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| --- |
| FINAL REGISTRATION REPORT  Part B  Section 7  Metabolism and Residues  Detailed summary of the risk assessment |
| Product code: RNB 012 A  Product name(s): FLENID  Chemical active substance:  Mesotrione, 100 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (authorization) |
| Applicant: Shandong Weifang Rainbow Chemical Co., Ltd.  Submission date: 09/2024  MS Finalisation date: 02/2025; 06/2025 |

Version history

|  |  |
| --- | --- |
| When | What |
| 02/2025 | ZRMS assessment |
| 06/2025 | The final Registration Report |
|  |  |
|  |  |

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# Metabolism and residue data (KCA section 6)

## Summary and zRMS Conclusion

**Storage stability**

The stability of residues during storage of samples was reviewed during the Annex I inclusion process and no further data is required.

Mesotrione is considered to be stable under freezer storage at -18ºC±5ºC for at least 42 months in maize grain and 31 months in maize forage. Frozen storage stability at -18ºC±5ºC of MNBA in maize grain and forage was demonstrated for at least 42 months.

**Metabolism in plants and animals**

Metabolism in plants and livestock data was provided during the EU review of mesotrione.

Plant residue definition for monitoring Mesotrione (cereals and pulses/oilseeds only) - EFSA journal 2016;14(3):4419,

Reg. (EU) 2024/1077: Mesotrione.

Plant residue definition for risk assessment:

Food commodities: Mesotrione (cereals and pulses/oilseeds only)

Feed commodities: Mesotrione and AMBA (including its conjugates) (Cereals, pulses and oilseeds only – Conventional crops) – Provisional. - EFSA journal 2016;14(3):4419

**Magnitude of residues in plants**

Proposed GAP for maize (1 application, BBCH 14-15, 100 g as/ha) is less critical than EU GAP (SANTE/11654/2016, 23 March 2017).

Sufficient unprotected data were submitted and evaluated in DAR and RAR, and considered enough to support the intended use in maize in NEU. Unprotected data from DAR are accepted in RAR.

An exceedance of the current MRL of 0.01 mg/kg for mesotrione on maize as laid down in Reg. (EC) No 396/2005 is not expected.

**Magnitude of residues in livestock**

No new data were submitted in the framework of this application and no required.

Animals are not exposed to residues via feed above the trigger value (0.004 mg/kg). Therefore livestock feeding studies are not required.

Dietary burden calculation with regard to AMBA conjugates residues in maize forage, fodder and total residues in maize grain from the metabolism data were tentatively estimated by EFSA (EFSA Journal 2016;14(3):4419).

EFSA (2016): *This assessment has to be reconsidered pending the outcome of data gap set for clarification of the genotoxic potential of AMBA and of its toxicological profile*.

According to the EFSA Supporting publication 2018:EN-1527, genotoxic potential of AMBA is considered clarified:

EFSA: *we agree with the RMS conclusion that the micronucleus test gave sufficient evidence of lack of genotoxic (clastogenic and aneugenic) potential of the metabolite AMBA since bone marrow exposure was demonstrated after 2 dosing with the substance with 24 h interval and measurement of AMBA in whole blood. We agree with the RMS that the confirmatory data requirement (1) has been fulfilled. It is however noted that the data gap identified in the EFSA conclusion (EFSA, 2016) regarding the relative toxicity of the metabolite compared with mesotrione has not been addressed.*

Since the residues are below 0.01 mg/kg, no further calculations are required.

**Magnitude of residues in processed commodities**

As residues of Mesotrione are not expected in treated crops, there is no need to investigate the effect of industrial and/or household processing. Specific processing factors for enforcement of processed commodities are therefore not proposed.

**Magnitude of residues in representative succeeding crops**

Magnitude of residues trials for rotational crops are not required as the available rotational metabolism data demonstrates that significant residues of mesotrione (greater than 0.01 mg/kg) are not expected in following crops as a result of the proposed use on maize.

No restrictions are necessary.

**Other / special studies**

Studies are not required. Maize is not a melliferous crop foraged by bees.

**Estimation of exposure through diet and other means**

The proposed uses of mesotrione in the formulation FLENID do not represent unacceptable acute and chronic risks for the consumer.

### Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation RNB 012 A are presented in Table 7.1‑1. They have been selected from the individual GAPs in the zone for maize. A list of all intended uses within the zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 mg/kg for mesotrione as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of mesotrione residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, Poland, zRMS agrees with the authorization of the intended use(s).

According to available data, no specific mitigation measures should apply.

Data gaps: none

Table 7.1‑1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | | 8 | | | | 9 | | | 10 | 11 | 12 |
| GAP number (see part B.0)\* | Crop and/  or situation \*\* | Zone | Product code | F, Fn, Fpn G, Gn, Gpn or I\*\*\* | Pests or  Group of pests  controlled | Formulation | | Application | | | | Application rate per treatment | | | PHI  (days) | Remarks | Conclusion |
| Type | Conc.  of as | method  kind | growth  stage & season | number  min max | interval between applications (min) | g as/hL  min max | water L/ha  min max | g as/ha  min max |
| **1** | Maize  **0500030** | N-EU | RNB 012 A | F | *Echinochloa crus-galli, Viola arvensis,Stellaria media,Lamium purpureum,Chenopodium album,Galium aparine,* *Fallopia convolvulus,**Anthemis arvensis, Amaranthus retroflexus,*  *Capsella bursa-pastoris,Thlaspi arvense,*  *Galinsoga parviflora* | SC | 100 g/L | Broadcast spraying | BBCH 14-15 | 1 | na | 33.33 - 50 | 200-300 | 100 | n.a. | Post emergence use | A |

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

\*\* Use also code numbers according to Annex I of Regulation (EU) No 396/2005

\*\*\* 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

Explanation for Column 11 “Conclusion”

|  |  |
| --- | --- |
| A | Exposure acceptable without risk mitigation measures, safe use |
| R | Further refinement and/or risk mitigation measures required |
| N | Exposure not acceptable, no safe use |

### Summary of the evaluation

The preparation RNB 012 A is composed of mesotrione.

Table 7.1‑2: 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, Peer review of the pesticide risk assessment of the active substance mesotrione | 2016 | 0.01 | mouse multigeneration | 200 |
| ARfD | EFSA Journal 2016;14(3):4419, Peer review of the pesticide risk assessment of the active substance mesotrione | 2016 | 0.02 | mouse multigeneration | 100 |

#### Summary for Mesotrione

Table 7.1‑3: Summary for mesotrione

| Use-No.\* | Crop | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample storage covered by stability data? | MRL compliance | Chronic risk for consumers identified? | Acute risk for consumers identified? |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | Maize | Yes | Yes (9) | Not relevant (PHI covered by the time between the last application and har-vest) | Yes | Yes | No | No |

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

Number of trials available for maize, sugar maize and popcorn fulfils the requirements for central Europe.

As residues of mesotrione do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

The proposed uses of mesotrione in the formulation FLENID do not represent unacceptable acute and chronic risks for the consumer.

#### Summary for RNB 012 A

Table 7.1‑4: Information on RNB 012 A (KCA 6.8)

| Crop | PHI for RNB 012 A  proposed by applicant | PHI/ Withholding period\* sufficiently supported for | PHI for RNB 012 A  proposed by zRMS | zRMS Comments  (if different PHI proposed) |
| --- | --- | --- | --- | --- |
| Mesotrione |
| Maize | F | NR |  |  |

NR: not relevant

\* Purpose of withholding period to be specified

\*\* F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 7.1‑5: Waiting periods before planting succeeding crops

|  |  |  |
| --- | --- | --- |
| Waiting period before planting succeeding crops | | Overall waiting period proposed by zRMS for RNB 012 A |
| Crop group | Led by mesotrione |
| NR | NR |  |

NR: not relevant

Assessment

## Mesotrione

General data on mesotrione are summarized in the table below

**Table 7.2‑1: General information on mesotrione**

|  |  |
| --- | --- |
| Active substance (ISO Common Name) | Mesotrione |
| IUPAC | 2-(4-mesyl-2-nitrobenzoyl) cyclohexane -1,3-dione |
| Chemical structure |  |
| Molecular formula | C14H13NO7S |
| Molar mass | 339.3 g/mol |
| Chemical group | Triketone |
| Mode of action (if available) | Selective, absorbed by roots and translocated. Bleaching: inhibition of 4-hydroxyphenyl-pyruvate-dioxygenase. |
| Systemic | Yes |
| Company (ies) | Syngenta\* |
| Rapporteur Member State (RMS) | UK |
| Approval status | Approved (01/10/2003)  Renewed  Date of (01/06/2017) and reference to decision (Commission Implementing Regulation (EU) 2017/725 of 24 April 2017) |
| Restriction | Only uses as herbicide may be authorised. |
| Review Report | SANTE/11654/2016, 23 March 2017 |
| Current MRL regulation | COMMISSION REGULATION (EU) 2017/626 of 31  March 2017  New MRL values for Mesotrione will apply on 06/11/2024 (based on Reg. (EU) 2024/1077) |
| Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed | Yes |
| EFSA Journal : Conclusion on the peer review | Yes\*\* |
| EFSA Journal: conclusion on article 12 | Yes\*\* |
| Current MRL applications on intended uses | None |

\* Notifier in the EU process to whom the a.s. belong(s)

\*\* If yes: EFSA, 2016 - see list of references

### Stability of Residues (KCA 6.1)

#### Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2‑2: Summary of stability data achieved at ≤ ‑ 18°C (unless stated otherwise)

| Matrix | Characteristics of the matrix | Acceptable Maximum Storage duration | Reference |
| --- | --- | --- | --- |
| **Data relied on in EU** |  |  |  |
| Plant products |  |  |  |
| Maize grain | Dry commodities | ~~17 months~~  42 months (mesotrione)  42 months (MNBA) | RMS, 1999  Wiebe, L.A., 1997, RR 97  042B INT |
| Maize forage | High water content | ~~18 months~~  31 months (mesotrione)  42 months (MNBA) | RMS, 1999  Wiebe, L.A., 1997, RR 97 042B INT |

Conclusion on stability of residues during storage

Storage stability of mesotrione and MNBA was demonstrated for a period of ~~18~~ 31 (mesotrione), 42 (MNBA) months at -18 °C in maize forage and for a period of ~~17~~ 42 months in maize grain.

The stability of residues for the mesotrione was reviewed during the Annex I inclusion and no further data is required.

#### Stability of residues in sample extracts (KCA 6.1)

The stability of the analytes in the extract when stored < 7 °C for up to 7 days for maize seed and 12 days for maize whole plant show no significant change after this period.

The stability of residues in sample extracts for the mesotrione was reviewed during the Annex I inclusion and no further data is required.

### Nature of residues in plants, livestock and processed commodities

#### Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2‑3: Summary of plant metabolism studies

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Crop Group | Crop | Label position | Application and sampling details | | | | | Reference |
| Method,  F or G (a) | Rate  (kg a.s./ha) | No | Sampling (DAT) | Remarks |
| **EU data** | | | | | | | | |
| Cereals | Maize | [cyclohexane 2-14C]  ZA1296 | F | 280–307 g a.s./ha (pre emergence) | 1 | Forage: 27  Fodder: 154 Grain: 154 | - | RMS, 1999 Wei Y and Dohn D.R (1997), Report no. RR 96-026B, |
| Maize | [phenyl-U 14C] ZA1296 | F | 161–164 g a.s./ha (post- emergence) | 1 | Forage: 28 Fodder: 125 Grain: 125 | - | Tarr J.B and van Neste L (1997), Report no. RR 96-007B |

Summary of plant metabolism studies reported in the EU

Plant metabolism was studied in maize (pre- and post-emergence) with mesotrione labelled on cyclohexane-2-14C and phenyl-U-14C. The metabolic pattern of mesotrione was found to be quantitatively different in conventional crops (maize) compared to genetically modified soya bean. In maize, parent mesotrione was hardly recovered (3% TRR in maize forage only) whilst the most pertinent metabolites identified in the feed items were MNBA (up to 20% TRR in maize forage leaves) and AMBA, free and conjugated (13% and 28% TRR respectively in maize forage leaves and fodder). The unextracted radioactivity was further characterized as carbohydrates (maize) incorporated into the natural constituents of the plant. 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 conventional maize.

Conclusion on metabolism in primary crops

The metabolism in primary crops for the mesotrione was reviewed during the Annex I inclusion and no further data is required.

#### Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.2‑4: Summary of metabolism studies in rotational crops

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Crop group | Crop | Label position | Application and sampling details | | | | | Reference |
| Method,  F or G \* | Rate  (kg a.s./ha) | Sowing intervals  (DAT) | Harvest  Intervals (DAT) | Remarks |
| **EU data** | | | | | | | | |
| Leafy vegetables | Broad leaves endive | [phenyl U-14C] ZA 1296 | G | 164 g a.s./ha | 120  300 | 78 | - | RMS, 1999 Spillner, C. et al, 1997, report no. not provided  Gorder, G.W et al, 1997 ; DP 59817 |
| Root and tuber vegetables | Radish | [phenyl U-14C] ZA 1296 | G | 164 g a.s./ha | 120  300 | 56 | - |
| Cereals | Wheat | [phenyl U-14C] ZA 1296 | G | 164 g a.s./ha | 120  300 | 22 57 134 | - |

\* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

The metabolism of mesotrione in rotational crops was found to be similar to the primary crops.

Conclusion on metabolism in rotational crops

The metabolism in rotational crops for the mesotrione was reviewed during the Annex I inclusion and no further data is required.

#### Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Based on results from residue trials, no mesotrione residues are expected at or above the limit of detection. It is therefore unlikely that mesotrione residues will be detected in processed fractions. Therefore, no study has been conducted regarding the effects of industrial processing and household preparation on the nature and magnitude of mesotrione residues.

Conclusion on nature of residues in processed commodities

Based on results from residue trials, no mesotrione residues are expected at or above the limit of detection. It is therefore unlikely that mesotrione residues will be detected in processed fractions. Therefore, no study has been conducted regarding the effects of industrial processing and household preparation on the nature and magnitude of mesotrione residues.

Taking above into consideration additional studies of residues in processed commodities are not regarded as necessary.

#### Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2‑5: Summary of the nature of residues in commodities of plant origin

|  |  |
| --- | --- |
| **Endpoints** | |
| Plant groups covered | Cereals (Maize) |
| Rotational crops covered | Root/tuber crops Leafy crops Cereal (small grain) |
| Metabolism in rotational crops similar to metabolism in primary crops? | Yes |
| Processed commodities | Hydrolysis studies addressing the nature of the residues in processed commodities are not triggered (mesotrione residue levels in maize grain < 0.01 mg/kg) |
| Residue pattern in processed commodities similar to pattern in raw commodities? | Hydrolysis studies addressing the nature of the residues in processed commodities are not triggered (mesotrione residue levels in maize grain < 0.01 mg/kg) |
| Plant residue definition for monitoring | Mesotrione (cereals and pulses/oilseeds only), (Regulation n° 2017/626); same definition will apply on 06/11/2024 in new Reg. (EU) 2024/1077 |
| Plant residue definition for risk assessment | Food commodities: Mesotrione (cereals and pulses/oilseeds only) Feed commodities: Mesotrione and AMBA (including its conjugates) (Cereals, pulses and oilseeds only – Conventional crops) – Provisional (EFSA 2016) |
| Conversion factor from enforcement to RA | Not applicable |

#### Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.2‑6: Summary of animal metabolism studies

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Group | Species | Label position | No of animal | Application details | | Sample details | | Reference |
| Rate  (mg/kg bw/d) | Duration  (days) | Commodity | Time of samp­ling |
| **EU data** | | | | | | | | |
| Lactating ruminants | Cow | [phenyl U- 14C] labelled AMBA | 1 | 0.4 | 7 | Milk | daily | RMS, 1999  XXX  , report no. not provided |
| Urine and faeces | daily |
| Tissues | at sacrifice |

Summary of livestock metabolism studies reported in the EU

A ruminant metabolism study was conducted with phenyl-U-14C AMBA. The total residues were below 0.01 mg/kg in all matrices except in kidney (0.053 mg/kg) and fat (0.018 mg/kg) with AMBA being the predominant compound that accounted for 79% TRR and 62% TRR, respectively.

Conclusion on metabolism in livestock

The metabolism in livestock for the mesotrione was reviewed during the Annex I inclusion and no further data is required.

#### Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2‑7: Summary on the nature of residues in commodities of animal origin

|  |  |
| --- | --- |
|  | Endpoints |
| Animals covered | Lactating goats |
| Time needed to reach a plateau concentration | 5 days in milk |
| Animal residue definition for monitoring | Not required for the representative use (provisional) |
| Animal residue definition for risk assessment | Not required for the representative use (provisional) |
| Conversion factor | Not applicable |
| Metabolism in rat and ruminant similar | Yes |
| Fat soluble residue | AMBA residues in muscle (<0.01 mg/kg) and in fat free muscle (0.003-0.018 mg/kg). AMBA is not expected to be fat solubl |

### Magnitude of residues in plants (KCA 6.3)

#### Summary of European data and new data supporting the intended uses

No new data are submitted in the framework of this application.

Table 7.2‑8: Summary of EU reported and new data supporting the intended uses of RNB 012 A and conformity to existing MRL

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL  (mg/kg)  \* | MRL compliance |
| Maize grain | RMS, 1999  Barnes J, RR 96-078B, 1997;  Barnes J., Atger J., Wiebe L., Miller M., RR 97-045B, 1997;  Miller M., Griehl T., Wiebe L., Elvira D., RR 97-063B, 1998;  Barnes J., Chamier O., Wiebe L., Miller M., RR 97-048B, 1997 | N-EU | Trials GAP: 1 x 0.15 – 0.2 kg as/ha, BBCH 16-18, outdoor  Forage, silage, grain: 9 x <0.01 | N/A | | | | |
| Overall supporting data for cGAP | N-EU | 9 x <0.01 | 0.01 | 0.01 | 0.01 | 0.01 | Yes |

\* Source of EU MRL: COMMISSION REGULATION (EU) 2017/626 of 31 March 2017, New Reg. (EU) 2024/1077 will apply on 06/11/2024

#### Conclusion on the magnitude of residues in plants

The stage of development of the crop at the time of application is within the range of intended use i.e. before forming the edible part of the crop. The application rates for the trials presented in DAR slightly above than the maximum recommended rate of FLENID (100 g a.s./ha). However it should be considered as a worst case. Moreover residue trials show that residues are below the limit of quantification. Since the objective is not new MRL setting but only MRL compliance, it is considered that all the trials are relevant to support registration of FLENID.

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

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

### Magnitude of residues in livestock

#### Dietary burden calculation

Table 7.2‑9: Input values for the dietary burden calculation (EFSA Journal 2016;14(3):4419)

| Feed Commodity | Median dietary burden | | Maximum dietary burden | |
| --- | --- | --- | --- | --- |
| Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Mesotrione | | | | |
| Maize grain | 0.01 | Median residue | 0.01 | Median residue |
| Maize fodder | 0.01 | Median residue | 0.01 | Median residue |
| Maize forage | 0.01 | Median residue | 0.01 | Median residue |
| AMBA (including its conjugates) | | | | |
| Maize grain | 0.014 | - | 0.014 | Total residues from the metabolism data |
| Maize fodder | 0.301 (provisional) | - | 0.301 (provisional) | Maximum residue levels of  total AMBA (including its  conjugates) recovered from  the metabolism data. Pending  clarification of the genotoxic  potential of AMBA and of its  toxicological profile GAP  compliant residue trials for  the determination of AMBA  conjugates residues in maize  fodder, forage may be needed  and the livestock dietary  burden to be revised  accordingly. |
| Maize forage | 0.043 (provisional) | - | 0.043 (provisional) |

Table 7.2‑10: Results of the dietary burden calculation

| Animal species | Median  dietary burden (mg/kg bw/d) | Maximum dietary burden  (mg/kg bw/d) | Highest contributing commodity | Max dietary burden (mg/kg DM) | Trigger exceeded (Y/N) |
| --- | --- | --- | --- | --- | --- |
| Mesotrione | | | | | |
| Beef cattle\* | 0.0009 | 0.0009 | Corn, field, gluten feed | 0.04 | N |
| Dairy cattle\* | 0.0013 | 0.0013 | Corn, field, gluten feed | 0.03 | N |
| Ram/ewe | 0.0007 | 0.0007 | Corn, field, gluten feed | 0.02 | N |
| Lamb | 0.0009 | 0.0009 | Corn, field, gluten feed | 0.02 | N |
| Breeding swine | 0.001 | 0.001 | Corn, field, gluten feed | 0.02 | N |
| Finishing swine\* | 0.001 | 0.001 | Corn, field, gluten feed | 0.02 | N |
| Broiler poultry | 0.001 | 0.001 | Corn, field, milled byproducts | 0.01 | N |
| Layer poultry\* | 0.002 | 0.002 | Corn, field, hominy meal | 0.02 | N |
| Turkey | 0.001 | 0.001 | Corn, field, hominy meal | 0.02 | N |
| Fish | - | - | - | > 0.1 mg/kg DM | N |
| AMBA (and its conjugates) (provisional) | | | | | |
| Beef cattle\* | 0.0025 | 0.0025 | Corn, field, forage/silage | Not calculated | N |
| Dairy cattle\* | 0.0036 | 0.0036 | Corn, field, forage/silage | Not calculated | N |
| Ram/ewe | 0.0010 | 0.0010 | Corn, field, gluten feed | Not calculated | N |
| Lamb | 0.0013 | 0.0013 | Corn, field, gluten feed | Not calculated | N |
| Breeding swine | 0.001 | 0.001 | Corn, field, forage/silage | Not calculated | N |
| Finishing swine\* | 0.001 | 0.001 | Corn, field, gluten feed | Not calculated | N |
| Broiler poultry | 0.001 | 0.001 | Corn, field, milled byproducts | Not calculated | N |
| Layer poultry\* | 0.003 | 0.003 | Corn, field, forage/silage | Not calculated | N |
| Turkey | 0.002 | 0.002 | Corn, field, hominy meal | Not calculated | N |
| Fish | - | - | - | - | N |

\* These categories correspond to those (formerly) assessed at EU level.

#### Livestock feeding studies (KCA 6.4.1-6.4.3)

**Available data**

No new data were submitted in the framework of this application.

Conclusion on feeding studies

Animals are not exposed to residues via feed above the trigger value established in Reg. (EC) No 1107/2009, above 0.004 mg/kg. Therefore livestock feeding studies are not required

### Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

**Available data**

No new data were submitted in the framework of this application.

Conclusion on feeding studies

No further studies has been performed. Mesotrione residue levels in maize grain are below 0.01 mg/kg. Therefore magnitude of residues in processed commodities are not requires.

### Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

Magnitude of residues trials for rotational crops are not required as the available rotational metabolism data demonstrates that significant residues of mesotrione (greater than 0.01 mg/kg) are not expected in following crops as a result of the proposed use on maize.

### Other / special studies (KCA6.10, 6.10.1)

Maize is not a melliferous crop foraged by bees. The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of RNB 012 A. Therefore, other special studies are not needed.

### Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

#### Input values for the consumer risk assessment

Table 7.2‑11: Input values for the consumer risk assessment

| Commodity | Chronic risk assessment | | Acute risk assessment | |
| --- | --- | --- | --- | --- |
| Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Mesotrione | | | | |
| Maize | 0.01 | MRL (acc. to reg. 2017/626 of 31 March 2017, New Reg. (EU) 2024/1077 will apply on 06/11/2024) | 0.01 | MRL (acc. to reg. 2017/626 of 31 March 2017, New Reg. (EU) 2024/1077 will apply on 06/11/2024) |
| All other commodities | various | - | - |

#### Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2‑12: Consumer risk assessment

|  |  |
| --- | --- |
| TMDI (% ADI) according to EFSA PRIMo | 12 % (based on NL toddler) |
| IEDI (% ADI) according to EFSA PRIMo | TMDI does not exceed ADI, therefore IEDI calculation is not required. |
| IESTI (% ARfD) according to EFSA PRIMo\* | Unprocessed commodities: 0.3% Maize/corn (children)  Unprocessed commodities: 0.1% Maize/corn (adults)  Processed commodities: 1% Maize/oil (children)  Processed commodities: 0.6% Maize/oil (adults |
| NTMDI (% ADI) \*\* | Not applicable |
| NEDI (% ADI)\*\* | Not applicable |
| NESTI (% ARfD) \*\* | Not applicable |

\* include raw and processed commodities if both values are required for PRIMo

\*\* if national model is available

The proposed uses of mesotrione in the formulation FLENID do not represent unacceptable acute and chronic risks for the consumer.

## Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

## References

|  |
| --- |
| EFSA Journal 2016;14(3):4419, Peer review of the pesticide risk assessment of the active substance mes otrione |
| EFSA Journal 2015;13(1):3976, Reasoned opinion on the review of the existing maximum residue levels (MRLs) for mesotrione according to Article 12 of Regulation (EC) No 396/2005 |
| Assessment report on the active substance Mesotrione prepared by the rapporteur Member State United Kingdom |
| COMMISSION REGULATION (EU) 2017/626 of 31 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products. |
| OMMISSION REGULATION (EU) 2024/1077 of 15 April 2024 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2,4-DB, iodosulfuron-methyl, mesotrione and pyraflufen-ethyl in or on certain products |

1. Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| - | - | - | - | - | - |

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| KCA 6.1 | Wiebe, L.A. | 1997 | ZA 1296: Stability of ZA 1296 and the Metabolite MNBA in Frozen Crops (Interim Report). Zeneca Report No:RR 97-042B INT  GLP,  Not published | N | SYN |
| KCA 6.2.1/01 | Wei Y et al | 1997 | [Cyclohexane-2-14C]ZA 1296: Nature of the Residues in Corn (Zea mays). Zeneca Agrochemicals  Report : RR 96-026B  GLP  Not published | N | SYN |
| KCA 6.2.1/02 | Tarr, J.B. et al | 1997 | [Phenyl-U-14C]ZA 1296: nature of the residues in corn  Report No: not provided  GLP  Not published | N | SYN |
| KCA 6.2.2-6.2.5 | XXX | XXX | AMBA: Metabolism of Orally Administrated Multiple doses in Lactating Cow  Report No: not provided  XXX  GLP  Not published | Y | SYN |
| KCA 6.6.1/01 | Spillner, C. *et al* | 1997 | [Cyclohexane-2-14C]ZA 1296: confined accumulation studies on rotational crops – low rate  Report No: not provided  GLP  Not published | N | SYN |
| KCA 6.6.1/02 | Gorder, G.W. *et al* | 1997 | [Phenyl-U-*14*C]ZA 1296: confined accumulation studies on rotational crops – low rate  Report No: not provided  GLP  Not published | N | SYN |
| KCA 6.3/01 | Barnes J. | 1997 | ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1995 (WRC-96-114) Zeneca Agrochemicals, Jealott’s Hill, United Kingdom,  RR 96-078B  GLP,  Not published | N | SYN |
| KCA 6.3/02 | Barnes J., Atger J., Wiebe L., Miller M. | 1997 | ZA1296: Residue Levels in Maize from Trials Carried out in France During 1996 (Postemergence) Zeneca Agrochemicals, Jealott’s Hill, United Kingdom,  RR 97-045B  GLP,  Not published | N | SYN |
| KCA 6.3/03 | Miller M., Griehl T., Wiebe L., Elvira D. | 1998 | ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1996 (Preemergence) Zeneca Agrochemicals, Jealott’s Hill, United Kingdom,  RR 97-063B  GLP,  Not published | N | SYN |
| KCA 6.3/04 | Barnes J., Chamier O., Wiebe L., Miller M. | 1997 | ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1996 (Postemergence) Zeneca Agrochemicals, Jealott’s Hill, United Kingdom,  RR 97-048B  GLP,  Not published | N | SYN |

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |

List of data relied on and not submitted by the applicant but necessary for evaluation

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |

1. Detailed evaluation of the additional studies relied upon
   1. Mesotrione
      1. Stability of residues

No new or additional studies have been submitted

* + 1. Nature of residues in plants, livestock and processed commodities

No new or additional studies have been submitted

* + 1. Magnitude of residues in plants

No new or additional studies have been submitted

* + 1. Magnitude of residues in livestock

No new or additional studies have been submitted

* + 1. Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new or additional studies have been submitted

* + 1. Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted

* + 1. Other/Special Studies

No new or additional studies have been submitted

1. Pesticide Residue Intake Model (PRIMo)
   1. TMDI calculations



* 1. IEDI calculations

TMDI does not exceed ADI, therefore IEDI calculation is not required.

* 1. IESTI calculations - Raw commodities



* 1. IESTI calculations - Processed commodities



1. Additional information provided by the applicant

No new or additional studies have been submitted