REGISTRATION REPORT
Part A

Risk Management

Product code:	**Border**
Active Substance:	**Mesotrione 100 g/L**

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: Czech Republic

NATIONAL ASSESSMENT

Applicant:	**Cheminova Deutschland GmbH**
Date:	**22/05/2017**

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of Border 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 "CHA2110 (Border)" Registration Report, Part B Sections 1-8 and Part C from Czech Republic 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 Border where that data has not been considered in the EU review. Otherwise assessments for the safe use of Border 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 Border.

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 Cheminova Deutschland GmbH & Co. KG on 11/12/2013.

The application was for approval of CHA 2110 – a new SC formulation containing 100 g/L mesotrione - in the Czech Republic, for use as an herbicide for the control of broad-leaf and grass weeds in maize. CHA 2110 is recommended as an early post-emergence spray.

1.2 Annex I inclusion

Mesotrione is a herbicide and was included in Annex I of 91/414 in October 2003 (Commission Directive 2003/68/EC), as amended by Commission Implementing Regulation (EU) No 540/2011 and Commission Regulation (EU) No 823/2012. As part of this inclusion there were no issues of concern raised requiring attention from member states.

The review report for mesotrione (SANCO/1416/2001 -Final – 14 April 2001) is considered to provide the relevant review information or a reference to where such information as considered appropriate for this application can be found.

1.3 Regulatory approach

To obtain re-approval/approval the product Border 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

Data protection is claimed for studies submitted with this registration. For details on data protection claims please refer to Appendix 1 of each section in the Registration Report.

1.5 Letters of Access

Within the context of this evaluation, Cheminova A/S has provided own data in support of the proposed product so a letter of access is not considered necessary.

2 Details of the authorisation

2.1 Product identity

Product Name	CHA 2110 (Border)
Authorization Number (for re-registration)	008110-00/00
Function	Herbicide
Applicant	Cheminova A/S
Composition	100 g/L mesotrione
Formulation type	Suspension concentrate [Code: SC]
Packaging	0.1-20 L bottle HDPE or COEX 0.1-20 L jerry can HDPE or COEX

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not proposed.

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

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

Hazard classes and categories:	
Skin Sens. 1, Eye Dam. 1	
Hazard pictograms:	
GHS05	corrosion
GHS07	exclamation mark
GHS09	environment
Signal word:	
Warning	
Hazard statements:	
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.
Precautionary statemtents:	
Not proposed by zRMS Germany, to be decided by applicant	
P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of 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 before reuse.
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:	
None	

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.
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.
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.
SS526	Wear face protection when applying/handling the product ready for application.
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
WH952	The indication identifying the mode of action must be assigned directly to each corresponding name of the active substance as supplementary information on the packaging and in the instructions for use.
NN3002	The product is classified as harmful for populations of relevant predatory mites and spiders.
NN2001	The product is classified as slightly 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)
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

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.
WP713	Damage is possible to replanted dicotyledonous crops.
WP734	Damage is possible to the crop.
Ecosystem protection	
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 "*".Drift reduction by 90% 1 m 75 % 1 m 50% 5 m
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. Buffer zone of 5 m
NW706	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 20 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

2.4 Product uses

Reg.-No.	008110-00/00		GAP rev. 2, date: 2016-12-05
PPP (product name/code):	Border / CHA 2110	Formulation type:	SC [a, b]
Active substance:	Mesotrione	Conc. of as:	100 g/L [c]
Applicant:	Cheminova Deutschland GmbH	Professional use:	☒
Zone(s):	central [d]	Non-professional use:	☐
Verified by MS:	yes		
Field of use:	herbicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

Zonal uses (field or outdoor uses, certain types of protected crops)													
1	DE	Maize (ZEAMX)	F	Echinochloa crus-galli (ECHCG), ~~Digitaria spp. (DIGSS),~~ annual dicotyle-donous weeds (TTTDS)	spraying	post-emergence, BBCH 12 to 18	a) 1 b) 1	-	a) 1.5 L/ha b) 1.50 L/ha	a) 0.15 kg/ha b) 0.15 kg/ha	100 - 400	F*	* 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. WH9161 WP713 WP734 NW605-1, NW606, NW706, NT108

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

(d) Select relevant

(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references

2 Use official codes/nomenclatures of EU Member States

3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)

4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.

6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

8 The maximum number of application possible under practical conditions of use must be provided.

9 Minimum interval (in days) between applications of the same product

10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.

11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).

12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.

13 PHI - minimum pre-harvest interval

14 Remarks may include: Extent of use/economic importance/restrictions

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:
CHA 2110 (Border®) is an opaque yellowish homogeneous liquid with a weak aromatic odour. It is not explosive, oxidising or flammable. No flash point was observed for the test conditions and no auto-ignition temperature was determined below 400°C. CHA 2110 (Border®) is slightly acidic (pH of 3.08 undiluted, pH of 3.41 as a 1 % aqueous solution). CHA 2110 (Border®) and its commercial container materials have been shown to be stable in an accelerated stability test (8 weeks at 40°C) and at low temperature (0°C for 7 days). A 2 year storage stability study at ambient temperature has been conducted. No problems are expected when the product is used according to label recommendations under normal field conditions.

Implications for labelling:
None.

Compliance with FAO specifications:
The product CHA 2110 (Border®) complies with FAO specifications.

Compliance with FAO guidelines:
The product CHA 2110 (Border®) complies with FAO specifications, as far as could be assessed.

Compatibility of mixtures:
No tank mixes 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 CHA 2110 (Border®) 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)

An analytical method based on high performance liquid chromatography (HPLC) with UV detection has been developed for the determination of the active substance mesotrione in SC formulations. The method has been validated according to specificity, linearity, sensitivity, recovery and precision and thus the method is considered adequate. There are no existing CIPAC methods for the analysis of mesotrione.

During the review for the inclusion of mesotrione in the positive list of the EU 1-Cyano-6-(methylsulfonyl)-7-nitro- 9H-xanthen-9-on was defined as relevant impurity. A method was provided for

the determination of this relevant impurity in CHA 2110 (Border®) using LC-MS/MS after separation on a Zorbax Eclipse Plus C18 column. The method was fully validated and is acceptable.

For the used source of technical active substance NMSBMK was defined as relevant impurity. The analytical method VAM 250-01 for the determination of NMSBMK in mesotrione technical and Mesotrione SC formulations has been validated and all validation results meet the criteria selected for this validation. The method is based on reverse phase liquid chromatography (HPLC) using Kinetex C-18 column, UV detection and quantification by external standard method. The method was fully validated and is acceptable.

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 they were provided in the EU review of mesotrione. The methods 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. Furthermore, a letter of access from Syngenta has been taken into account. 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.

3.1.3 Mammalian Toxicology

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

3.1.3.1 Acute Toxicity

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

3.1.3.2 Operator Exposure

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

3.1.3.3 Bystander Exposure

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

3.1.3.4 Worker Exposure

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

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

See 2.2

3.1.4 Residues and Consumer Exposure

The intended use in maize will not result in residues above the MRLs set in Regulation (EC) No 396/2005. A risk for consumers through the consumption of food possibly containing residues of the active substances is not expected.
For further details please refer to the registration report of the zonal RMS CZ.

3.1.4.1 Residues

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

3.1.4.2 Consumer exposure

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

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

A full exposure assessment for the plant protection product Border (R) in its intended use in maize is documented in detail in the core assessment of the plant protection product Border (R) dated from October 2013 performed by Czech Republic.
The following chapters summarize specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of Border (R) in Germany according to its intended use in maize (Use No. 00-001).
Due to the dates of application and core assessment, endpoints from the Renewal Assessment Report (RAR, February 2015) were used. Updated endpoints were published in the EFSA Conclusion (03/2016), but they underlied 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 (NA) of the metabolites is required (see CA). However, for the soil metabolites of mesotrione, occurring in soil at 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 Border (R) 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 slow degradation of the metabolite AMBA of mesotrione in soil (DT_{90} > 365 d, FOMC, laboratory data) the accumulation potential of AMBA needs to be considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} considering the relevant soil depth of 2.5 cm or 1.0 cm, respectively.
The results for PEC_{soil} for the active substance and the metabolites were used for the eco-toxicological risk assessment.

3.1.5.2 Predicted Environmental Concentration in Ground Water (PEC_{GW}) (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 ≥ 0.1µg/L in the intended use of Border (R) in maize according to use No. 00-001.
For the metabolites MNBA and AMBA concentrations of ≥ 0.1µg/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, groundwater contamination at concentrations ≥ 0.1 µg/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 (PEC_{SW}) (Part B, Section 5, Points 9.7 and 9.8)

For the intended use of the plant protection product Border (R) 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 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.
The results for PEC_{sw} for the active substance and its metabolites were used for the eco-toxicological risk assessment.

3.1.5.4 Predicted Environmental Concentration in Air (PEC_{Air}) (Part B, Section 5, Point 9.9)

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 by the active substance mesotrione due to deposition following volatilization was not considered.

Implications for labelling resulting from environmental fate assessment

For the authorization of the plant protection product Border (R) following labelling and conditions of use are mandatory.

Classification and labelling
Based on the data on the active substance mesotrione the plant protection product Border (R) 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 Border (R) in its intended use in maize is documented in detail in the core assessment of the plant protection product

Border (R) dated from November 2013 performed by Czech Republic. The intended use of Border (R) in Germany is generally covered by the uses evaluated in the course of the core assessment by Czech Republic.
The authorization in Czech Republic is linked with risk mitigation measures regarding effects on non-target organisms (see Part A, National Assessment - Czech Republic).
The following chapters summarize specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of Border (R) 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 Czech Republic indicate an acceptable acute and long-term risk for birds due to the intended use of Border (R) in maize that is also transferable to the intended use of Border (R) in Germany.

Terrestrial vertebrates:
The results of the risk assessment by zRMS Czech Republic indicate an acceptable acute and long-term risk for mammals due to the intended use of Border (R) in maize that is also transferable to the intended use of Border (R) 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 use of Border (R) in maize based on FOCUS surface water including 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 separately, (i) spraydrift and volatilization with subsequent deposition and (ii) run-off and drainage, 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*: ErC50 = 4.5 µg a.i./L), the national labelling NW265 is assigned.

1. Exposure by spraydrift and deposition following volatilization
Based on the relevant toxicity of mesotrione, the calculated TER values for the risk to aquatic organisms resulting from an exposure of surface water by spraydrift to Border (R) according to 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 (75 % technique at 1m or 5 m distance without 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 10 – 18, spring
Intended use group:	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	-	-	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_yC_{50} = 4.5 µg a.s./L (*Lemna gibba*) Relevant TER: 10								
Buffer zone [m]					**TER**			
1					**3.2**	**6.5**	13.0	32.5
5					15.8	31.6	63.2	157.9
Risk mitigation measures			**NW 605/606**					

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 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 (20 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_yC_{50} = 4.5 µg a.s./L (*Lemna gibba*)	
Relevant TER:	10	
Run-off		
Buffer zone	**PEC**	**TER**
[m]	**[µg/L]**	
0	0,80	**5,64**
5	0,69	**6.5**
10	0,59	**7,59**
20	0,42	10,84
Drainage		
Time of application	**PEC**	**TER**
	[µg/L]	
Autumn/winter/early spring	Not relevant	**-**

Spring/summer	0.33	13.67
Risk mitigation measures	**NW 706** (20 m vegetated buffer strip)	

PEC: predicted environmenral 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

Toxicity

Effects on bees for CHA 2110 were not evaluated as part of the EU review of Mesotrione. Data on CHA 2110 is evaluated, and risk assessments with the proposed use pattern, are provided here and are considered adequate.

The EU agreed honeybee toxicity endpoints are presented in Table 3.1.6.3-1 for mesotrione.

Table 3.1.6.3-1: EU agreed honeybee toxicity endpoints

Active substance	EU agreed endpoints (Review Report; SANCO/1416/2001-Final, 14 April 2003)	Endpoints used in risk assessment
Mesotrione	Oral LD_{50} > 11 µg a.s./bee Contact LD_{50} > 9.1 µg a.s/bee	Oral LD_{50} > 11 µg a.s./bee Contact LD_{50} > 9.1 µg a.s/bee

The toxicity of CHA 2110 to honeybees is given in Table 3.1.6.3-2.

Table 3.1.6.3-2: Toxicity of CHA 2110 (Mesotrione 100 g/L SC) to honeybees

Substance	Endpoint	Value	Reference
CHA 2110	48-h oral LD_{50}	>84.6 µg a.s./bee (equivalent to >0.846 µL product/bee)	Sekine, T. (2013) 134 MES
	96-h contact LD_{50}	74.7 µg a.s./bee (equivalent to 0.747 µL product/bee)	

Risk Assessment

Honeybees may be exposed to mesotrione by direct contact from spray applications of mesotrione containing products while foraging in crops, flowers or weeds (in areas adjacent to the crops). Bees may also be exposed through contact with fresh or dry residues or by oral uptake of contaminated pollen, nectar and honey dew.

Mesotrione is a herbicide used in maize, application is made at early growth stages BBCH 10-18 for post-emergence use, therefore direct contact via the crop will be minimal, however fields may contain flowering weeds in-field at the time of application or in the area adjacent to the crop. The maximum single application rate is 150 g a.s./ha. Mesotrione does not exhibit insect growth regulator activity. The hazard quotients for bees are calculated based on the worst-case proposed use.

Hazard quotients (HQ)

The risk assessment for effects of CHA 2110 on honeybees has been conducted in accordance with the Guidance document on terrestrial ecotoxicology, SANCO/10329/2002 rev 2 final, (2002)[1]. The calculated hazard quotients (HQ) are presented in Table 3.1.6.3-3. The acute risk to honeybees from use of CHA

[1] European Commission Working Document – SANCO/10329/2002 rev 2 Final. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC.

2110 was assessed using the worst-case maximum single application rate for the proposed uses and the LD50 values (µg a.s./bee) to calculate hazard quotients (EPPO 2003) as follows:

$$\text{Hazard Quotient (HQ)} = \frac{\text{Maximum single application rate (g a.s./ha or g formulation/ha)}}{\text{Acute } LD_{50} \text{ (µg a.s./bee or µg formulation/bee)}}$$

Hazard quotients were calculated for oral exposure and contact exposure and were evaluated against a trigger value of 50. Values below 50 are considered to indicate a low risk to bees in the field.

Table 3.1.6.3-3: Hazard quotients (HQ) for honey bees

Test substance	Use pattern	Exposure route	Endpoint LD_{50} (µg a.s./bee	Maximum single application rate (g a.s./ha)	Hazard quotient (HQ)	HQ assessment trigger
Mesotrione	1 × 150 g a.s./ha	Oral	>11	150	<13.6	50
		Contact	>9.1		<16.5	
CHA 2110	1 × 150 g a.s./ha	Oral	>84.6	150	<1.77	50
		Contact	74.7		2.01	

Conclusions
The HQ values for oral and contact exposure to mesotrione are below the trigger value of 50. Therefore, CHA 2110 is considered to pose a low acute oral and contact risk to honeybees following application in accordance with the proposed uses.
Label NB6641 is assigned to the product.

Other non-target arthropods

For details please refer to the core assessment Part B, section 6, chapter 6.6.

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

For details please refer to the core assessment Part B, section 6, chapter 6.7.
The german risk assessment is based on maximum PECsoil concentrations at a soil depth of 2.5 cm The calculated TER values achieve the acceptability criterion TER ≥ 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 Border (R) in maize according to the label.

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

For details please refer to the core assessment Part B, section 6, chapter 6.7.

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

For details please refer to the core assessment Part B, section 6, chapter 6.8.

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 Border (R) in off-field areas, the TER values describing the risk for non-target plants following exposure to Border (R) according to the GAP of the formulation Border (R) achieve the acceptability criteria TER ≥ 5 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, 75% drift reducing techniques).

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	**Entry via spraydrift**		**Entry via deposition following volatilization**		**PER$_{off-field}$; conventional and drift reducing technique**			
					0% conv.	**90% red.**	**75% red.**	**50% red.**
[m]	**[%]**	**[g/ha]**	**[%]**	**[g/ha]**	**[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} = 1.95 g a.s./ha (*Beta vulgaris*) Relevant TER: 5								
Buffer zone [m]					**TER**			
1					**0.47**	**4.64**	**1.88**	**0.94**
5					**2.27**	21.7	9.29	**4.53**
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:

For the authorization of the plant protection product Border (R) the following labelling and conditions of use are mandatory:

Classification and labelling

Relevant toxicity	Active substance: Mesotrione (content 10 %) EbC50 = 0.0077 mg/L (*Lemna gibba*) M-factor = 100
Classification and labelling according to Regulation 1272/2008	
Hazard sysmbol	GHS09
Signal word	Warning
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 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 "*".Drift reduction by 90% 1 m 75 % 1 m 50% 5 m
NW 606	The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters - except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro. Buffer zone of 5 m
NW706	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 20 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

Following the latest publications on www.weedscience.org the compound belongs to the chemical class of Callistemones, while in other publications the compound is classified as a member of the chemical class of Triketones. In general, Mesotrione acts as a pigment inhibitor, but in a different way than other pigment inhibiting herbicides, by interfering with different sites of action. Mesotrione inhibits the enzyme

4-Hydroxyphenylpyruvat dioxygenase (HPPD), a key enzyme of the biochemical pathway of the Plastoquinone-Tocopherol synthesis which is one of the essential preliminary stages of the Carotinoid biosynthesis. After rapid take-up by a sensitive plant – most of the applied compound is taken up through the treated foliage, and only a minor part is absorbed via soil – the compound is translocated in the phloem by both acropetal and basipetal movement. Primarily meristems and new leaves are affected, leading to bleaching effects and necrosis on young plant tissues. In consequence of the defective Carothinoid biosynthesis light energy destroys the chlorophyll leading finally to the die-off of susceptible plants.
According to recent information published by HRAC Mesotrione is categorized in the F2 group of herbicides (inhibition of 4-hydroxyphenyl-pyruvate-dioxygenase, 4-HPPD).
The label WMF2 is assigned to the product.

Efficacy
The Core Biological Assessment Dossier was prepared to support the label claims of CHA 2110 (Mesotrione: 100 gai/L; SC) when applied post-emergence for weed control in Maize.
The submission is based on efficacy and selectivity field trials performed throughout the EU in 2012 and 2013. The objectives of this dossier are to prove and to support the efficacy and crop safety of CHA 2110 in Maize for an effective control of a wide range of annual mono and dicot weed species at the intended rate of 0.75-0.15 kg ai/ha, applied post-emergence.
The evaluation is based on efficacy and selectivity data obtained from field studies conducted in Maize growing areas of the countries intended for the submission of the requested authorisation. To demonstrate the excellent weed control and crop safety of CHA 3110 under a wide range of conditions the BAD also contains the trials data generated in the Mediterranean EPPO climate zone.
As mesotrione has been registered and widely used throughout the EU for many years preliminary range finding tests are not required.
In the central zone to constantly control weeds in maize the proposed application rate of 0.75 to 1.5 l/ha CHA 2110 should be applied, if rates below this are used the level and consistancy and control and are reducded. In the central registration zone CHA 2110 applied at 1.5 l/ha achieves excellent weed control in maize.
For some weeds which are described in the label as being controlled well, only a few or no efficacy results have been submitted. Also for some weeds a sufficient number of results exists but the level of efficacy is relatively low.
Therefore, the request WH9161 has been appointed.

Effects on yield or quality
CHA 2110 applied at the maximum proposed label rate of 1.5 l/ha or the 2N overlapping rate causes no reductions in maize yield or quality.

Phytotoxicity
In a few trials minor phytotoxic effects are initially seen after an application of CHA 2210, however these are transient and quickly out ground by the crop.

Effects on succeeding crops
For succeeding crops, DT_{50} values for the degradation of Mesotrione in soil PEC_{soil}-values were calculated for different soil depths and along a timeline from 30 to 360 days after application to provide the basis for the risk assessment for relevant potential succeeding and replacement crops under European agricultural and cultivation conditions. As a result, label recommendations are given to minimize any risk for potential succeeding and replacement crops under usual crop growing conditions. However, as the zRMS states that “under usual crop rotation conditions the cultivation of all succeeding crops is possible after regular Maize harvest if the product was used before 1st July and in accordance with the principles of Good Agricultural Practice. The growing of dicot catch crops and sensitive dicot crops (e.g. Sugar beet, Pea, Bean, Oilseed rape, Sunflower, and Vegetables) is recommended after ploughing. The growing of cereals and grasses is possible without ploughing.” the label warning WP713 is assigned to the use.

Effects on adjacent crops
Vegetative vigour test according to the OECD Guideline No. 227 were conducted to determine the effect of CHA 2110 on adjacent crops based on these, some label recommendations are given for the proper use of CHA 2110 under common agricultural conditions.

Adverse effects on beneficial organisms (other than bees)
The test product CHA 2110 caused effects between 30 – 80% on *Aphidius rhopalosiphi* in the range of the proposed rate, the LR50 was 185.9 g a.s./ha. A formulation comparable to the test product caused effects between 30 – 80% on *Typhlodromus pyri* at the proposed rate, the LR50 of CHA 2135 was 173.4 g a.s./ha. The effects of a formulation comparable to the test product on spiders of the genus *Pardosa* are expected to be > 50%, when the test product is applied according to the recommended use pattern.
Consequently labels NN2001 and NN3002 are assigned to the product.

Resistance
The resistance status of mesotrione is classified by HRAC as group F2 and if the product is used according to the requested GAP the resistance risk for CHA 2110 is considered as low. Nonetheless, in order to minimize any risk of a possible development of resistance or cross-resistance - particularly if Maize is grown repeatedly in succession - integrated weed control management strategies should be used as a matter of principle, e.g. as mechanical weeding, alternation of herbicides from different mode of action groups, etc.

3.2 Conclusions

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

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

Regarding efficacy/IPM and sustainable use including effects on honeybees 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

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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.008110-00/00.95732
(bitte bei Antwort angeben)

DATUM 29. Mai 2017

ZV3 008110-00/00

Border (R)

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit dem Wirkstoff:	100 g/l	Mesotrione
Zulassungsnummer:	008110-00	
Versuchsbezeichnungen:	CHE-02110-H-0-SC	
Antrag vom:	11. Dezember 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
008110-00/00-001	Hühnerhirse, Einjährige zweikeimblättrige Unkräuter	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
Flasche	COEX	1	12	1,00	20,00	l
Flasche	COEX	1	24	0,10	1,00	l
Flasche	HDPE	1	12	1,00	20,00	l

Verpackungs-art	Verpackungs-material	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Flasche	HDPE	1	24	0,10	1,00	l
Kanister	COEX	1	24	0,10	20,00	l
Kanister	COEX	1	24	1,00	20,00	l
Kanister	HDPE	1	24	0,10	1,00	l
Kanister	HDPE	1	12	1,00	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:

Kennzeichnungsauflagen:

(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.

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

(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.

(SS526)
Gesichtsschutz tragen bei der Ausbringung/Handhabung des anwendungsfertigen Mittels.

(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:

(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.

(P261)
Einatmen von Staub/Rauch/Gas/Nebel/Dampf/Aerosol vermeiden.

(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
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: 008110-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Hühnerhirse, Einjährige zweikeimblättrige Unkräuter

Pflanzen/-erzeugnisse/Objekte: Mais

Verwendungszweck:

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 100 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: 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 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 1,95 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.

(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 EyC50 von 4,5 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.

(NW706)
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 20 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 4,5 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.

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product Code: Border

Reg. No.: 008110-00/00

Active Substance: mesotrione 100 g/L

Central Zone

Zonal Rapporteur Member State: CZ

National Addendum Germany

Applicant: Cheminova A/S

Evaluator: Julius Kühn-Institut

Date: 2015-08-28

Table of Contents

IIIA1 6 Efficacy Data and Information on the Plant Protection Product

General information

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: 2015-07-24	**Product: Border**
Use No.	008110-00/00-001
Field of use	Agriculture (field crops)
Crop(s)/object(s)	maize (ZEAMX)
Crop stage(s) (BBCH)	12 to 18
Pest(s)/target(s)	*Echinochloa crus-galli* (ECHCG), *Digitaria* spp. (DIGSS)*, annual dicotyledonous weeds (TTTDS)
Area of application	Outdoors
Timing of application	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)	1.5 L/ha in 100 to 400 L water/ha
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*should be deleted

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

For some weeds which are described in the label as being controlled well, only a few or no efficacy results exist. Also for some weeds a sufficient number of results exists but the level of efficacy is relatively low. So 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 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

This is not an EC data requirement.

IIIA1 6.2.3 Adverse effects on site of application

This is not an EC data requirement.

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

The herbicide Border (=CHA 2110, 100 g/L mesotrione, SC) is proposed for one post emergence treatment in maize with a field rate of 1.5 L/ha, corresponding to 150 g mesotrione/ha.

The applicant stated with regard to the information given in the individual reports on efficacy and selectivity testing of CHA 2110 in maize executed in various European countries in the years 2012 and 2013 that no side effects were observed on beneficial or non-target organisms.

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 (November 2013).
Various formulations of Mesotrione 100 g/L SC were tested.

A laboratory test on an artificial substrate with the indicator species *Aphidius rhopalosiphi* using the test product CHA 2110 (Table 6.2.4-1) resulted in a LR_{50} of 185.9 g as/ha.

Table 6.2.4-1: Effects of Mesotrione 100 g/L SC (CHA 2110) (99 g/L mesotrione) in a laboratory test on an artificial substrate

Species (Exposed Stage)	Substrate	Rate Product [L/ha]	Corrected Mortality [%]	Sublethal Effect (Reproduction) [%]	Reference
*A. rhopalosiph*i (A)	Glass	7.5	92		CVA-12-12 (Stevens, 2013)
		3.75	76		
		1.875	46	-57	
		0.9375	24	-16	
		0.46875	16	-83	

PN = protonymphs, A = adults

A laboratory test on an artificial substrate with the indicator species *Typhlodromus pyri* using the formulation Mesotrione 100 g/L SC (CHA 2135) (Table 6.2.4-2) resulted in a LR_{50} of 173.4 g as/ha.

Table 6.2.4-2: Effects of Mesotrione 100 g/L SC (CHA 2135) (102 g/L mesotrione) in a laboratory test on an artificial substrate

Species (Exposed Stage)	Substrate	Rate Product [L/ha]	Corrected Mortality [%]	Sublethal Effect (Reproduction) [%]	Reference
*T. pyr*i (PN)	Glass	4	81		CVA-12-13 (Fallowfield, 2013)
		1.6	42	35	
		0.64	12	36	
		0.256	30	25	
		0.1024	11		

PN = protonymphs, A = adults

Furthermore, results of laboratory tests on artificial substrates, extended laboratory tests and aged residue tests using ZA 1296 SC 100 (Mesotrione 100 g/L SC) have been available from the Review Report on mesotrione (SANCO/1416/2001-Final,14 April 2003) (table 6.2.4-3).

According to the Review Report, a field study with *Pardosa* spp. using ZA 1296 SC 100 (150 g as/ha) showed that population in test plots mirrored that in control plots. No long term adverse effects have seen.
As specific data was not available, the information could not contribute to an assessment.

Table 6.2.4-3: Effects of ZA 1296 SC 100 (Mesotrione 100 g/L SC) in laboratory tests on artificial substrates, extended laboratory tests on natural substrates and aged residue tests

Species (Exposed Stage)	Substrate	Rate [g as/ha]	Corrected Mortality [%]	Sublethal Effect [%]	Reference according to Section 6, IIIA 10.5
T. pyri (PN)	Glass	200	100		Review Report (SANCO/ 1416/2001- Final, 14 April 2003)
A. rhopalosiphi (A)	Glass	200	3	9.3 (Re)#	
C. carnea (La)	Glass	200	14.6	19.2 (Re)	
P. cupreus (A)	Quartz sand	200	0	12.5 (F)	
A. bilineata (A)	Quartz sand	200	9.7	4.5 (Re)	
Pardosa spp. (A)	Quartz sand	150	64.3	9.3 (F)	
	Soil	6	27.8	56.5 (F)	
		150	100	50 (F)	
	Soil	6	22	-20 (F)	
		75	92	-51 (F)	
		150	97	-51 (F)	
	Soil 1 DAT	150	93	-34 (F)	
	5 DAT	150	92	-38 (F)	
	12 DAT	150	75	71 (F)	

PN = protonymphs, A = adults, La = larvae, Re = reproduction, F = food consumption

The test product CHA 2110 caused effects between 30 – 80% on *Aphidius rhopalosiphi* in the range of the proposed rate. However, ZA 1296 SC 100, a formulation comparable to the test product, caused only marginal effects at 1.3fold the proposed rate.
Aphidius rhopalosiphi is not yet relevant at the proposed application time. At the later occurrence of this species, the test product should not have effects ≥ 25% due to its relatively quick degradation. However, a definite assessment is not possible so far.

A formulation comparable to the test product caused effects between 30 – 80% on *Typhlodromus pyri* at the proposed rate. The predatory mite is not a relevant antagonist in the proposed crops. However, the results for this species indicate that the test product may cause similar effects on populations of relevant predatory mites.
The effects on spiders of the genus Pardosa are expected to be > 50%, when the test product is applied according to the recommended use pattern.

On the basis of the effects of a formulation comparable to the test product on the lacewing *Chrysoperla carnea*, the ground beetle *Poecilus cupreus* and the rove beetle *Aleochara bilineata* the test product is not expected to have effects ≥ 25% on population of these species, when the test product is applied according to the recommended use pattern.

Classification scheme of the effects:
Laboratory tests on artificial substrates (glass, quartz sand)
< 30% = not harmful
30 – 80% = slightly harmful
> 80% = harmful
Extended laboratory tests on natural substrates, semi-field and field tests
< 25% = not harmful
25 - 50% = slightly harmful
> 50% = harmful

Proposal for classification:

The test product is classified as not harmful for populations of *Chrysoperla carnea*, *Poecilus cupreus* and *Aleochara bilineata.*
The test product is classified as slightly harmful for populations of relevant predatory mites.
The test product is classified as harmful for populations of spiders of the genus Pardosa.

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

The zRMS CZ states that: “under usual crop rotation conditions the cultivation of all succeeding crops is possible after regular Maize harvest if the product was used before 1st July and in accordance with the principles of Good Agricultural Practice. The growing of dicot catch crops and sensitive dicot crops (e.g. Sugar beet, Pea, Bean, Oilseed rape, Sunflower, and Vegetables) is recommended after ploughing. The growing of cereals and grasses is possible without ploughing.” Therefore the label warning WP713 (Damage is possible to succeeding crops, i.e. dicotyledonous catch 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

This is not an EC data requirement.

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 and the Authorization Certificate of the Reference Member State and the label.

Appendix 2: GAP table

Reg.-No.	**008110-00/00**		**GAP rev.1, date: 2015-07-24**
PPP (product name/code)	**Border**	**Formulation Type:**	**SC**
active substance 1	**Mesotrione**	**Conc. of a.s. 1:**	**100.00 g/L**
active substance 2	**0**	**Conc. of a.s. 2:**	**0**
active substance 3	**0**	**Conc. of a.s. 3:**	**0**
active substance 4	**0**	**Conc. of a.s. 4:**	**0**
active substance 5	**0**	**Conc. of a.s. 5:**	**0**
Applicant:	**Cheminova Deutschland GmbH**	**professional use**	**Yes**
Zone(s):	**central/EU**	**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	*Echinochloa crus-galli* (ECHCG), ~~*Digitaria* spp. (DIGSS),~~ annual dicotyledonous weeds (TTTDS)	spraying	After emergence 12 to 18	a) 1 b) 1	a) 1.5 L/ha b) 1.50 L/ha	a) 0.15 kg/ha b) 0.15 kg/ha	100 - 400	-	