|  |
| --- |
| FINAL REGISTRATION REPORT  Part B  Section 8  Environmental Fate  Detailed summary of the risk assessment |
| Product code: RBN 012 A  Product name: 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: September 2024  MS Finalisation date: 03.2025; 06.2025 |

Version history

|  |  |
| --- | --- |
| When | What |
| 03.2025 | zRMS assessment |
| 06.2025 | The final Registration Report |
|  |  |
|  |  |

Table of Contents

[8 Fate and behaviour in the environment (KCP 9) 4](#_Toc159840722)

[8.1 Critical GAP and overall conclusions 5](#_Toc159840723)

[8.2 Metabolites considered in the assessment 7](#_Toc159840724)

[8.3 Rate of degradation in soil (KCP 9.1.1) 8](#_Toc159840725)

[8.3.1 Aerobic degradation in soil (KCP 9.1.1.1) 8](#_Toc159840726)

[8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1) 10](#_Toc159840727)

[8.4 Field studies (KCP 9.1.1.2) 11](#_Toc159840728)

[8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1) 11](#_Toc159840729)

[8.4.2 Soil accumulation testing (KCP 9.1.1.2.2) 11](#_Toc159840730)

[8.5 Mobility in soil (KCP 9.1.2) 11](#_Toc159840731)

[8.5.1 Column leaching (KCP 9.1.2.1) 13](#_Toc159840732)

[8.5.2 Lysimeter studies (KCP 9.1.2.2) 14](#_Toc159840733)

[8.5.3 Field leaching studies (KCP 9.1.2.3) 14](#_Toc159840734)

[8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3) 14](#_Toc159840735)

[8.7 Predicted Environmental Concentrations in soil (PECsoil) (KCP 9.1.3) 15](#_Toc159840736)

[8.7.1 Justification for new endpoints 15](#_Toc159840737)

[8.7.2 Actives substance(s) and relevant metabolite(s) 15](#_Toc159840738)

[8.7.2.1 Mesotrione and its metabolites 15](#_Toc159840739)

[8.7.2.2 PECsoil of FLENID 17](#_Toc159840740)

[8.8 Predicted Environmental Concentrations in groundwater (PECgw) (KCP 9.2.4) 18](#_Toc159840741)

[8.8.1 Justification for new endpoints 18](#_Toc159840742)

[8.8.2 Active substance(s) and relevant metabolites (KCP 9.2.4.1) 18](#_Toc159840743)

[8.9 Predicted Environmental Concentrations in surface water (PECsw) (KCP 9.2.5) 23](#_Toc159840744)

[8.9.1 Justification for new endpoints 23](#_Toc159840745)

[8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5) 23](#_Toc159840746)

[8.9.2.1 Mesotrione and its metabolites 24](#_Toc159840747)

[PECsw/sed of FLENID 34](#_Toc159840748)

[8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1) 35](#_Toc159840749)

[Appendix 1 Lists of data considered in support of the evaluation 37](#_Toc159840750)

[Appendix 2 Detailed evaluation of the new Annex II studies 37](#_Toc159840751)

[Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data) 37](#_Toc159840752)

# Fate and behaviour in the environment (KCP 9)

## Critical GAP and overall conclusions

Table 8.1‑1: Critical use pattern of the formulated product

| 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) | **Conclusion** |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | Min. interval between applications (days) | kg or L product / ha  a) max. rate per appl.  b) max. total rate per crop/season | g or kg as/ha  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min / max | PECgw |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | |  |
| 1 | Poland | Maize | 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* | Broadcast spraying | BBCH 14-15 | 1 | na | a) 1.0 L product /ha per application  b) 1.0 L product/ha per season | a) 100 g a.i./ha per application  b) 100 g a.i./ha per season | 200-300 | na | Post-emergence | A |

Explanation for column 15 “Conclusion”

|  |  |
| --- | --- |
| A | Safe use |
| R | Further refinement and/or risk mitigation measures required |
| C | To be confirmed by cMS |
| N | No safe use |

Table 8.1‑2: Assessed (critical) uses during approval of Mesotrione concerning the Section Environmental Fate

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
| Use-No. | 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 |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | Min. interval between applications (days) | kg or L product/ha  a) max. rate per appl.  b) max. total rate per crop/season | g or kg as/ha  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min/max |
| 1 | NEU  SEU  CEU | Maize | F | Annual broadleaved weeds and some annual grasses such as *Echinochloa crusgalli* | Foliar spray | BBCH 12-18 | application) 1  b) 1 | - | - | a) 150  b) 150 | 200-400 | n/a | - |

## Metabolites considered in the assessment

Table 8.2‑1: Metabolites of Mesotrione potentially relevant for exposure assessment

| Metabolite | Molar mass | Chemical structure | Maximum observed occurence in compartements | Exposue assessment required due to |
| --- | --- | --- | --- | --- |
| MNBA | 245 | 4-(methylsulfonyl)-2-nitrobenzoic acid  O=S(C)(=O)c1cc(c(cc1)C(=O)O)N(=O)=O | Soil: 57.2%  Water/Sediment: 7.9% | PECgw / PECsoil / PECsw/sed |
| AMBA | 215 | 2-amino-4-(methylsulfonyl)benzoic acid  O=S(C)(=O)c1cc(N)c(cc1)C(=O)O | Soil: 9.7%  Water/Sediment: 24.6% | PECgw / PECsoil / PECsw/sed |
| SYN546974 | 291 | 9-hydroxy-6-(methylsulfonyl)-3,4-dihydroacridin- 1(2H)-one  CS(=O)(=O)c1cc2nc3CCCC(=O)c3c(O)c2cc1 | Soil: 1 x 10-10%  Water/sediment: 33% | PECsw/sed |

## Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

### Aerobic degradation in soil (KCP 9.1.1.1)

Table 8.3.1‑1: Summary of aerobic degradation rates for Mesotrione - laboratory studies

| Mesotrione, Laboratory studies, aerobic conditions | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Soil type | pH  water | t.oC | MWHC % | DT50 (d) | DT90 (d) | DT50 (d) 20°C  pF2/10kPa\* | Chi2 (%) | Kinetic model | Evaluated on EU level y/n Reference |
| Sandy loam (ERTC) | 6.4 | 20 | 19a | 11.6 | 38.5 | 8.2 | 18 | SFO | y/EFSA Journal 2016;14(3):4419 |
| Loam (Toulouse) | 7.7 | 20 | 25a | 4.3 | 14.3 | 4.0 | 16.4 |
| Clay loam (Pickett Piece) | 7.1 | 20 | 28a | 5.3 | 17.7 | 5.3 | 6.5 |
| Clay loam (721) | 5.6 | 25 | 28a | 20.2 | 67.1 | 32.3 | 4.1 |
| Silty clay loam (722) | 5.7 | 25 | 30a | 10.3 | 34.2 | 16.5 | 3.9 |
| Silt loam (723) | 5.4 | 25 | 26a | 17.6 | 58.5 | 28.2 | 3.4 |
| Loamy sand (724) | 4.8 | 25 | 14a | 23.8 | 78.9 | 31.1 | 4.3 |
| Loam (725) | 5.8 | 25 | 25a | 6.1 | 20.3 | 9.5 | 7.6 |
| Clay loam (727) | 5.1 | 25 | 28a | 20.8 | 69.2 | 32.4 | 6.4 |
| Sandy loam (728) | 5.9 | 25 | 25a | 7.2 | 24 | 9.7 | 5.6 |
| Silt loam (729) | 5.6 | 25 | 26b | 12.7 | 42.2 | 20.3 | 1.6 |
| Clay loam (730) | 5.3 | 25 | 28a | 17.1 | 56.9 | 26.9 | 8.9 |
| Silty Clay Loam (731) | 6.1 | 25 | 30a | 14.1 | 46.9 | 22.6 | 1.0 |
| Silty Clay Loam (732) | 5.0 | 25 | 30a | 14.0 | 46.4 | 22.4 | 5.3 |
| Silty Clay Loam (741) | 5.7 | 25 | 30a | 28.7 | 95.3 | 44.3 | 4.5 |
| Silty Clay Loam (742) | 7.2 | 25 | 34.4a | 9.7 | 32.1 | 15.5 | 5.5 |
| Silt Loam (Vispetto & Tovshteyn, 1997) | 6.2 | 25 | 32.04b | 13.2 | 44.0 | 14.68  Average DT50ref of 15.5 & 13.9  days given identical soil descriptions in these 2 studies). | 3.1 |
| Silt Loam (Subba-Rao, 1996) | 6.2 | 25 | 32.04b | 11.8 | 39.3 | 4.9 |
| Silt Loam (Miller, 1997) | 6.1 | 20 | 32.04b | 14.2 | 47.2 | 11.5 | 46 |
| Geometric mean/median | | | | | Not relevant as pH dependant | | | | |
| pH dependent | | | | | Yes, dergradation increases with increasing pH  DT50 y = -9.766 x pH + 77.692  r2 0.4687 (non log) | | | | |

\*) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

aFOCUS default; bmeasured pF2

Table 8.3.1‑2: Summary of aerobic degradation rates for MNBA - laboratory studies

| MNBA, Laboratory studies, aerobic conditions | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Soil type | pH  water | t.oC | MWHC % | DT50 (d) | DT90 (d) | DT50 (d) 20°C  pF2/10kPa\* | Chi2 (%) | Kinetic model | Evaluated on EU level y/n  Reference |
| silty clay loamb (722) | 5.7 | 25 | 30a | 0.6 | 1.89 | 1.0 | 10 | SFO | y/EFSA Journal 2016;14(3):4419 |
| Loam (725) | 5.8 | 25 | 25a | 0.5 | 1.5 | 0.8 | 10.8 |
| sandy loam (728) | 5.9 | 25 | 25a | 5.1 | 16.97 | 6.9 | 3.1 | Decline from peak |
| silt loam (729) | 5.6 | 25 | 26b | 1.66 | 5.52 | 2.7 | 3.88 | SFO |
| clay loam  (730) | 5.3 | 25 | 28a | 2.81 | 9.35 | 4.4 | 14.17 |
| silty clay loam (731) | 6.1 | 25 | 30a | 15.7 | 52.3 | 25.2 | 1.6 |
| sandy loam  (ERTC) | 6.4 | 20 | 19a | 6.2 | 20.7 | 4.4 | 21.89 | Decline from peak |
| loam  (Toulouse) | 7.7 | 20 | 25a | 5 | 16.65 | 4.6 | 13.08 |
| Silt loam  Richmond  (Subba-Rao, 1996) | 6.2 | 25 | 32.04b | 1.1 | 3.67 | 1.3 | 11.2 | SFO |
| Silt loam  Richmond  (Miller, 1997) | 6.1 | 20 | 32.04b | 6.3 | 21.03 | 5.1 | 20.13 | Decline from peak |
| Geometric mean (n=10) | | | | | | 3.4 | | | |
| pH-dependency | | | | | | No | | | |

\*) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

aFOCUS default; bmeasured pF2

Table 8.3.1‑3: Summary of aerobic degradation rates for AMBA - laboratory studies

| AMBA, Laboratory studies, aerobic conditions | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Soil type | pH water | t.oC | MWHC % | DT50 (d) | DT90 (d) | DT50 (d) 20°C  pF2/10kPa\* | Chi2 (%) | Kinetic model | Evaluated on EU level y/n  Reference |
| Wisborough | 4.9 | 20 | - | 7.8 | - | 3.7 | 5.52 | DFOP  DT90/3.32 | y/EFSA Journal 2016;14(3):4419 |
| Wisconsin | 6.4 | 20 | - | 33 | 109 | 23.5 | 7.98 | DFOP  K2 |
| East Anglia | 7.9 | 20 | - | 58.7 | 195 | 47.4 | 3.66 | DFOP  K2 |
| Spinks | 6.7 | 20 | - | 10.2 | 34 | 9.7 | 6.94 | FOMC |
| Richmond | 6.2 | 25 | - | 13.6 | 45.2 | 16.0 | 14.8 | SFO |
| Richmond | *6.1* | *20°* | *-* | *>1000* | *>1000* | *>1000\*\** | *26.6* | *SFO* |
| Geometric mean (n=5) | | | | | | 14.5 | | | |
| pH-dependency | | | | | | No | | | |

**\*) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7**

**\*\*Italics - outlier**

### Anaerobic degradation in soil (KCP 9.1.1.1)

Table 8.3.2‑1 Summary of aerobic degradation rates for AMBA - laboratory studies

| Mesotrione, Laboratory studies, dark anaerobic conditions | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Soil type | pH water | t.oC | MWHC % | DT50 (d) | DT90 (d) | DT50 (d) 20°C\* | St. (X2) | Method of calculation |
| Wisconsin silt loam cyclohexane-label | 6.2 | 25°C | - | 4 days | 14 days | - | r2=0.98 | First order (linear least squares fit of natural log of concentration vs. Sampling interval) |
| Wisconsin silt loam phenyl-label | 6.2 | 25°C | - | 4 days | 12 days | - | r2=0.97 |
| Geometric mean/Median | | | | | |

\*) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

## Field studies (KCP 9.1.1.2)

### Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

Table 8.4.1‑1: Summary of aerobic degradation rates for Mesotrione - field studies

| Mesotrione, Field studies – from original DAR | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Soil type | Location | pH | Depth (cm) | DissT50 (d)  actual | DT90 (d) actual | St.  (2) | Method of calculation | Evaluated on EU level y/n Reference |
| clay loam (bare soil) | France | 6.0 | 0-10 | 7 | 73 | - | sqrt 1st order -linear regression | y/EFSA Journal 2016;14(3):4419 |
| clay loam (bare soil) | Italy | 6.1 | 0-10 | 5 | 59 | - |
| sandy loam (bare soil) | Italy | 8.0 | 0-10 | 4 | 39 | - |
| sandy loam (bare soil) | Germany | 6.2 | 0-10 | 7 | 78 | - |
| loam (bare soil) | Germany | 5.8 | 0-10 | / | / | - |
| loam (bare soil) | Germany | 7.0 | 0-10 | 3 | 36 | - |
| sandy clay loam (bare soil) | Germany | 6.9 | 0-10 | 3 | 38 | - |
| Maximum (n=7) | | | | 7 | 78 | - | - | - |

### Soil accumulation testing (KCP 9.1.1.2.2)

According to the EU Review of Mesotrione, soil accumulation and plateau concentration are not triggered (same as initial PECsoil). Soil accumulation testing is therefore not relevant.

## Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Table 8.5‑1: Summary of soil adsorption/desorption for Mesotrione

| Mesotrione | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Soil type | OC  (%) | pH | Kf  (mL/g) | Kfoc  (mL/g) | 1/n  (-) | Evaluated on EU level y/n  Reference |
| Wisborough Green  silty clay loam | 2.63 | 5.1 | 4.46 | 171 | 0.902 | y/EFSA Journal 2016;14(3):4419 |
| Wisconsin  silt loam | 1.58 | 6.2 | 0.74 | 47 | 0.921 |
| Toulouse  clay | 1.79 | 6.5 | 1.25 | 70 | 0.915 |
| Garonne  loam | 1.03 | 7.8 | 0.15 | 14 | 0.971 |
| Visalia  sandy loam | 0.53 | 8.2 | 0.13 | 25 | 0.959 |
| Wisconsin  silt loam | 1.28 | 6.1 | 0.61 | 48 | 0.947 |
| ERTC  sandy loam | 0.58 | 6.4 | 0.33 | 57 | 0.950 |
| Pickett Piece  clay loam | 3.31 | 7.1 | 0.97 | 29 | 0.932 |
| Garonne  loam | 0.87 | 7.7 | 0.16 | 18 | 0.954 |
| Champaign (1:2 ratio)  silty clay loam | 3.0 | 4.4 | 6.16 | 354 | 0.94 |
| Geometric mean (n=10) | | | | 50.1 | - |  |
| Arithmetic mean (n=10) | | | | 83.3 | 0.94 | - |
| Worst case | | | | 14 | - | - |
| pH-dependency | | | | Yes, sorption decreases as pH increases. Kfoc  y= 8583.4e-0.785x (log) r2 0.8977 | | |

Table 8.5‑2: Summary of soil adsorption/desorption for MNBA

| MNBA | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Soil Type | OC  (%) | pH | Kf  (mL/g) | Kfoc  (mL/g) | 1/n  (-) | Evaluated on EU level y/n  Reference |
| Wisborough Green  silty clay loam | 2.63 | 5.1 | 0.16 | 6.1 | 0.32 | y/EFSA Journal 2016;14(3):4419 |
| Wisconsin  silt loam | 1.58 | 6.2 | 0.05 | 3.2 | 0.61 |
| Worst case | | | | 3.2 | 0.9b | - |
| pH-dependency | | | | No | | |

a) FOCUS default

Table 8.5‑3: Summary of soil adsorption/desorption for AMBA

| AMBA | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Soil Type | OC  (%) | pH  (-) | Kf  (mL/g) | Kfoc  (mL/g) | 1/n  (-) | Evaluated on EU level y/n  Reference |
| Wisborough Green  silty clay loam | 2.63 | 5.1 | 3.2 | 122 | 0.83 | y/EFSA Journal 2016;14(3):4419 |
| Wisconsin  silt loam | 1.58 | 6.2 | 0.71 | 44.9 | 0.85 |
| Toulouse  clay | 1.79 | 6.5 | 0.91 | 51.0 | 0.85 |
| Garonne  loam | 1.03 | 7.8 | 0.18 | 18.1 | 0.82 |
| Visalia  sandy loam | 0.53 | 8.2 | 0.12 | 23.9 | 0.90 |
| Arithmetic mean (if not pH dependent) | | | | pH dependent (51.9) | 0.85 | - |
| Worst case | | | | 18.1 | - | - |
| pH-dependency | | | | Yes, sorption decreases as pH increases.  Kfoc  y = 1865e-0.563x(log) r2 0.9062 | | |

Table 8.5‑4: Summary of soil adsorption/desorption for SYN546974

| SYN546974 | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Soil Type | OC  (%) | pH | Kf  (mL/g) | Kfoc  (mL/g) | 1/n  (-) | Evaluated on EU level y/n  Reference |
| Gartenacker  Loam | 1.8 | 7.2 | 30.63 | 1702 | 0.82 | y/EFSA Journal 2016;14(3):4419 |
| 18 Acres  Sandy Clay Loam | 2.2 | 5.7 | 220.07 | 10003 | 0.96 |
| Marysville  Clay Loam | 1.6 | 7.6 | 432.49 | 27031 | 0.96 |
| Sarpy  Silt loam | 1.7 | 6.5 | 376.10 | 22124 | 0.88 |
| Seven Springs  Loamy sand | 0.6 | 5.2 | 19.56 | 3260 | 0.84 |
| Geometric mean (n=5) | | | | 8021 | - | - |
| Artihmetic mean (n=5) | | | | - | 0.89 |  |
| pH-dependency | | | | No | | |

### Column leaching (KCP 9.1.2.1)

No data was provided during the EU Review of Mesotrione as considered as not required.

### Lysimeter studies (KCP 9.1.2.2)

No data was provided during the EU Review of Mesotrione as considered as not required.

### Field leaching studies (KCP 9.1.2.3)

No data was provided during the EU Review of Mesotrione as considered as not required.

## Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Table 8.6‑1: Summary of degradation in water/sediment of Mesotrione

| Mesotrione Distribution (max. water 98.7% after 0d, max. sediment 4.3% after 1 day) | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Water/sediment system | pH  water | pH sed | DegT50  whole syst.  (d) | Kinetic, Fit | DissT50 water  (d) | Kinetic, Fit | Method of calculation | Evaluated on EU level y/n  Reference |
| Basing (Phenyl) | 7.86 | 7.86 | 2.6 | 6.8 | 2.5 | 6.8 | SFO | y/EFSA Journal 2016;14(3):4419 |
| Basing (Cyclohexane) | 7.86 | 7.86 | 4.2 | 13.3 | 4.2 | 13.3 |
| Virginia (Phenyl) | 7.4 | 7.4 | 5.5 | 12.3 | 5.3 | 13.5 |
| Virginia  (Cyclohexane) | 7.4 | 7.4 | 7.2 | 14.4 | 7.0 | 13.4 |
| Calwich (Phenyl) | 8.4/7.8 (aerobic/anaerobic) | 7.6 | 6.6 | 4.5 | 6.7 | 3.4 |
| Swiss (Phenyl) | 7.4/7.5 (aerobic/anaerobic) | 6.1 | 11.1 | 3.5 | 11.0 | 3.3 |
| Geometric mean at 20°Cb (n=6) | | - | 5.6 | - | 5.5 | - | - | - |

a) Normalized using a Q10 of 2.58

Table 8.6‑2: Summary of observed metabolites

|  |  |  |
| --- | --- | --- |
| MNBA  Water/sediment system | Max. in water/sediment 7.4 % after 3 d  Max. in water 7.4 % after 3 d  Max. in sediment <1 % | y/EFSA Journal 2016;14(3):4419 |
| AMBA  Water/sediment system | Max. in water/sediment 24.6 % after 46 d  Max. in water 15.8 % after 46 d  Max. in sediment 8.8 % after 46 d |
| SYN546974  Water/sediment system | Max. in water/sediment 33 % after 29 d  Max. in water 9.4 % after 29 d  Max. in sediment 25.6 % after 102 d |

## Predicted Environmental Concentrations in soil (PECsoil) (KCP 9.1.3)

### Justification for new endpoints

There are no deviations from the EU agreed endpoints.

### Actives substance(s) and relevant metabolite(s)

Table 8.7‑1: Input parameters related to application for PECsoil calculations

|  |  |
| --- | --- |
| Use No. | 1 |
| Crop | Maize |
| Application rate (g as/ha) | Mesotrione: 100 |
| Number of applications/interval | 1/- |
| Crop interception (%) | 25 |
| Depth of soil layer (cm) | 5 cm (worst case) |

\* already authorized

Table 8.7‑2: Input parameter for Mesotrione and relevant metabolites for PECsoil calculation

| Compound | Molecular weight (g/mol) | Max. occurrence (%) | DT50  (days) | Value in accordance to EU endpoint y/n  Reference |
| --- | --- | --- | --- | --- |
| Mesotrione | 339 | - | 34.3 d (the longest of laboratory studies, not normalized) | y/EFSA Journal 2016;14(3):4419 |
| MNBA | 245 | 57.2 | 15.7(the longest of laboratory studies, not normalized) |
| AMBA | 215 | 9.7 | 58.7(the longest of laboratory studies, not normalized) |

PECsoil values for metabolites were calculated taking into account the molecular weight (MW) and the maximum amount of each metabolite formed aerobically in soil (%). The results of PECsoil calculations are presented below.

#### Mesotrione and its metabolites

Table 8.7‑3: PECsoil for Mesotrione on maize

| PECsoil  (mg/kg) | | Maize | |
| --- | --- | --- | --- |
| Single application | |
| Actual | TWA |
| Initial | | 0.100 | - |
| Short term | 24h | 0.098 | 0.099 |
| 2d | 0.096 | 0.098 |
| 4d | 0.092 | 0.096 |
| Long term | 7d | 0.087 | 0.093 |
| 14d | 0.075 | 0.087 |
| 21d | 0.065 | 0.081 |
| 28d | 0.057 | 0.076 |
| 50d | 0.036 | 0.063 |
| 100d | 0.013 | 0.043 |
| Plateau concentration (20 cm)  after year | | - | - |
| PECaccumulation  (PECact +PECsoil plateau) | | - | - |

PECsoil of metabolites

PECsoil values for the metabolites were determined as for the parent with an application rate corrected taking into account the molecular weights (MW) and the maximum occurrence of the metabolite in soil as following:

Application ratemetabolite = (MWmetabolite/ MWparent) x (% maximum occurrence/100) x application rateparent

The corresponding application rates for each metabolite are summarized in the table below.

Table 8.7‑4: Corrected application rates for the metabolites

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Parent** | **Metabolite** | **Application rate of the parent**  **(g/ha)** | **MWparent** | **MWmetabolite** | **Maximum occurrence in soil**  **(%)** | **Corrected application rate**  **(g/ha)** |
| Mesotrione | MNBA | 100 | 339 | 245 | 57.2 | 41.34 |
| AMBA | 215 | 9.7 | 6.15 |

Table 8.7‑4: PECsoil for MNBA on maize

|  |  |  |  |
| --- | --- | --- | --- |
| PECsoil  (mg/kg) | | Maize | |
| Single application | |
| Actual | TWA |
| Initial | | 0.041 |  |
| Short term | 24h | 0.040 | 0.040 |
| 2d | 0.038 | 0.040 |
| 4d | 0.035 | 0.038 |
| Long term | 7d | 0.030 | 0.036 |
| 14d | 0.022 | 0.031 |
| 21d | 0.016 | 0.027 |
| 28d | 0.012 | 0.024 |
| 50d | 0.005 | 0.017 |
| 100d | 0.001 | 0.009 |
| Plateau concentration (20 cm)  after year | | - | - |
| PECaccumulation  (PECact +PECsoil plateau) | | - | - |

Table 8.7‑5: PECsoil for AMBA on maize

|  |  |  |  |
| --- | --- | --- | --- |
| PECsoil  (mg/kg) | | Maize | |
| Single application | |
| Actual | TWA |
| Initial | | 0.006 | - |
| Short term | 24h | 0.006 | 0.006 |
| 2d | 0.006 | 0.006 |
| 4d | 0.006 | 0.006 |
| Long term | 7d | 0.006 | 0.006 |
| 14d | 0.005 | 0.006 |
| 21d | 0.005 | 0.005 |
| 28d | 0.004 | 0.005 |
| 50d | 0.003 | 0.005 |
| 100d | 0.002 | 0.004 |
| Plateau concentration (20 cm)  after year | | - | - |
| PECaccumulation  (PECact +PECsoil plateau) | | - | - |

#### PECsoil of FLENID

Table 8.7‑6: PECsoil for FLENID on maize

| Preparation | Application rate (g/ha) | PECact (mg/kg) | Tillage depth (cm) |
| --- | --- | --- | --- |
| FLENID | 1050.2 | 1.050 | 5 |

\*FLENID is applied as 1.0 L/ha, and specific density of FLENID is 1.0502 g/ml (please refer to the Part C).

## zRMS comments:

PECsoil calculations (use 1) has been accepted for the active substance mesotrione and its metabolites MNBA and AMBA.

The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific EFSA Journal 2016;14 (3):4419. Interception is appropriate to the proposed BBCH of crops (guidance 2014). It is noted that for mesotrione the maximum non-normalised laboratory DT50 of 34.3 days was recommended for calculation of the soil exposure in EFSA report.

The acceptable predicted environmental concentrations of mesotrione and its metabolites in soil are appropriate to be used for the subsequent risk assessment

Mesotrione: PECs = 0.100 mg/kg

MNBA: PECs = 0.041 mg/kg

AMBA: PECs = 0.006 mg/kg

Flenid: PECs = 1.050 mg/kg

## Predicted Environmental Concentrations in groundwater (P

## ECgw) (KCP 9.2.4)

### Justification for new endpoints

Same endpoints as the EU agreed endpoints (EFSA Journal 2016;14(3):4419) were used.

### Active substance(s) and relevant metabolites (KCP 9.2.4.1)

Table 8.9‑1: Input parameters related to application for PECgw calculations

|  |  |
| --- | --- |
| Use No. | 1 |
| Crop | Maize |
| Application rate (g as/ha) | Mesotrione: 100 |
| Number of applications/interval (d) | 1/- |
| Relative application date | - |
| Crop interception (%) | 25 |
| Frequency of application | annual |
| Models used for calculation | FOCUS PEARL v5.5.5 / FOCUS PELMO 6.6.4 / FOCUS MACRO v5.5.4\* |

**\* MACRO can only handle one parent compound and one metabolite in a single simulation. Hence, additional simulations are required. The degradation pathway includes a chain of degradation where a metabolite is formed from another metabolite, the PECgw for the metabolite of concern is simulated by using its precursor metabolite as “parent”. In this cases, the applied dose in MACRO was adjusted to represent the occurrence of the precursor metabolite in soil according to following: Applied dose= Dose parent x (1-i) x ff met x (Mwmet / Mw par).**

Due to the pH dependency of Mesotrione, PEC calculations were performed with different pH to cover the whole potential cases. Calculations were performed using DT50 and Kfoc values at pH 5.1, 6.5 and 7.9 and for worst case also.

Table 8.8‑2: Input parameters related to active substance Mesotrione and metabolites for PECgw calculations

| Compound | Mesotrione | MNBA | AMBA | Value in accordance with EU endpoint y/n/  Reference |
| --- | --- | --- | --- | --- |
| Molecular weight (g/mol) | 339 | 245 | 215 | y/EFSA Journal 2016;14(3):4419 |
| Water solubility (mg/mol): | 160 at 20°C | 32400\*  (20) | 23000\*  (20) |
| Saturated vapour pressure (Pa): | 0 at 20°C | 0 at 20°C | 0 at 20°C |
| DT50 in soil (d) | 4 (Worst case)  27.88 (linear fit, pH 5.1 value)  14.2 (linear fit, pH 6.5 value)  5.4 (linear fit, pH 7.9 value)  (normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58) | 3.4 (geomean of normailized at 20ºC and pF2, Q10 2.58, lab studies, n=10) | 14.5 (geomean of normailized at 20ºC and pF2, Q10 2.58, lab studies, n=5) |
| Kfoc (mL/g)/Kfom | 14 / 8.12 (Worst case)  156.7 / 90.9 (log fit, pH 5.1 value)  52.2 / 30.3 (log fit, pH 6.5 value)  17.4 / 10.1 (log fit, pH 7.9 value) | 3.2 / 1.86 (worst case) | 18.1 / 10.5 (Worst case)  105.61 / 61.3 (log fit, pH 5.1)  48.02 / 27.9 (log fit, pH 6.5)  21.8 / 12.7 (log fit, pH 7.9) |
| 1/n | 0.97 (corresponding to lowest Kfoc)  0.94 | 0.9 (default) | 0.82 (corresponding to lowest Kfoc)  0.85 |
| Plant uptake factor | 0 | 0 | 0 |
| Formation fraction | - | 1.0 from Parent | 0.25 from MNBA |

\* Renewal Assessment Report (RAR) for mesotrione, Volume 3 – B.8 (AS), RMS UK, 2015

Table 8.8‑3: Application dates used for groundwater risk assessment

| Crop | Scenario | Application dates (absolute)\* |
| --- | --- | --- |
| Maize (BBCH 14) | Châteaudun | 16/05 |
| Hamburg | 17/05 |
| Kremsmünster | 17/05 |
| Okehampton | 02/06 |
| Piacenza | 26/05 |
| Porto | 16/05 |
| Sevilla | 21/03 |
| Thiva | 28/04 |

**\*According to AppDate v 3.06 (28/06/2019)**

Table 8.8‑4: PECGW for mesotrione and metabolites on maize BBCH 00 (with FOCUS PEARL ~~6.6.4~~ 5.5.5)

| Crop | Scenario | 80th Percentile PECGW at 1 m Soil Depth (μg/L) | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Mesotrione | | | | MNBA | | | | AMBA | | | |
| lowest DT50 and Koc | pH 5.1 | pH 7.9 | pH 6.5 | lowest DT50 and Koc | pH 5.1 | pH 7.9 | pH 6.5 | lowest DT50 and Koc | pH 5.1 | pH 7.9 | pH 6.5 |
| Maize  100 g as/ha | Châteaudun | <0.001 | <0.001 | <0.001 | 0.003 | <0.001 | 0.005 | <0.001 | 0.005 | 0.002 | <0.001 | 0.004 | 0.001 |
| Hamburg | 0.001 | 0.004 | 0.002 | 0.016 | 0.005 | 0.066 | 0.008 | 0.045 | 0.024 | 0.016 | 0.032 | 0.020 |
| Kremsmünster | <0.001 | 0.002 | 0.001 | 0.011 | 0.002 | 0.012 | 0.002 | 0.012 | 0.021 | 0.002 | 0.023 | 0.008 |
| Okehampton | 0.002 | 0.005 | 0.004 | 0.026 | 0.006 | 0.031 | 0.009 | 0.032 | 0.052 | 0.005 | 0.059 | 0.013 |
| Piacenza | <0.001 | 0.003 | <0.001 | 0.006 | <0.001 | 0.010 | <0.001 | 0.004 | 0.004 | 0.002 | 0.005 | 0.003 |
| Porto | <0.001 | 0.001 | <0.001 | 0.001 | <0.001 | 0.010 | <0.001 | 0.002 | <0.001 | <0.001 | <0.001 | <0.001 |
| Sevilla | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | 0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
| Thiva | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | 0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

Table 8.8‑5: PECGW for mesotrione and metabolites on maize BBCH 00 (with FOCUS PELMO 6.6.4)

| Crop | Scenario | 80th Percentile PECGW at 1 m Soil Depth (μg/L) | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Mesotrione | | | | MNBA | | | | AMBA | | | |
| lowest DT50 and Koc | pH 5.1 | pH 7.9 | pH 6.5 | lowest DT50 and Koc | pH 5.1 | pH 7.9 | pH 6.5 | lowest DT50 and Koc | pH 5.1 | pH 7.9 | pH 6.5 |
| Maize  100 g as/ha | Châteaudun | <0.001 | <0.001 | <0.001 | 0.002 | <0.001 | 0.004 | <0.001 | 0.004 | 0.001 | <0.001 | 0.002 | 0.001 |
| Hamburg | <0.001 | 0.004 | 0.001 | 0.012 | 0.001 | 0.082 | 0.002 | 0.035 | 0.007 | 0.010 | 0.012 | 0.010 |
| Kremsmünster | 0.001 | 0.002 | 0.001 | 0.010 | 0.002 | 0.020 | 0.002 | 0.016 | 0.018 | 0.002 | 0.020 | 0.007 |
| Okehampton | 0.003 | 0.004 | 0.006 | 0.029 | 0.008 | 0.049 | 0.011 | 0.038 | 0.048 | 0.004 | 0.053 | 0.012 |
| Piacenza | <0.001 | 0.005 | <0.001 | 0.008 | <0.001 | 0.018 | 0.001 | 0.008 | 0.005 | 0.003 | 0.007 | 0.005 |
| Porto | <0.001 | 0.001 | <0.001 | 0.002 | <0.001 | 0.020 | <0.001 | 0.003 | <0.001 | <0.001 | 0.001 | <0.001 |
| Sevilla | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | 0.002 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |
| Thiva | <0.001 | <0.001 | <0.001 | 0.001 | <0.001 | 0.003 | <0.001 | 0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

Table 8.8‑6: PECGW for mesotrione and metabolites on maize BBCH 00 (with FOCUS MACRO v 5.5.4)

| Crop | Scenario | 80th Percentile PECGW at 1 m Soil Depth (μg/L) | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Mesotrione | | | | MNBA | | | | AMBA | | | |
| lowest DT50 and Koc | pH 5.1 | pH 7.9 | pH 6.5 | lowest DT50 and Koc | pH 5.1 | pH 7.9 | pH 6.5 | lowest DT50 and Koc | pH 5.1 | pH 7.9 | pH 6.5 |
| Maize  100 g as/ha | Châteaudun | <0.001 | <0.001 | <0.001 | 0.001 | <0.001 | 0.004 | <0.001 | 0.003 | <0.001 | <0.001 | <0.001 | <0.001 |

**zRMS comments**

The modelling results PECgw are acceptable to describe predicted environmental concentrations of mesotrione and its metabolites in groundwater. All input parameters considered in the groundwater modelling for mesotrione and its metabolites were EU agreed values (EFSA Scientific Report (2007) 120, 1-91). In simulations PUF value of 0 was assumed for all compounds is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance.

PECgw for mesotrione and its metabolites AMBA and MNBA are below 0.1 µg/L for all modelled scenarios and for application rate 100 g/ha

No unacceptable risk of groundwater contamination is expected for the formulated product according to the intended uses.

Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using FOCUS models.

## Predicted Environmental Concentrations in surface water (PECsw) (KCP 9.2.5)

**zRMS comments**

The PECsw calculations for mesotrone have been approved for applications proposed in GAP. PECsw and PECsed calculations were carried out according to the FOCUS recommendations. The Applicant has been used FOCUS models: STEPS1-2 and Step 3. PECsw/sed were also carried out at Step 4 according to FOCUS L&M Guidance for 10m and 20m buffer zone and VFSMOD program and simulation, according to the Austrian Environmental Agency AGES were carried out for 5m and 15m buffer zone.

The Applicant used the geometric mean value. In opinion of the zRMS this is acceptable, as being in line with current requirements concerning selection of Kfoc to be used for modelling purposes.

PECsw/sed are acceptable to describe predicted environmental concentrations of mesotrione and its metabolites in surface water and sediment and are appropriate to be used for the subsequent risk assessment for aquatic and sediment organisms.

MS should identify risk reduction measures at the national level.

### for new endpoints

All EU agreed endpoints have been maintained (EFSA Journal 2016;14(3):4419).

### Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

Table 8.9‑1: Input parameters related to application for PECSW/SED calculations

|  |  |
| --- | --- |
| Plant protection product | FLENID |
| Use No. | 1 |
| Crop | Maize |
| Application rate (kg as/ha) | Mesotrione: 0.100 |
| Number of applications/interval (d) | 1/- |
| Application window | March-May, minimal crop cover (relevant for STEP 1 and 2 only) |
| Application method | Ground spray |
| CAM (Chemical application method) | CAM 2 |
| Soil depth (cm) | 4 |
| Models used for calculation | FOCUS STEP 1&2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1,  FOCUS MACRO v5.5.4, FOCUS TOXWA v4.4.3 |

Table 8.9‑2: FOCUS Step 3 Scenario related input parameters for PECsw/sed calculations for the application of FLENID

| Crop | Scenario | Application window used in modelling\* |
| --- | --- | --- |
| Maize | D3 | 12/05 |
| D4 | 18/05 |
| D5 | 15/05 |
| D6 | 25/04 |
| R1 | 10/05 |
| R2 | 09/05 |
| R3 | 08/05 |
| R4 | 15/04 |

**\*According to AppDate v3.06 (June 2019)**

#### Mesotrione and its metabolites

Table 8.9‑3: Input parameters related to active substance Mesotrione and metabolites for PECsw/sed calculations STEP 1/2 and 3/4

| Compound | Mesotrione | MNBA | AMBA | SYN546974 | Value in accordance to EU endpoint y/n  Reference |
| --- | --- | --- | --- | --- | --- |
| Molecular weight (g/mol) | 339 | 245 | 215 | 291 | y/EFSA Journal 2016;14(3):4419  \* Renewal Assessment Report (RAR) for mesotrione, Volume 3 – B.8 (AS), RMS UK, 2015  \*\*parent value |
| Saturated vapour pressure (Pa) | 1x10-10 (20°C) | 1x10-10 (20°C) | 1x10-10 (20°C) | 1x10-10 (20°C) |
| Water solubility (mg/L) | 160 (pH 7, 20°C) | 32400\*  (20) | 23000\*  (20) | 160\*\*  (---) |
| Diffusion coefficient in water (m²/d) | 4.3 x 10-5 | - | - | - | Default |
| Diffusion coefficient in air (m²/d) | 0.43 | - | - | - | Default |
| Kfoc (mL/g) | 156.7 (Log fit, pH5.1 value)  52.2 (Log fit, pH 6.5 value)  17.4 (Log fit, pH7.9 value) | 3.2 (worst case) | 105.6 (Log fit, pH5.1 value)  48.0 (Log fit, pH 6.5 value)  21.8 (Log fit, pH 7.9 value) | 8021 (geomean, n=5) | y/EFSA Journal 2016;14(3):4419 |
| Freundlich Exponent  1/n | 0.94 | - | - | - | y/EFSA Journal 2016;14(3):4419 |
| Plant Uptake | 0 | - | - | - |
| Wash-Off factor from Crop (1/mm) | 0.05 (MACRO)  0.50 (PRZM) | - | - | - | Default |
| DT50,soil (d) | 27.88 (Linear fit, pH 5.1 value)  14.2 (Linear fit, pH 6.5 value)  5.4 (Linear fit, pH 7.9 value)  (normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58) | 3.6 (geomean of normailized at 20ºC and pF2, Q10 2.58, lab studies, n=10) | 14.5 (geomean of normailized at 20ºC and pF2, Q10 2.58, lab studies, n=5) | 0.1 (not observed in soil, default values used for Step 1/2) | y/EFSA Journal 2016;14(3):4419 |
| DT50,water (d) | 5.5 (Step 1+2) | 1000 | 1000 | 1000 |
| DT50,sed (d) | 5.6 (Step 1+2)  1000 (Step 3+4) | 1000 | 1000 | 1000 |
| DT50,whole system (d) | 5.6 | 1000 | 1000 | 1000 |
| Maximum occurrence observed (% molar basis with respect to the parent) | Sediment: 4.3 | Soil: 57.2  Water: 7.9 Sediment: 7.9  Total system: 7.9 | Soil: 9.7  Water: 24.6  Sediment: 24.6  Total system: 24.6 | Soil: 1x10-10 (not observed in soil, default values used)  Water: 33  Sediment: 33  Total system: 33 |

PECsw/sed

Table 8.9‑4: FOCUS Step 1, 2 and 3 PECSW and PECSED for mesotrione following single application of FLENID - parameter set for acidic soils (pH 5.1)

| Scenario FOCUS | Waterbody | Max PECSW (μg/L) | Dominant entry route | 21 d-PECSW,twa (µg/L) | Max PECSED (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| **Maize, 1 x 100 g as/ha, BBCH 12 - pH 5.1** | | | | | |
| Step 1 | --- | 28.49 | - | 10.10 | 43.21 |
| Step 2 | | | | | |
| Northern Europe | Mar – May | 4.23 | - | 1.48 | 6.38 |
| Southern Europe | Mar – May | 7.98 | - | 2.80 | 12.25 |
| Step 3 | | | | | |
| D3 | ditch | 0.525 | Spray drift | 0.028 | 0.139 |
| D4 | pond | 0.057 | Drainage | 0.053 | 0.109 |
| D4 | stream | 0.452 | Spray drift | 0.046 | 0.090 |
| D5 | pond | 0.038 | Spray drift | 0.031 | 0.072 |
| D5 | stream | 0.478 | Spray drift | 0.018 | 0.074 |
| D6 | ditch | 0.528 | Spray drift | 0.028 | 0.146 |
| R1 | pond | 0.077 | Runoff | 0.049 | 0.085 |
| R1 | stream | **1.621** | Runoff | 0.068 | 0.377 |
| R2 | stream | **1.223** | Runoff | 0.039 | 0.333 |
| R3 | stream | **3.125** | Runoff | 0.125 | 0.684 |
| R4 | stream | **3.385** | Runoff | 0.160 | 0.942 |

Table 8.9‑5: FOCUS Step 1, 2 and 3 PECSW and PECSED for mesotrione following single application of FLENID - parameter set for neutral soils (pH 6.5)

| Scenario FOCUS | Waterbody | Max PECSW (μg/L) | Dominant entry route | 21 d-PECSW,twa (µg/L) | Max PECSED (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| **Maize, 1 x 100 g as/ha, BBCH 12 - pH 6.5** | | | | | |
| Step 1 | --- | 32.08 | - | 11.41 | 16.27 |
| Step 2 | | | | | |
| Northern Europe | Mar – May | 4.38 | - | 1.54 | 2.19 |
| Southern Europe | Mar – May | 8.22 | - | 2.89 | 4.20 |
| Step 3 | | | | | |
| D3 | ditch | 0.525 | Spray drift | 0.029 | 0.086 |
| D4 | pond | 0.022 | Drainage | 0.011 | 0.015 |
| D4 | stream | 0.451 | Spray drift | 0.008 | 0.026 |
| D5 | pond | 0.022 | Spray drift | 0.011 | 0.018 |
| D5 | stream | 0.473 | Spray drift | 0.011 | 0.032 |
| D6 | ditch | 0.526 | Spray drift | 0.026 | 0.085 |
| R1 | pond | 0.050 | Runoff | 0.028 | 0.031 |
| R1 | stream | **1.112** | Runoff | 0.042 | 0.149 |
| R2 | stream | **2.296** | Runoff | 0.070 | 0.371 |
| R3 | stream | **3.943** | Runoff | 0.140 | 0.535 |
| R4 | stream | **3.916** | Runoff | 0.159 | 0.667 |

Table 8.9‑6: FOCUS Step 1, 2 and 3 PECSW and PECSED for mesotrione following single application of FLENID - parameter set for alcalic soils (pH 7.9)

| Scenario FOCUS | Waterbody | Max PECSW (μg/L) | Dominant entry route | 21 d-PECSW,twa (µg/L) | Max PECSED (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| **Maize, 1 x 100 g as/ha, BBCH 12 - pH 7.9** | | | | | |
| Step 1 | --- | 33.50 | - | 11.92 | 5.67 |
| Step 2 | | | | | |
| Northern Europe | Mar – May | 3.47 | - | 1.22 | 0.57 |
| Southern Europe | Mar – May | 6.40 | - | 2.25 | 1.08 |
| Step 3 | | | | | |
| D3 | ditch | 0.525 | Spray drift | 0.028 | 0.056 |
| D4 | pond | 0.021 | Drainage | 0.011 | 0.007 |
| D4 | stream | 0.449 | Spray drift | 0.002 | 0.015 |
| D5 | pond | 0.021 | Spray drift | 0.010 | 0.006 |
| D5 | stream | 0.469 | Spray drift | 0.001 | 0.012 |
| D6 | ditch | 0.524 | Spray drift | 0.024 | 0.053 |
| R1 | pond | 0.026 | Runoff | 0.018 | 0.012 |
| R1 | stream | **1.052** | Runoff | 0.025 | 0.071 |
| R2 | stream | **2.730** | Runoff | 0.082 | 0.287 |
| R3 | stream | **3.296** | Runoff | 0.110 | 0.299 |
| R4 | stream | **3.390** | Runoff | 0.132 | 0.385 |

FOCUS Step 4

Table 8.9‑7: Global maximum PECSW values for mesotrione, following single application of FLENID according to surface water Step 4 – parameter set for acidic soils (pH 5.1)

| PECsw (µg/L) | Scenario | STEP 4 Mesotrione | | | |
| --- | --- | --- | --- | --- | --- |
| Nozzle  reduction | Vegetative strip (m) | 5 | 10 | 15 | 20 |
| No spray buffer (m) | 5 | 10 | 15 | 20 |
| None | R1 stream | **1.054** | 0.734 | **-** | **-** |
| 50 % | **1.054** | - | **-** | **-** |
| None | R2 stream | **0.783** | 0.539 | **-** | **-** |
| 50 % | **0.783** | **-** | **-** | **-** |
| None | R3 stream | **2.025** | **1.410** | **1.081** | 0.738 |
| 50 % | **2.025** | **1.410** | **1.081** | - |
| None | R4 stream | **2.208** | **1.538** | **1.181** | **0.806** |
| 50 % | **2.208** | **1.538** | **1.181** | **0.806** |

Table 8.9‑8: Global maximum PECSW values for mesotrione, following single application of FLENID according to surface water Step 4 VFSMOD– parameter set for acidic soils (pH 5.1)

| PECsw (µg/L) | Scenario | STEP 4 Mesotrione VFSMOD |
| --- | --- | --- |
| Nozzle  reduction | Vegetative strip (m) | 10 |
| No spray buffer (m) | 10 |
| None | R4 stream | 0.081  -  - |

Table 8.9‑9: Global maximum PECSW values for mesotrione, following single application of FLENID according to surface water Step 4 – parameter set for neutral soils (pH 6.5)

| PECsw (µg/L) | Scenario | STEP 4 Mesotrione | | | |
| --- | --- | --- | --- | --- | --- |
| Nozzle  reduction | Vegetative strip (m) | 5 | 10 | 15 | 20 |
| No spray buffer (m) | 5 | 10 | 15 | 20 |
| None | R1 stream | 0.679 | - | - | - |
| 50 % | - | - | - | - |
| None | R2 stream | **1.470** | **1.013** | **0.773** | 0.525 |
| 50 % | **1.470** | **1.013** | **0.773** | - |
| None | R3 stream | **2.557** | **1.780** | **1.365** | **0.931** |
| 50 % | **2.557** | **1.780** | **1.365** | **0.931** |
| None | R4 stream | **2.555** | **1.780** | **1.366** | **0.933** |
| 50 % | **2.555** | **1.780** | **1.366** | **0.933** |

Table 8.9‑10: Global maximum PECSW values for mesotrione, following single application of FLENID according to surface water Step 4 VFSMOD– parameter set for neutral soils (pH 6.5)

| PECsw (µg/L) | Scenario | STEP 4 Mesotrione VFSMOD |
| --- | --- | --- |
| Nozzle  reduction | Vegetative strip (m) | 10 |
| No spray buffer (m) | 10 |
| None | R3 stream | 0.114 |
| None | R4 stream | 0.081  - |

Table 8.9‑11: Global maximum PECSW values for mesotrione, following single application of FLENID according to surface water Step 4 – parameter set for alkaline soils (pH 7.9)

| PECsw (µg/L) | Scenario | STEP 4 Mesotrione | | | |
| --- | --- | --- | --- | --- | --- |
| Nozzle  reduction | Vegetative strip (m) | 5 | 10 | 15 | 20 |
| No spray buffer (m) | 5 | 10 | 15 | 20 |
| None | R1 stream | 0.642 | **-** | **-** | **-** |
| 50 % | **-** | **-** | **-** | **-** |
| None | R2 stream | **1.747** | **1.205** | **0.920** | 0.624 |
| 50 % | **1.747** | **1.205** | **0.920** | - |
| None | R3 stream | **2.137** | **1.488** | **1.141** | **0.779** |
| 50 % | **2.137** | **1.488** | **1.141** | **0.779** |
| None | R4 stream | **2.211** | **1.541** | **1.183** | **0.808** |
| 50 % | **2.211** | **1.541** | **1.183** | **0.808** |

Table 8.9‑10: Global maximum PECSW values for mesotrione, following single application of FLENID according to surface water Step 4 VFSMOD– parameter set for alkaline soils (pH 7.9)

| PECsw (µg/L) | Scenario | STEP 4 Mesotrione VFSMOD |
| --- | --- | --- |
| Nozzle  reduction | Vegetative strip (m) | 10 |
| No spray buffer (m) | 10 |
| None | R3 stream | 0.114 |
| None | R4 stream | 0.081  - |

Metabolites of Mesotrione

Table 8.9‑12: FOCUS Step 1, 2 PECSW and PECSED for MNBA following single application - parameter set for acidic soils (pH 5.1)

| Scenario FOCUS | Waterbody | Max PECSW (μg/L) | Dominant entry route | 21 d- PECSW,twa  (µg/L) | Max PECSED (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| **Maize, 1 x 100 g as/ha, BBCH 12 - pH 5.1** | | | | | |
| Step 1 | --- | 15.67 | - | 15.56 | 0.50 |
| Step 2 | | | | | |
| Northern Europe | Mar – May | 1.26 | - | 1.25 | 0.04 |
| Southern Europe | Mar – May | 2.47 | - | 2.45 | 0.08 |

Table 8.9‑13: FOCUS Step 1, 2 PECSW and PECSED for MNBA following single application - parameter set for neutral soils (pH 6.5)

| Scenario FOCUS | Waterbody | Max PECSW (μg/L) | Dominant entry route | 21 d- PECSW,twa  (µg/L) | Max PECSED (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| **Maize, 1 x 100 g as/ha, BBCH 12 - pH 6.5** | | | | | |
| Step 1 | --- | 15.67 | - | 15.56 | 0.50 |
| Step 2 | | | | | |
| Northern Europe | Mar – May | 1.24 | - | 1.23 | 0.04 |
| Southern Europe | Mar – May | 4.43 | - | 4.41 | 0.08 |

Table 8.9‑14: FOCUS Step 1, 2 PECSW and PECSED for MNBA following single application - parameter set for alkaline soils (pH 7.9)

| Scenario FOCUS | Waterbody | Max PECSW (μg/L) | Dominant entry route | 21 d- PECSW,twa  (µg/L) | Max PECSED (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| **Maize, 1 x 100 g as/ha, BBCH 12 - pH 7.9** | | | | | |
| Step 1 | --- | 15.67 | - | 15.56 | 0.50 |
| Step 2 | | | | | |
| Northern Europe | Mar – May | 1.18 | - | 1.17 | 0.04 |
| Southern Europe | Mar – May | 2.30 | - | 2.28 | 0.07 |

Table 8.9‑15: FOCUS Step 1, 2 PECSW and PECSED for AMBA following single application - parameter set for acidic soils (pH 5.1)

| Scenario FOCUS | Waterbody | Max PECSW (μg/L) | Dominant entry route | 21 d- PECSW,twa  (µg/L) | Max PECSED (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| **Maize, 1 x 100 g as/ha, BBCH 12 - pH 5.1** | | | | | |
| Step 1 | --- | 6.50 | - | 6.44 | 6.84 |
| Step 2 | | | | | |
| Northern Europe | Mar – May | 0.97 | - | 0.96 | 1.02 |
| Southern Europe | Mar – May | 1.81 | - | 1.80 | 1.91 |

Table 8.9‑16: FOCUS Step 1, 2 PECSW and PECSED for AMBA following single application - parameter set for neutral soils (pH 6.5)

| Scenario FOCUS | Waterbody | Max PECSW (μg/L) | Dominant entry route | 21 d- PECSW,twa  (µg/L) | Max PECSED (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| **Maize, 1 x 100 g as/ha, BBCH 12 - pH 6.5** | | | | | |
| Step 1 | --- | 6.96 | - | 6.90 | 3.33 |
| Step 2 | | | | | |
| Northern Europe | Mar – May | 0.98 | - | 0.97 | 0.47 |
| Southern Europe | Mar – May | 1.82 | - | 1.81 | 0.87 |

Table 8.9‑17: FOCUS Step 1, 2 PECSW and PECSED for AMBA following single application - parameter set for alkaline soils (pH 7.9)

| Scenario FOCUS | Waterbody | Max PECSW (μg/L) | Dominant entry route | 21 d- PECSW,twa  (µg/L) | Max PECSED (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| **Maize, 1 x 100 g as/ha, BBCH 12 - pH 7.9** | | | | | |
| Step 1 | --- | 7.19 | - | 7.13 | 1.57 |
| Step 2 | | | | | |
| Northern Europe | Mar – May | 0.84 | - | 0.83 | 0.18 |
| Southern Europe | Mar – May | 1.54 | - | 1.53 | 0.34 |

Table 8.9‑18: FOCUS Step 1, 2 PECSW and PECSED for SYN546974 following single application - parameter set for acidic soils (pH 5.1)

| Scenario FOCUS | Waterbody | Max PECSW (μg/L) | Dominant entry route | 21 d- PECSW,twa  (µg/L) | Max PECSED (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| **Maize, 1 x 100 g as/ha, BBCH 12 - pH 5.1** | | | | | |
| Step 1 | --- | 1.07 | - | 0.83 | 66.50 |
| Step 2 | | | | | |
| Northern Europe | Mar – May | 0.26 | - | 0.13 | 10.57 |
| Southern Europe | Mar – May | 0.26 | - | 0.22 | 19/36 |

Table 8.9‑19: FOCUS Step 1, 2 PECSW and PECSED for SYN546974 following single application - parameter set for neutral soils (pH 6.5)

| Scenario FOCUS | Waterbody | Max PECSW (μg/L) | Dominant entry route | 21 d- PECSW,twa  (µg/L) | Max PECSED (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| **Maize, 1 x 100 g as/ha, BBCH 12 - pH 6.5** | | | | | |
| Step 1 | --- | 1.07 | - | 0.83 | 66.50 |
| Step 2 | | | | | |
| Northern Europe | Mar – May | 0.26 | - | 0.12 | 9.77 |
| Southern Europe | Mar – May | 0.26 | - | 0.20 | 17.75 |

Table 8.9‑20: FOCUS Step 1, 2 PECSW and PECSED for SYN546974 following single application - parameter set for alkaline soils (pH 7.9)

| Scenario FOCUS | | Waterbody | Max PECSW (μg/L) | Dominant entry route | 21 d- PECSW,twa  (µg/L) | Max PECSED (μg/kg) |
| --- | --- | --- | --- | --- | --- | --- |
| **Maize, 1 x 100 g as/ha, BBCH 12 - pH 7.9** | | | | | | |
| Step 1 | --- | | 1.07 | - | 0.83 | 66.50 |
| Step 2 | | | | | | |
| Northern Europe | Mar – May | | 0.26 | - | 0.09 | 7.59 |
| Southern Europe | Mar – May | | 0.26 | - | 0.15 | 13.40 |

#### PECsw/sed of FLENID

The PECSW for FLENID was calculated using the following equation:



The application of FLENID is 1.0 L/ha, corresponding to 1050.2 g/ha. The depth of the static water body was assumed to be 30 cm. The resulting maximum instantaneous PECSW value is presented in the next table.

PECsw for FLENID following single application to maize

| Crop | Distance  (m) | Drift  (%) | Max PECsw (μg/l) |
| --- | --- | --- | --- |
|
| Maize | 1 | 2.77 | 9.70 |

The PECsed for FLENID was calculated using the following equation:



The application of FLENID is 1.0 L/ha, corresponding to 1050.2 g/ha. The percentage of Mesotrione in the sediment is 4.3 The height of the sediment was assumed to be 5 cm and the sediment density was assumed to be 1.3 g/cm3. The resulting maximum instantaneous PECsed value is presented in the next table.

PECsed for FLENID following single application to maize

| Crop | Distance  (m) | Drift  (%) | % of Mesotrione in sediment | Max PECsed (μgkg) |
| --- | --- | --- | --- | --- |
| Maize | 1 | 2.77 | 4.3 | 1.92 |

**zRMS comments**

The PECsw calculations for mesotrone have been approved for proposed in GAP.

PECsw and PECsed calculations were carried out according to the FOCUS recommendations.

The Applicant has been used FOCUS models: STEPS1-2 and Step 3. PECsw/sed were also carried out at Step 4 according to FOCUS L&M Guidance for 10m and 20m buffer zone. The Applicant used the geometric mean value. In opinion of the zRMS this is acceptable, as being in line with current requirements concerning selection of Kfoc to be used for modelling purposes.

PECsw/sed are acceptable to describe predicted environmental concentrations of mesotrione and its metabolites in surface water and sediment and are appropriate to be used for the subsequent risk assessment for aquatic and sediment organisms.

The applicant made the calculation using VFSMOD program in Step 4.

Additionaly, applicant carried out according to the Austrian Environmental Agency AGES were carried out for 5m and 15m buffer zone also.

MS should identify risk reduction measures at the national level.

## Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Table 8.10‑1 Summary of atmospheric degradation and behaviour

|  |  |
| --- | --- |
| Compound | Mesotrione |
| Direct photolysis in air | No data requested. |
| Quantum yield of direct phototransformation  **(Source : SANCO/1416/2001-Final)** | 1.3x10-4 at pH 4  < 4.6x10-6 at pH 7  < 1.6x10-5 at pH 9 |
| Photochemical oxidative degradation in air | DT50 (h): 17.635 derived by the Atkinson model  OH (12h) concentration assumed = 1.5x106 OH/cm3 |
| Volatilisation | From plant surfaces (BBA guideline): < 10% after 24 hours  From soil surfaces (BBA guideline): < 10% after 24 hours  Vapour pressure (Pa): < 5.7x10-6 at 20°C  Henry's Law Constant (Pa.m3/mol): >5.1x10-7 at 20°C |
| Metabolites | Not relevant |

The vapour pressure at 20 °C of the active substance Mesotrione is < 10‑5 Pa. Hence the active substance Mesotrione is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Mesotrione due to volatilization with subsequent deposition should not be considered.

**zRMS comment:**

Accepted.

1. Lists of data considered in support of the evaluation
2. Detailed evaluation of the new Annex II studies
3. Additional information provided by the applicant (e.g. detailed modelling data)