6.4.1 Survey of alternative pest control measures

This is not an EC data requirement.

IIIA1 6.4.2 Compatibility with current management practices including IPM

This is not an EC data requirement.

IIIA1 6.4.3 Contribution to risk reduction

This is not an EC data requirement.

IIIA1 6.5 Other/special studies

Refer to Registration Report for further information.

IIIA1 6.6 Summary and assessment of data according to points 6.1 to 6.5

Refer to Registration Report for further information.

IIIA1 6.7 List of test facilities including the corresponding certificates

Refer to Registration Report for further information.

Appendix 1: List of data submitted in support of the evaluation

The evaluation is based on the Registration Report Part A, Part B7, Part B6, the Authorization Certificate of the Reference Member State and the label.

Appendix 2: GAP table

Reg.-No. **007938-00/00** **GAP rev.1, date: 2014-10-30**

PPP (product name/code) **A14203B**
active substance 1 **Mesotrione**
active substance 2 **0**
active substance 3 **0**
active substance 4 **0**
active substance 5 **0**

Formulation Type: **WG**
Conc. of a.s. 1: **500 g/kg**
Conc. of a.s. 2: **0**
Conc. of a.s. 3: **0**
Conc. of a.s. 4: **0**
Conc. of a.s. 5: **0**

Applicant: **Syngenta Agro GmbH**
Zone(s): **central/EU**

professional use **Yes**
non professional use **No**

Verified by MS: **yes**

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	maize (ZEAMX)	F	annual dicotyledonous weeds (TTTDS), *Echinochloa crus-galli* (ECHCG), ~~*Digitaria sanguinalis* (DIGSA)~~ (BBCH -21)	spraying	Spring, after emergence 12 to 19	a) 1 b) 1	a) 300 g/ha b) 300.00 g/ha	a) 150.00 kg/ha b) 150.00 kg/ha	~~80200~~ - 400	-	It should be added: „in combination with a non-ionic or oil-based surfactant“