

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: SHA 4300 A

Product name(s): MIGHTY

Chemical active substance:

Mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: December 2018

MS Finalisation date: 04/06/2024

Version history

| When | What |
|----------------|---|
| February 2020 | Dossier sent for evaluation |
| September 2023 | zRMS finalised evaluation |
| November 2023 | Applicant update |
| April 2024 | zRMS updated comments following change in GAP |
| June 2024 | Final version prepared by zRMS after the second commenting period |

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Sharda Cropchem España S.L.

The application is for approval of MIGHTY (MESOTRIONE 10% SC), a Suspension Concentrate formulation containing 100 g/L of Mesotrione, for use on maize as an herbicide.
zRMS: Poland.

1.2 Letters of Access

Applicant provided a letter of access for mesotrione technical used in the PPP.

1.3 Justification for submission of tests and studies

This dossier relies on test and studies providing data and information specific to the formulation MIGHTY (MESOTRIONE 10% SC) as required by the EU regulations.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of reference.

2 Details of the authorization decision

2.1 Product identity

| | |
|---|---|
| Product code | SHA 4300 A |
| Product name in MS | MIGHTY |
| Authorization number | First registration |
| Function | herbicide |
| Applicant | Sharda Cropchem España S.L. |
| Active substance(s) (incl. content) | Mesotrione; 100 g/L |
| Formulation type | SC (Suspension Concentrate) |
| Packaging | 0.25L, 0.5L, 1L, 5L, 10L COEX; 20 L, Fluorinated HDPE |
| Coformulants of concern for national authorizations | — |
| Restrictions related to identity | - |
| Mandatory tank mixtures | — |
| Recommended tank mixtures | — |

2.2 Conclusion

2.3 Substances of concern for national monitoring

Not relevant.

2.4 Classification and labelling

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

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

| | |
|-------------------------------|---------------------------------|
| Hazard class(es), categories: | Aquatic Chronic 1; Repr. Cat. 2 |
|-------------------------------|---------------------------------|

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

| | |
|-------------------------------|--|
| Hazard pictograms: | GHS08, GHS09 |
| Signal word: | Warning |
| Hazard statement(s): | H361d, H410 |
| Precautionary statement(s): | P202, P280, P308 + P313, P391, P501 |
| Additional labelling phrases: | To avoid risks to man and the environment, comply with the instructions for use. [EUH401] |
| | Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. [EUH208] |

| | |
|--|--|
| Special rule for labelling of plant protection product (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: | |
| EUH208 | Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. |

See Part C for justifications of the classification and labelling proposals.

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

| | |
|------|---|
| SP 1 | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). |
| SPe3 | To protect aquatic organisms respect an unsprayed vegetated buffer zone of 20 m to surface water bodies. To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land OR the use of 75% drift reducing nozzles |

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

| | |
|---|---|
| – | – |
|---|---|

2.5 Risk management

2.5.1 Restrictions linked to the PPP

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

| | |
|----------------------|---|
| Operator protection: | |
| - | Work wear (arms, body and legs covered) M/L and A Considering classification of product operator should wear the personal protective equipment: protective gloves and protective clothing when handling the concentrate (mixing-loading) and during application. |
| Worker protection: | |
| - | Work wear (arms, body and legs covered) |

| | |
|---|---|
| – | Treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried |
| Integrated pest management (IPM)/sustainable use: | |
| – | – |
| Environmental protection | |
| SP 1 | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). |
| SPe3 | To protect aquatic organisms respect an unsprayed vegetated buffer zone of 20 m to surface water bodies. To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land OR the use of 75% drift reducing nozzles |
| Other specific restrictions | |
| – | – |

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

| | |
|---|---|
| Integrated pest management (IPM)/sustainable use: | |
| – | – |

2.5.2 Specific restrictions linked to the intended uses

Not relevant.

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 0, date: 2015-September-30th

PPP (product name/code): MESOTRIONE 10% SC / SHA 4300 A
Active substance 1: Mesotrione
Active substance 2: -
Safener: -
Synergist: -
Applicant: Sharda Cropchem España S.L.
Zone(s): Central zone ^(d)
Verified by MS: yes

Formulation type: Suspension concentrate (SC)^(a, b)
Conc. of as 1: 100 g/L ^(c)
Conc. of as 2: - ^(c)
Conc. of safener: - ^(c)
Conc. of synergist: - ^(c)
Professional use: ☒
Non professional use: ☐

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 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) | | | | | | | | | | | | | |
| † | PL | Maize | F | Broadleaved and grass weeds | Foliar Spray | BBCH 10-14 (*) | a) 1 b) 1 | N.A | a) 1.5 b) 1.5 | a) 150 b) 150 | 200- 600 | - | (*) Weeds at early stages |
| 1 | PL | Maize | F | Broadleaved and grass weeds | Foliar Spray | BBCH 10-14 (*) | a) 1 b) 1 | N.A | a) 1.0 b) 1.0 | a) 100 b) 100 | 200- 600 | - | (*) Weeds at early stages |

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 | 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 |
| | 2 | Use official codes/nomenclatures of EU Member States | 8 | The maximum number of application possible under practical conditions of use must be provided. |
| | 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) | 9 | Minimum interval (in days) between applications of the same product |
| | 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 | 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. |
| | 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. | 11 | The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha). |
| | 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. | 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 Background of authorization decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of yellow thick liquid, with a characteristic (citrus) odour. It is not explosive, has no oxidising properties. The product is not flammable and has a flash point of 65.5 °C. In aqueous solution, it has a pH value around 2.92. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C 14 days at 54 °C and two-year study at ambient temperature neither the active ingredient content nor the technical properties were changed. Its technical characteristics are acceptable for a Suspension Concentrate formulation.

The intended concentration of use is 9.73% w/w (100 g/L).

3.2 Efficacy (Part B, Section 3)

The ecotoxicology section has change the max. dose – 1,0 l/ha of the product, therefore max dose of 1,0 l/ha can be accepted by the efficacy section.

Mesotrione 10% SC is an herbicide for post-emergence application to maize crops for the control of annual grasses and broadleaved weeds. MIGHTY (MESOTRIONE 10% SC) is a Suspension Concentrate (SC) formulation containing 100 g/L mesotrione.

In compliance with the GAP the following dose rates are applied for registration:

- Single application in maize to grasses and broadleaved weeds, target rate: 1.0 L/ha

This document serves the registration of MIGHTY (MESOTRIONE 10% SC) in the Central zone of the EU. The objective of this biological assessment dossier is to prove and support the label claims of the herbicidal efficacy and crop safety of MIGHTY (MESOTRIONE 10% SC) in maize crops, as claimed in the GAP table.

Comprehensive field trials were conducted in England, Germany, France, Poland, Latvia, Lithuania, Bulgaria, Romania, Spain and Italy in 2015. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

The data demonstrate that the weed control and safety to the crop of MIGHTY (MESOTRIONE 10% SC) is comparable to that of the mesotrione reference products registered in the EU Central zone, and the applicant therefore wishes to cite the original registrant's data on mesotrione now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal evaluator extrapolate from those data.

3.3 Efficacy data

Preliminary tests

The activity of mesotrione is well known, as it has been marketed since 2001 to control mono- and dicotyledonous weeds in maize and other crops. Based on the knowledge about the active substance (+15 years) and the experiences with using mesotrione in the label claimed crops at the proposed dose rates, the necessary application rates to obtain sufficient control of the pest organism are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Minimum effective dose tests

Mesotrione 10% SC was tested in the efficacy trials at a range of dose rates. The purpose of "Section 6.1.2, Minimum effective dose tests" is to demonstrate the dose response of Mesotrione 10% SC on mono- and dicotyledonous weeds in maize.

Control of annual grasses and broadleaved weeds in maize: In order to prove and to support the requested dose rates of 1.0 L/ha MIGHTY (MESOTRIONE 10% SC) [100 g mesotrione per hectare] for

the control of annual grasses and broadleaved weeds in maize, the assessment results of twenty-three efficacy trials performed in the Maritime (4) EPPO zone, the North-east (14) EPPO zone, the South-east (1) EPPO zone and the Mediterranean (4) EPPO zone in 2015 are reported. Mesotrione 10% SC was included in these trials at 1.0 L/ha to demonstrate the recommended dose rate at the lower dose rates (0.75 L/ha). As the most accurate representation of whole plot product performance, the assessment data at 15-73 days after the application, obtained by visually estimating control obtained by the applied products are summarized and presented.

Based on results achieved in 23 trials, it can be concluded that the recommended dose rate of 1.0 L/ha Mesotrione 10% SC applied once post emergence is required for consistent control of the label claimed annual grasses and broadleaved weed species in maize.

Conclusion: MIGHTY (MESOTRIONE 10% SC) applied at 1.0 L/ha in maize to control annual grasses and broadleaved weeds achieved good to excellent control of all target weeds. As grasses and broadleaved weeds often occur as a complex of several weed species with different susceptibility towards mesotrione, one application of MIGHTY (MESOTRIONE 10% SC) at the recommended rate should be used to efficiently control all weeds claimed on the label.

This document clearly demonstrates that the efficacy and crop safety of Mesotrione 10% SC is equivalent to that of the standard mesotrione reference product to which it was compared. The applicant therefore wishes to cite the original registrant's data on mesotrione now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

NE EPPO climate zone -PL

The dose justification of Mesotrione 10% SC has been supported by data from 14 efficacy trials on maize against grass weeds and broadleaved weeds for which efficacy of Mesotrione 10% SC is claimed. Efficacy of the claimed dose rate 1,0 l/ha was compared with the reduced dose rate of 0,75 /ha. In the NE EPPO climatic zone efficacy trials Mesotrione 10% SC at the dose rate of 1,0 l/ha showed higher level of efficacy than the reduced dose rate 0,75 l/ha in half presented trials.

1,0 l/ha dose rate of Mesotrione 10% SC can be considered the minimum effective dose rate.

Efficacy tests and conclusions regarding authorization of intended uses

In total, data from 23 efficacy trials have been included in this biological assessment dossier to support the label claims and recommendations on efficacy and selectivity in the EU Central Registration zone. The included efficacy trials have been conducted in the Maritime EPPO zone (4; i.e. N-France (1), Germany (2) and the United Kingdom (1)), the North-east EPPO zone (14; i.e. Poland (8), Latvia (3) and Lithuania (3)), the South-east EPPO zone (1; Romania) and the Mediterranean EPPO zone (4; i.e. Italy (2), S-France (1) and Spain (1)) in 2015.

Control of annual grass weeds in maize: When applied at 1.0 L/ha in the Maritime, the North-east, the South-east and the Mediterranean EPPO zones, MIGHTY (MESOTRIONE 10% SC) obtained moderate to excellent levels of control when applied to annual grass weeds. The highest level of control was obtained on the key monocotyledonous weeds, i.e. DIGSS, ECHSS and SETSS, whereas the control obtained against LOLPE and POAAN was more variable. All these grass weeds are commonly found in maize and are known to cause losses in production. In all species evaluated, the effect obtained with Mesotrione 10% SC was comparable with the effect obtained with the mesotrione reference product applied in the trials.

Control of broadleaved weeds in maize: When applied at 1.0 L/ha in the Maritime, the North-east, the South-east and the Mediterranean EPPO zones, MIGHTY (MESOTRIONE 10% SC) obtained good to excellent control when applied to dicotyledonous weeds in maize. The highest level of control was obtained on the key dicotyledonous weeds, i.e. AMASS, CAPBP, CHEAL, DATST, LAMPU, MATSS, POLSS, SENVU, STEME and VIOAR, whereas the control obtained against e.g. POROL was more variable. All these broadleaved weeds are commonly found in maize and are known to cause losses in production. In all species evaluated, the effect obtained with MIGHTY (MESOTRIONE 10% SC) was comparable with the effect obtained with the mesotrione reference product applied in the trials.

Conclusion: Based on the results of 23 field trials carried out in 2015, the following can be concluded for the intended use '*Control of grasses and broadleaved weeds*' from MIGHTY (MESOTRIONE 10% SC) applied post-emergence at the dose rate of 1.0 L/ha in maize:

- MIGHTY (MESOTRIONE 10% SC) provides a high level control of mono- and dicotyledonous weeds, like DIGSS, ECHSS, SETSS, AMASS, CHEAL, LAMPU, and STEME and a number of other annual grasses and broadleaved weed species with the recommended dose rate in maize. As weeds often occur as a complex of several weeds with different susceptibility towards mesotrione, one application of Mesotrione 10% SC at the recommended rate should be used to efficiently control all weeds claimed on the label.
- A high level of control may also be obtained against less susceptible weed species if treated with the recommended dose rate under optimal conditions, i.e. early growth stages and good weather conditions.
- Compared to the mesotrione reference product, the efficacy obtained with MIGHTY (MESOTRIONE 10% SC) is equivalent against all weed species.
- The trial results are considered valid for all intended EU Central zone countries.

Mesotrione 10% SC is suitable for the control of annual grasses and broadleaved weeds in maize.

As it has been demonstrated in 23 efficacy trials, the efficacy and crop safeness of Mesotrione 10% SC in maize is equivalent to the efficacy and cropsafetyness of the standard mesotrione reference products (i.e. Callisto 100 SC) against which MIGHTY (MESOTRIONE 10% SC) was compared.

Therefore, for weeds and dose rates in maize claimed on the label not supported with trials, the applicant wishes to bridge to the trials conducted in maize where equivalence between the effectiveness of MIGHTY (MESOTRIONE 10% SC) and the reference mesotrione products from Syngenta was demonstrated. The applicant therefore wishes to cite the original registrants data on mesotrione now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Rapporteur extrapolate from those data.

NE EPPO climate zone -PL

The applicant submitted 14 trials carried out in NE EPPO climate zone, on maize.

Weed species have been classified as:

susceptible (S) – 85%

moderately susceptible (MS) - 70-85%

moderately tolerant (MT) - 60-70%

tolerant (T) - < 60%

At the dose rate 1.0l/ha, the target weed species were categorized as:

- susceptible (S): AMARE, CAPBP, CHEAL, LAMPU, VIOAR, SOLNI

- moderately susceptible (MS): MATIN, POLCO, POLPE, STEME,

- moderately tolerant (MT): ECHCG

For SOLNI, one trial from DE was taken into account because of high level of control and similar effects like for PL trial.

What is more, the number of trials for the following weeds (1 trial per weed) is insufficient to conclude on efficacy: AVEFA, POAAN, SETPF, GALAP, LAMAM, LAPCO, POLLA, THLAR, VERAG, VERAR.

To sum up, it might be concluded that the application of MESOTRIONE 10% SC at dose rate 1.0 l/ha, post-emergence provided benefit against weeds on maize comparable to the standard product.

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

Resistance is a natural phenomenon embodied in the process of the evolution of biological systems and has been experienced over and over again in the past. According to Heap (2014¹) resistance is the naturally occurring inheritable ability of some weed biotypes within a population to survive an herbicide treatment that would, under normal conditions of use, effectively control that weed population. Selection of resistant biotypes may eventually result in control failures.

The risk of resistance was analyzed following the EPPO-Standard (2003²), the classification of the Herbicide Resistance Action Committee (HRAC)³ and the international Survey of Herbicide Resistant Weeds (Heap, 2016). So far 6 cases of resistance in two dicotyledonous weed species (both *Amaranthus* spp.) have been reported to have developed resistance to mesotrione. All cases have been reported from the United States of America. The active substance is therefore classified as having a low inherent risk.

The evaluation of the agronomic risk comes to the conclusion, that MIGHTY (MESOTRIONE 10% SC) bears a low risk of resistance.

The Registration of MIGHTY (MESOTRIONE 10% SC) is endorsed.

No resistance to mesotrione has yet been reported in Europe for over 10 years. ZRMS considers inherent risk of resistance developing to mesotrione to be low. Because target species like CHEAL, AMARE AND ECHCG have an inherently high risk of developing resistance therefore the inherent risk of resistance developing towards the target weeds should be considered moderate to high. ZRMS consider the overall risk of resistance developing to mesotrione for the proposed use low to moderate.

To avoid resistance developing in targeted weeds the resistance management strategy proposed by the applicant has to be implemented and placed on the label.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

Phytotoxicity was assessed in 39 trials, i.e. 23 efficacy trials and 16 crop safety trials, which were conducted in the Maritime zone (8; Germany (4), the United Kingdom (2) and N-France (2)), the North-east zone (21; Poland (12), Latvia (6) and Lithuania (3)), the South-east zone (3; Bulgaria (1) and Romania (2)) and the Mediterranean zone (7; Spain (2), Italy (3) and S-France (2)) in 2015.

MIGHTY (MESOTRIONE 10% SC) applied post-emergence at the applied dose rates did not caused phytotoxicity in the vast majority of the trials conducted on maize. In the trials where adverse effects were observed, minor phytotoxicity (as minor chlorosis, necrosis, stunting, deformation, bleaching and/or slightly reduced crop vigour) was observed in nine trials, but in all nine trials, the symptoms were transient and outgrown by the crop. Furthermore, no differences in the harvest data were observed and it is therefore considered safe to apply MIGHTY (MESOTRIONE 10% SC) in the GAP claimed crops at the recommended dose rates.

As this document also clearly demonstrates, then the efficacy and crop safety of MIGHTY (MESOTRIONE 10% SC) is equivalent to the standard mesotrione products to which it was compared. The applicant wishes to cite the original registrant's data on mesotrione now out of protection in additional support of any recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal evaluator extrapolate from those data.

Effects on yield and quality

Sixteen selectivity trials were harvested. The trials harvested were conducted in the Maritime zone (four trials), the North-east zone (7 trials), the South-east zone (two trials) and the Mediterranean (three trials) in 2015 to evaluate the effect of MIGHTY (MESOTRIONE 10% SC) on yield of maize.

¹ Heap, I. M., 2014: The International Survey of Herbicide Resistant Weeds. Web site visited Nov 2014.
<http://www.weedscience.com>

² EPPO 2003: Standard PP 1/213 (2): Resistance risk analysis.

³ HRAC: <http://www.HRACglobal.com>. Web site visited November 2014.

When applied at 1.5 and 3.0 L/ha, MIGHTY (MESOTRIONE 10% SC) did not adversely affect yield of the maize crops harvested.

Moisture content, oil content, protein content, starch content and Thousand Grain Weight was measured in a number of trials harvested. MIGHTY (MESOTRIONE 10% SC) did not adversely affect the yield quality parameters evaluated at any of the dose rates tested (i.e. the proposed label dose rate and the 2N dose rate simulating sprayer overlap).

Furthermore, the data obtained in trials harvested demonstrate that MIGHTY (MESOTRIONE 10% SC) is as safe to the crop as the mesotrione reference product used in the trials.

As this document clearly demonstrates, the efficacy and crop safety of MIGHTY (MESOTRIONE 10% SC) is equivalent to the standard mesotrione product to which it was compared. The applicant therefore wishes to cite the original registrant's data on mesotrione now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

The ecotoxicology section has change the max. dose – 1,0 l/ha of the product, therefore max dose of 1,0 l/ha can be accepted by the efficacy section. All field trials have been conducted at higher dose (1,5 l/ha) than is currently proposed (1,0 l/ha). Selectivity data presented for the higher dose stay valid for the lower dose.

Effect on transformation processes

MIGHTY (MESOTRIONE 10% SC) is composed of mesotrione which has been widely used for a number years on maize crops without identifying any quality problems on the treated crops.

MIGHTY (MESOTRIONE 10% SC) is applied early in the season (up to BBCH 14), before inflorescence emergence and heading, and as the active ingredient is not systemic, it is therefore not expected that the active ingredient is transferred to the grains.

Impact on treated plants or plant products to be used for propagations

Special tests to investigate this purpose are not required.

Not applicable.

3.3.3 Observations on other undesirable or unintended side-effects

Impact on succeeding crops.

Not relevant.

No significant residue levels are to be expected in rotational crops following application of mesotrione according to the proposed GAP.

In the opinion of ZRMS, in case of treated maize crop failure (e.g. by hail, dis-ease, pests or frost), maize may be sown on the field. After harvesting maize grown under normal growing conditions, winter cereals can be sown after deep ploughing (at least 20 cm). In the spring all crops can be cultivated.

According to the literature, sensitive crops such as oilseed rape, vegetable, beet, legumes, sunflowers and early-sown winter cereals under unfavorable conditions for the decomposition of the active substance can cause crop damage.

Impact on other plants including adjacent crops

Risk assessments were conducted according to EPPO Guideline PP1/256 and the results confirm that no further testing is necessary and that no negative impact on adjacent crops is expected, if a buffer zone as well as drift reducing nozzles are employed.

Effects on beneficial and other non-target organisms

There were no adverse effects on beneficial and other non-target organisms observed in any of the efficacy and crop safety trials conducted.

3.4 Methods of analysis (Part B, Section 5)

Analytical methods for Mesotrione in water, air, soil, liquid media, feed and in the formulation MIGHTY (MESOTRIONE 10% SC) are available.

3.4.1 Analytical method for the formulation

An analytical method for the determination of Mesotrione in MIGHTY (MESOTRIONE 10% SC) has been developed and sufficiently validated. Mesotrione content in the preparation MIGHTY (MESOTRIONE 10% SC) is determined by using HPLC-DAD.

According to the SANCO/3030/99 rev.4 guidance document, the analytical method for the determination of Mesotrione in the MIGHTY (MESOTRIONE 10% SC) was validated.

| | Mesotrione |
|--|---|
| Author(s), year | Berrios, Mónica, 2016 |
| Principle of method | HPLC-DAD |
| Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r) | Linear between 25 mg/mL and 400 mg/ml R = 0.9995 |
| Precision – Repeatability Mean n = 5 (%RSD) | 1.69 |
| Accuracy n = XX (% Recovery) | Not required. |
| Interference/ Specificity | No interference, the method is specific |
| Comment | - |

Furthermore, applicant sent additional data used for analysing 1,2 dichloroethane, R-287432 and R-287431 impurities of Mesotrione in the PPP. 1,2 dichloroethane was determined by gas chromatography using MSD (mass spectrometry detector) and internal standardisation. R-287432 and R-287431 were determined by LC using MSD (Triple Quadrupole detector) and internal standardisation./These data are sufficient.

3.4.2 Analytical methods for residues

Analytical methods for Mesotrione are provided for plant, animal, soil, water and air.

| Crop/Matrix | | | |
|----------------------------|--------------------------------------|---|--|
| Food/feed of plant origin | Mesotrione | LC-MS/MS, LOQ: 0.01 mg/kg (maize: grain, forage and silage) ILV: LC-MS/MS, LOQ: 0.01 mg/kg (maize: grain, forage and silage) | EU agreed EFSA journal 2016;14(3):4419 |
| Food/feed of animal origin | Mesotrione | LC-MS/MS, LOQ: 0.01 mg/kg (milk, eggs, muscle, kidney/liver) ILV: LC-MS/MS, LOQ: 0.01 mg/kg (milk, eggs, kidney/liver) | EU agreed EFSA journal 2016;14(3):4419 |
| Soil | Mesotrione, MNBA and AMBA metabolite | LC-MS/MS, LOQ: 0.002 mg /kg | EU agreed EFSA journal 2016;14(3):4419 |

| | | | |
|------------------------------------|--------------------------------------|---|--|
| Water (drinking and surface water) | Mesotrione, MNBA and AMBA metabolite | LC-MS/MS, LOQ: 0.05 µg/L ILV: LC-MS/MS, LOQ: 0.05 µg/L | EU agreed EFSA journal 2016;14(3):4419 |
| Air | Mesotrione | LC-MS/MS, LOQ: 0.45 µg/m ³ | EU agreed EFSA journal 2016;14(3):4419 |
| Body fluids and tissues | Mesotrione | LC-MS/MS, LOQ: 0.01 mg/kg | EU agreed EFSA journal 2016;14(3):4419 |

3.5 Mammalian toxicology (Part B, Section 6)

Acute toxicity studies for MIGHTY (MESOTRIONE 10% SC) were not evaluated as part of the EU review of mesotrione. Therefore, all relevant data were provided and are considered adequate.

All toxicological studies are being performed.

The toxicological classification of MIGHTY (MESOTRIONE 10% SC) was calculated.

Classification according to Regulation (EC) No 1272/2008: Repr.2, H361 d

Additional labelling phrases:

EUH401: To avoid risks to human health an the environment, comply with the instructions for use.

EUH208 Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction.

3.5.1 Acute toxicity

Acute toxicity studies for MIGHTY (MESOTRIONE 10% SC) were not evaluated as part of the EU review of mesotrione. Therefore, all relevant data were provided and are considered adequate. The results are summarised in the table below:

| Type of test, species, model system (Guideline) | Result | Acceptability | Classification (acc. to the criteria in Reg. 1272/2008) | Reference |
|---|------------------------|---------------|---|------------------|
| LD ₅₀ oral, rat (OECD 423) | 5000 mg/kg bw | Yes | None | C.C. Magar, 2017 |
| LD ₅₀ dermal, rat (OECD 402) | > 2000 mg/kg bw | Yes | None | C.C. Magar, 2017 |
| LC ₅₀ inhalation, rat (OECD 403) | > 4.37 mg/L air | Yes | None | J.J. Patil, 2017 |
| Skin irritation calculation method | Non-Irritant | Yes | None | |
| Eye irritation calculation method | Non-Irritant | Yes | None | |
| Skin sensitisation, guinea pig (OECD 406) | Non-sensitizer | Yes | None | C.C. Magar, 2017 |
| Supplementary studies for combinations of plant protection products | No data – not required | | | |

3.5.2 Operator exposure

Operator exposure to MIGHTY (MESOTRIONE 10% SC) was not evaluated as part of the EU review of mesotrione for this submitted rate/crop. Therefore all relevant data and risk assessments have been provided and are considered to be adequate.

Estimations of potential operator exposure have been undertaken for mesotrione using the AOEM model.

Conclusion:

According to the AOEM model, calculations, it can be concluded that the risk for the operator using

MIGHTY (MESOTRIONE 10% SC) is acceptable with the use of working clothing (long sleeved shirt and trousers) during mixing /loading and application.

Implication for labelling: None

According to the exposure calculations it can be concluded that the risk for the operator using MIGHTY (MESOTRIONE 10% SC) is acceptable without PPE. However, considering classification of product (Reproductive toxicity cat 2) operator should wear the personal protective equipment: protective gloves and protective clothing when handling the concentrate (mixing-loading) and during application.

An adequate statement should be placed on the label in the section concerning the protection of the person performing the agrochemical procedure:

“Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu”.

3.5.3 Worker exposure

Worker exposure to MIGHTY (MESOTRIONE 10% SC) was not evaluated as part of the EU review of mesotrione. Therefore, all relevant data and risk assessments have been provided and are considered adequate.

It is concluded that no unacceptable risk is anticipated for the worker re-entering the treated crop even without suitable protective clothing after inspection.

Moreover, as a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

Implication for labelling: None

3.5.4 Bystander and resident exposure

Bystander and resident exposures to MIGHTY (MESOTRIONE 10% SC) was not evaluated as part of the EU review of mesotrione. Therefore, all relevant data and risk assessments have been provided and are considered adequate. Calculations were made using the AOEM model.

It is concluded that there is no undue risk to any bystander after accidental short-term exposure nor to any resident exposure to MIGHTY (MESOTRIONE 10% SC).

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

During the commenting stage, the Applicant proposed lowering the application dose from 0.15 kg a.s./ha to 0.10 kg a.s./ha. It was accepted. The assessment covers a more critical scenario.

The preparation SHA4300A is composed of mesotrione.

Toxicological reference values for the dietary risk assessment of Mesotrione:

| Reference value | Source | Year | Value | Study relied upon | Safety factor |
|-----------------|------------------------------|------|-------|------------------------|---------------|
| Mesotrione | | | | | |
| ADI | EFSA Journal 2016;14(3):4419 | 2016 | 0.01 | Mouse multi-generation | 200 |
| ARfD | EFSA Journal 2016;14(3):4419 | 2016 | 0.02 | Mouse multi-generation | 100 |

An acceptable acute and chronic risk for the consumer is expected after the use of MIGHTY (MESOTRIONE 10% SC) according to the intended GAP.

3.6.1 Residues

The stability of residues for the active substance Mesotrione was reviewed during the annex II inclusion

process and no further data is required.

Plant metabolism was studied in maize (pre- and post-emergence) with mesotrione labelled on cyclohexane-2-¹⁴C and phenyl-U-¹⁴C. The metabolism of mesotrione in maize proceeds by oxidation of the parent molecule to 4/5-hydroxy mesotrione and to MNBA with subsequent reduction to AMBA and its conjugates observed in maize.

The residues definition for food and plant origin is Mesotrione (cereals and pluses/oilseeds only) for food commodities and both mesotrione and AMBA including its conjugates (cereals, pulses/oilseed only – conventional crops) for feed commodities.

For the use of Maize, are available in the RAR enough trials to cover the proposed GAP. 5 trials carried out with dose of 150 g ai/ha and 4 trials carried out with dose of 200 g ai/ha, and all results below LOQ (<0,01 mg/kg).

According to the available data, the intended uses on maize is considered acceptable, for outdoor uses.

3.6.2 Consumer exposure

This dossier is presented to support the product MIGHTY (MESOTRIONE 10% SC) for the use on maize. New dietary risk assessments for the active substance Mesotrione were carried out and presented. Calculations were performed using the EFSA PRIMo model rev. 3

The results of the TMDI calculations show that there is no chronic risk for consumer for the active substance. The TMDI estimation according to the EU calculations varies between 1% (PL general population) and 12 % (NL toddler) and 7% (NL child) of the ADI.

For the active substance, the result of the IESTI calculations demonstrate that in no case the IESTI is above the acute reference dose (ARfD) of 0.02 mg/kg bw. Thus the acute risk to the consumer based on the short-term intake of residues of the active substance is considered to be acceptable.

Based on the different calculations made to estimate the risk for consumer through diet and other uses, it can be concluded that the use of MIGHTY (MESOTRIONE 10% SC) does not lead to unacceptable risk for consumer when applied according to the intended uses and recommendations.

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

Concentrations of MIGHTY (MESOTRIONE 10% SC) in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentrations (PEC values) in soil, surface water, sediment, groundwater and air are provided. The intended use pattern of Mesotrione 10% SC concerns single application of 150 g mesotrione/ha at maize growth stage BBCH 10-14.

The Applicant has added a new application pattern of 100 g a.s./ha. The former application rate of 150 g a.s./ha covers the added one. No further assessment is required.

The impact of formulants is limited to short-term effects such as formation of stable spray dispersions of to facilitate uptake by target organisms, while their influence on long-term processes, such as degradation and distribution is negligible. Therefore, for the purposes of this exposure assessment, it is assumed that formulants do not influence the fate and behaviour of an active substance in the environment and were not considered.

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

The PEC_s of Mesotrione, its soil metabolites MNBA and AMBA and the formulated product MIGHTY (MESOTRIONE 10% SC) have been assessed with the FOCUS model and the DT₅₀ values estimated in the EU review.

PEC_s for the active substance Mesotrione were calculated according to the following end-points:

- DT₅₀ of 43.4 days

- The maximum rate: 1 application of 150 g a.s./ha on maize with 25% crop interception.

Maximum PEC_s for were 0.150, 0.062, 0.009 and 1.565 mg/kg, for Mesotrione, MNBA, AMBA and MIGHTY respectively following application on maize.

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

The PEC_{GW} of MIGHTY (MESOTRIONE 10% SC) in groundwater has been assessed with the FOCUS PELMO and FOCUS PEARL models, the interception values, the DT₅₀ and the soil sorption values established in the EU review.

PEC_{GW} for the active ingredient Mesotrione and its metabolites MNBA and AMBA were calculated according different pH endpoints.

The PEC_{GW} values for Mesotrione and its soil metabolite AMBA were below the drinking water limit of 0.1 µg/L, but for metabolite MNBA max PEC_{GW} was of 0.170 µg/L, and the assessment of its relevance in groundwater was presented in Section 10.

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

The PEC_{SW/SED} of MIGHTY (MESOTRIONE 10% SC) has been assessed with the models FOCUS STEP 1/2, FOCUS SWASH, FOCUS PRZM, FOCUS MACRO, FOCUS TOXSWA and FOCUS SWAN, and with the DT₅₀ and the soil sorption values established in the EU review.

These calculations have been done for all scenarios for a maize use. PEC_{SW/SED} calculations have been performed until step 4 for 6 scenarios (D3, D6, R1, R2, R3 and R4). Mitigation measures considered at step 4 were:

- non-spray buffer zones from 5 m to 20 m without drift reduction techniques
- vegetative buffer strips of 10 m and 20 m.

The relevant mitigation measures will be proposed in Section 9

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

Mesotrione is considered as a non-volatile substance. Therefore, PEC_{AIR} assessment is not relevant.

3.8 Ecotoxicology (Part B, Section 9)

According to the risk assessment for MIGHTY (MESOTRIONE 10% SC), the following risk mitigation measure should be considered:

SPe3: *To protect aquatic organisms respect an unsprayed vegetated buffer zone of 20 m to surface water bodies.*

SPe3: To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land OR the use of 75% drift reducing nozzles

3.8.1 Effects on terrestrial vertebrates

For birds a low acute risk via acute exposure was concluded at the screening step for the representative uses on maize. A low long-term risk was concluded at tier 1 for all the generic focal species via dietary exposure for the representative use. The risk for consumption of contaminated water was assessed as low. For wild mammals a low acute risk via dietary exposure was concluded at the screening level for the representative use on maize. No safe use was concluded following application of MIGHTY at 1.5 L/ha (corresponding to 150 g a.s./ha) and further refinement is required. The high long-term and drinking water risk was identified.

No secondary poisoning assessment was triggered for Mesotrione and its metabolites (not required since LogKow<3).

The Applicant was requested to submit the additional data necessary to refined the risk to mammals and/or to consider a reduction of the maximum application rate.

Currently, the Applicant has access to following higher tier studies:

1. Von Blanckenhagen F., Grimm T., 2013: Generic field study on small mammals focal species and wood mouse (*Apodemus sylvaticus*) PT in maize fields in Germany. Report P12225. Applicant has access to this study and LoA is provided.
2. Katzschner I., Grimm T., 2019: Generic monitoring of European hares to determine proportion of time spent foraging in early maize in Central Europe. Report R1740045.
3. Allen L. (2019): Mesotrione – Foliage decline study on clover in Hungary, Germany, United Kingdom, Northern France and Belgium in 2019. Report CEMR-8397.
4. North L. (2016): Mesotrione – Foliage Decline study with A127379A on maize in Northern France and the United Kingdom in 2015. Report A12739A_11065.

The Letters of Access do not authorize Sharda CropChem España S.L. to inspect any of the studies or receive copies thereof, as a whole or in part, in original form or as a copy.

Those studies were evaluated and used in the risk assessment in the CEU Core Assessment for Callisto (A12739A), dated 21/09/2021. Having regard to the clauses in LoA, in current evaluation the accepted values/approaches were taken directly from mentioned above zonal report, without any details. Those studies were not re-evaluated.

The safe use is concluded only for application rate of 1.0 L product/ha (100 g a.s./ha). **However, in the proposed use pattern of MIGHTY such a dose rate is not included.**

As the risk to mammals via food (chronic) and drinking water is still unacceptable following application of MIGHTY at 1.5 L/ha (corresponding to 150 g a.s./ha), the only dose included in the GAP, **currently no safe use can be concluded for the product.**

3.8.2 Effects on aquatic species

Most PEC/RAC values for Mesotrione are below the trigger value of 1 at step 3, indicating that Mesotrione poses a low risk to aquatic organisms. However, some PEC/RAC values taken from the assessment of *Lemna gibba* are above the trigger value of 1 (D3, D6, R1, R2 and R3 scenarios), indicating that Mesotrione poses a potential risk to higher plant. Based on the results of the risk assessment at step 4, the following conclusions regarding buffer zones and vegetative buffer strips may be drawn for a maize use:

- A 20m no spray buffer zone and a 20m vegetative buffer strip are required.

The risk to aquatic organisms for metabolites AMBA, MNBA and SYN546974 was assessed as low at FOCUS step 1 for the representative use on maize.

In addition, no unacceptable risk for the formulated MIGHTY (MESOTRIONE 10% SC) is expected under GAP conditions.

Spe3: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 20 m to surface water bodies.

3.8.3 Effects on bees

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

A low risk to bees is expected after the application of MIGHTY (MESOTRIONE 10% SC) according to the proposed GAP.

The data requirements in accordance with Commission Regulation (EU) No 284/2013 for the chronic toxicity to adult honeybees and honeybee larvae are fulfilled.

3.8.4 Effects on other arthropod species other than bees

No in-field risk to non-target arthropods is expected after the application of MIGHTY (MESOTRIONE 10% SC) according to the proposed GAP.

Based on the Tier II data for *Aphidius rhopalosiphii* and *Aleochara bilineata*, with effects below the triggers, the off-field risk is low. Nevertheless, for *Typhlodromus pyri* effects on reproduction were obtained below 38.3 g a.s./ha (lowest dose tested in extended laboratory study). Thus, no reproduction

endpoint is available. In this case, based on the aged residue study, where only 4.82% and 9.30% of effects on mortality and reproduction respectively were found at 150 g a.s./ha in fresh residue (at 0DAA) the acceptable risk can be identified.

3.8.5 Effects on soil organisms

A low acute and long-term risk was assessed for earthworms, other non-target soil meso- and macrofauna for the representative use on maize.

In addition, on the basis of the results of nitrogen transformation tests, it was concluded that MIGHTY (MESOTRIONE 10% SC) did not have any long-term adverse effect on the process of carbon and nitrogen transformation in aerobic surface soils.

3.8.6 Effects on non-target terrestrial plants

No explanation was given as why for the herbicide only one formation study on terrestrial plants was performed. Moreover, based on data from LoEP the lowest endpoint for representative formulation is from vegetative vigour test. Nevertheless, the Applicant didn't performed this type of test, and only seedling emergence study for MIGHTY is available. There is also no explanation on what basis the Applicant assumed that a representative formulation covers the risk to MIGHTY. Since different plant species have been tested in the seedling emergence test, it is not possible to compare the toxicity of both formulations. Moreover, in seedling emergence study for MIGHTY the *Lactuca sativa* was not tested (the most sensitive species based on Callisto 100 SC data). Therefore, the vegetative vigour test for MIGHTY is required.

The Applicant was requested to submit the vegetative vigour test with MIGHTY.

The new study was provided and used in the risk assessment.

Application rate 1.5 L/ha (150 g a.s./ha)

SPe3: to protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land OR the use of 75% drift reducing nozzles

Application rate 1.0 L/ha (100 g a.s./ha)

SPe3: to protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land OR the use of 50% drift reducing nozzles

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.9 Relevance of metabolites (Part B, Section 10)

The predicted PEC_{gw} for the Mesotrione metabolites were below 0.1 µg/L, therefore the relevance assessment is not needed.

Appendix 1 Copy of the product label

Uwagi do etykiety:

Fizykochemia – Wnioskodawca przedłożył do oceny badanie dwuletnie. Ze względu na brak danych związanych z poziomami istotnych zanieczyszczeń mezotriou, które należało by oznaczyć przed i po 2 letnim okresie przechowywania, wspomniane badanie jest niezaakceptowane. Jednakże, należy mieć na uwadze, że wszystkie pozostałe parametry fizykochemiczne były akceptowalne. Z tego powodu Wnioskodawca powinien wystąpić do Ministerstwa o przyznanie warunkowego okresu ważności do czasu gdy przedłoży odpowiednie dane dotyczące poziomów istotnych zanieczyszczeń mezotriou analizowanych w „badaniu dwuletnim”. Wnioskodawca przedłożył nowe dane, dotyczące poziomów istotnych zanieczyszczeń mezotriou przed i po upływie dwóch lat przechowywania środka, co umożliwia zaakceptowanie okresu ważności wynoszącego dwa lata dla tego środka w Polsce.

Toksykologia – dodano pictogram GHS08, dodano zwroty: H361d, P202, P280, P308+P313.

Pozostałości – brak uwag do etykiety.

Los i zachowanie w środowisku – brak uwag do etykiety.

Ekotoksykologia – nie można potwierdzić bezpiecznego stosowania środka dla dawki 1,5 l/ha. Potwierdzono bezpieczne stosowanie środka dla dawki 1,0 l/ha.

Skuteczność działania – zmieniono treść etykiety w zakresach: „DZIAŁANIE NA CHWASTY”, „NASTĘPSTWO ROŚLIN”, „ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ”.

Załącznik do decyzji MRiRW nr R - z dnia r.

Posiadacz zezwolenia: Sharda Cropchem España S.L., Edificio Atalayas Business Center, Carril Condomina n° 3, 12th Floor, 30006 Murcia, Królestwo Hiszpanii, tel.: +34868127589, fax.: +34868127588, e-mail: eu.regn@shardaintl.com

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

Sharda Poland Sp. z o.o., ul. Bonifraterska 17, 00-203 Warszawa, tel. (22) 886 9328 lub (17) 240 13 07, e-mail: eu.sales@shardaintl.com

**Przestrzegaj etykiety środka ochrony roślin
w celu ograniczenia ryzyka dla ludzi i środowiska**


MIGHTY

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji aktywnej:

mezotriou (związek z grupy trójketonów) - 100 g/l (9.33 % w/w)

Zezwolenie MRiRW nr R - z dnia r.

| | |
|---|--|
|  | |
| Uwaga | |
| H361d | Podjezuwa się, że działa szkodliwie na dziecko w łonie matki |
| H410 | Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki. |

| | |
|-----------|---|
| EUH208 | Zawiera 1,2-benzoizotiazolin-3-on. Może powodować wystąpienie reakcji alergicznej. |
| EUH401 | W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia. |
| P202 | Nie używać przed zapoznaniem się i zrozumieniem wszystkich środków bezpieczeństwa |
| P280 | Stosować rękawice ochronne i odzież ochronną |
| P308+P313 | W przypadku narażenia lub styczości: Zasięgnąć porady/zgłosić się pod opiekę lekarza. |
| P391 | Zebrać wyciek. |
| P501 | Zawartość / pojemnik usuwać zgodnie z przepisami krajowymi. |

OPIS DZIAŁANIA

MIGHTY jest środkiem chwastobójczym, w postaci koncentratu w formie stężonej zawiesiny do rozcieńczania wodą, stosowanym nalistnie, przeznaczonym do zwalczania chwastów dwuliściennych i niektórych jednoliściennych w kukurydzy.

Środek jest selektywnym herbicydem o działaniu układowym. Pobierany jest głównie poprzez liście oraz dodatkowo poprzez korzenie chwastów i szybko przemieszczany w roślinie, hamując ich wzrost i rozwój. Powoduje zahamowanie biosyntezy karotenoidów w roślinach chwastów, w następstwie czego następuje zniszczenie chlorofilu, objawiające się bieleniem liści. Pierwsze objawy działania środka widoczne są po 5-7 dniach od wykonania zabiegu. Zamieranie chwastów następuje po około 14 dniach.

DZIAŁANIE NA CHWASTY

Chwasty wrażliwe np.: fiołek polny, gwiazdnica pospolita, jasnota purpurowa, komosa biała, maruna bezwonna, psianka czarna, rdest plamisty, rdest powojowaty, szarłat szorstki, tasznik pospolity;

Chwasty średnio wrażliwe np.: chwastnica jednostronna, maruna bezwonna, rdest powojowaty, rdest plamisty, gwiazdnica pospolita;

Chwasty średnio odporne: chwastnica jednostronna

ZAKRES STOSOWANIA, TEMRINY I DAWKI

KUKURYDZA

Maksymalna dawka dla jednorazowego zastosowania: 1.5 L/ha

Zalecana dawka dla jednorazowego zastosowania: 1.5 L/ha.

Stosować środek stosować po wschodach w fazach od 1 liścia do 4 liści kukurydzy.(BBCH 10-14).

Zabieg wykonać po wschodach chwastów w okresie, gdy mają one rozwinięte 2-6 liści, najlepiej, gdy większość z nich

znajduje się w fazie 4 liści.

Zalecana ilość wody: 200 – 600 l/ha.

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Maksymalna dawka dla jednorazowego zastosowania: 1.0 L/ha

Zalecana dawka dla jednorazowego zastosowania: 1.0 L/ha.

Stosować środek stosować po wschodach w fazach od 1 liścia do 4 liści kukurydzy.(BBCH 10-14).

Zabieg wykonać po wschodach chwastów w okresie, gdy mają one rozwinięte 2-6 liści, najlepiej, gdy większość z nich

znajduje się w fazie 4 liści.

Zalecana ilość wody: 200 – 600 l/ha.

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

NASTĘPSTWO ROŚLIN

Środek nie stwarza zagrożenia dla roślin uprawianych następnie w normalnym cyklu zmianowania. **Jesienią można wysiać zboża ozime po uprzedniej głębokiej orce (min. 20 cm).**

W przypadku wcześniejszej likwidacji plantacji można siać bez ograniczeń kukurydzę jako roślinę następczą.

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

Środka nie stosować:

- na rośliny osłabione lub uszkodzone przez szkodniki, przymrozki, zalanie lub suszę,
- podczas wiatru stwarzającego możliwość znoszenia cieczy użytkowej na sąsiednie rośliny uprawne.

Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych,
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.
- **liczba zastosowań w uprawach kukurydzy powinna być ograniczona do 1 zastosowania w jednym sezonie.**
- **w przypadku wielokrotnego stosowania herbicydów do zwalczania chwastów jedno i dwuliściennych w sezonie uprawowym lub w kolejnych sezonach uprawowych, należy stosować wyłącznie herbicydy o innym sposobie działania.**
- **aby zminimalizować presję chwastów, zaleca się głęboką uprawę gleby (pług) i późny siew**

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Zawartość opakowania przed użyciem wstrząsnąć. Odmierzoną ilość środka wsypać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszałem) i uzupełnić wodą do potrzebnej ilości.

Po wysypaniu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne ciecz w zbiorniku mechanicznie wymieszać.

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

Po pracy aparaturę dokładnie wymyć.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych, w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:

- po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe, lub,
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub,
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy roboczej i które zwróciły się o taką informację.

Środki ostrożności dla osób stosujących środek:

Nie jeść, nie pić ani nie palić podczas używania produktu.

Unikać wdychania rozpylonej cieczy.
Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.

Środki ostrożności związane z ochroną środowiska naturalnego:

Zebrać wyciek.
Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.
Nie myć aparatury w pobliżu wód powierzchniowych.
Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie 20 metrowej nieopryskiwanej, zadarnionej strefy ochronnej od zbiorników i cieków wodnych.

W celu ochrony roślin niebędących celem zwalczania konieczne jest wyznaczenie 5 metrowej nieopryskiwanej strefy ochronnej od terenów nieużytkowanych rolniczo lub redukcji znosu cieczy użytkowej na poziomie 50%.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta:

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji)

Nie dotyczy

Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz):

Nie dotyczy

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:

Nie dotyczy, należy uwzględnić NASTĘPSTWO ROŚLIN.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą.

Przechowywać w dobrze wentylowanych miejscach z dala od źródeł ciepła, w temperaturze nie przekraczającej zakresu 0°C - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić warunki do odpoczynku w pozycji umożliwiającej swobodne oddychanie.

W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ lub lekarzem.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 2 Letter of Access

Applicant has provided the letter of access acquired from Shandong Binnong Technology Co., Ltd. for the source of mesotrione technical equivalent to the reference source after renewal.

Appendix 3 Lists of data considered for national authorization

Please refer to the reference list.