

FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: FLD-HER 306 SE

Product name: -

Chemical active substances:

2,4-D, 300 g/L
florasulam, 6.25 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant:

Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: January 2021

MS Finalisation date: 08/2021; 11/2021

Version history

| When | What |
|---------------|--|
| August 2021 | ZRMs evaluated the dRR submitted by Applicant. |
| November 2021 | Final Registration Report |
| | |
| | |

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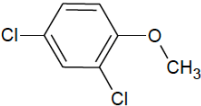
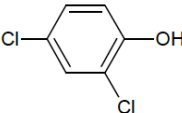
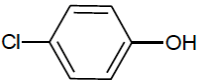
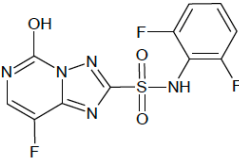
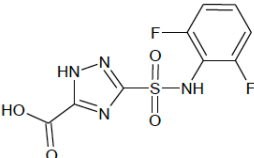
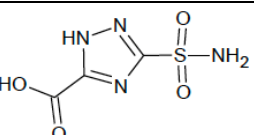
10 Relevance of metabolites in groundwater

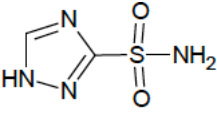
10.1 General information

In accordance with modelling performed in dRR Part B8, metabolites ASTCA and TSA are predicted to occur in groundwater at concentration above 0.1 µg/L. The assessment of the relevance of above metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10 is therefore required.

General information on the metabolites are provided in Table 10.1-1. The impact of the relevance assessment on whether a particular GAP use leads to acceptable risk or not is presented in the summary of the GAP evaluation in chapter 8.1 of the dRR Part B8 (Environmental fate and behaviour).

Table 10.1-1: General information on the metabolites

| Name of active substance | Metabolite name and code | Structural/molecular formula | Trigger for relevance assessment | |
|--------------------------|--------------------------|---|----------------------------------|--|
| | | | Max PEC _{gw} | |
| 2,4-D | 2,4-DCA |  | Max PEC _{gw} | 0.00 µg/L |
| | | | Based on: | PEARL 4.4.4 – all relevant scenarios PELMO 5.5.3 – all relevant scenarios |
| | 2,4-DCP |  | Max PEC _{gw} | 0.00 µg/L |
| | | | Based on: | PEARL 4.4.4 – all relevant scenarios PELMO 5.5.3 – all relevant scenarios |
| | 4-CP (4-chlorophenol) |  | Max PEC _{gw} | 0.00 µg/L |
| | | | Based on: | PEARL 4.4.4 – all relevant scenarios PELMO 5.5.3 – all relevant scenarios |
| florasulam | 5-OH Florasulam |  | Max PEC _{gw} | 0.014 µg/L |
| | | | Based on: | PEARL 4.4.4 – Okehampton scenario |
| | DFP-ASTCA |  | Max PEC _{gw} | 0.004 µg/L |
| | | | Based on: | PEARL 4.4.4 – Okehampton scenario |
| | ASTCA |  | Max PEC _{gw} | 0.248 µg/L |
| | | | Based on: | PEARL 4.4.4 – Hamburg scenario |

| Name of active substance | Metabolite name and code | Structural/molecular formula | Trigger for relevance assessment | |
|--------------------------|--------------------------|---|------------------------------------|---|
| | TSA |  | Max PEC _{gw} Based on: | 0.238 µg/L PEARL 4.4.4 – Hamburg scenario |

10.2 Relevance assessment of ASTCA

Summary:

The relevance of the groundwater metabolite ASTCA has already been assessed and the assessment agreed at EU level (see EFSA Journal 2015; 13(1):3984), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). ASTCA is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 – rev.10. A summary of the relevance assessment is given in Table 10.2-1 and the corresponding studies are listed in the corresponding sections.

Table 10.2-1: Summary of the relevance assessment for ASTCA

| | Assessment step | | Result of assessment | |
|---|-----------------|---------------------------------|---|---|
| | STEP 1 | | Metabolite of no concern? | yes |
| Quantification of groundwater contamination | STEP 2 | | Max PEC _{gw} | 0.248 µg/L |
| | | | Based on | PEARL 4.4.4 – Hamburg scenario |
| Hazard assessment | STEP 3 | Stage 1 | Biological activity comparable to the parent? | no |
| | | Stage 2 | Genotoxic properties of metabolite | non-genotoxic Ames test: negative Gene mutation assay <i>in vitro</i> with mammalian cells: negative Chromosomal aberration assay <i>in vitro</i> : negative |
| | | Stage 3 | Toxic properties of metabolite; | |
| | | | Classification of parent | Not classified as toxic or very toxic |
| | | | Classification of metabolite | Not classified as toxic or very toxic |
| | | Consumer health risk assessment | STEP 4 | |
| STEP 5 | | | Refined risk assessment | N/A* |
| | | | Predicted exposure (% of ADI) | N/A* |
| | | | ADI based on | N/A* |

* N/A: not applicable

10.3 Relevance assessment of TSA

Summary:

The relevance of the groundwater metabolite TSA has already been assessed and the assessment agreed at EU level (see EFSA Journal 2015; 13(1):3984), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). TSA is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 – rev.10. A summary of the relevance assessment is given in Table 10.2-1 and the corresponding studies are listed in the corresponding sections.

Table 10.3-1: Summary of the relevance assessment for TSA

| | Assessment step | | Result of assessment | |
|---|-------------------------------|---------------------------------|---|---|
| | STEP 1 | | Metabolite of no concern? | yes |
| Quantification of groundwater contamination | STEP 2 | | Max PEC _{gw} | 0.238 µg/L |
| | | | Based on | PEARL 4.4.4 – Hamburg scenario |
| Hazard assessment | STEP 3 | Stage 1 | Biological activity comparable to the parent? | no |
| | | Stage 2 | Genotoxic properties of metabolite | non-genotoxic Ames test: negative Gene mutation assay <i>in vitro</i> with mammalian cells: negative Chromosomal aberration assay <i>in vitro</i> : negative |
| | | Stage 3 | Toxic properties of metabolite; | |
| | | | Classification of parent | Not classified as toxic or very toxic |
| | | | Classification of metabolite | Not classified as toxic or very toxic |
| | | Consumer health risk assessment | STEP 4 | |
| STEP 5 | Refined risk assessment | | N/A * | |
| | Predicted exposure (% of ADI) | | N/A * | |
| | | | ADI based on | N/A * |

* N/A: not applicable

The PEC_{gw} the metabolites ASTCA and TSA were above 0.1 µg/L but these metabolites are of no toxicological concern so it may be therefore concluded that the threshold of concern 0.75 µg/L is not exceeded.

Florasulam

Statement” In accordance with modelling performed in dRR Part B8, metabolites ASTCA and TSA are predicted to occur in groundwater at concentration above 0.1 µg/L. The assessment of the relevance of above metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10 is therefore required” is acceptable

The relevance of the groundwater metabolite ASTCA and TSA have already been assessed and the assessment agreed at EU level (see EFSA Journal 2015; 13(1):3984), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR).

The PEC_{gw} the metabolites ASTCA and TSA were above 0.1 µg/L but these metabolites are of no toxicological concern so it may be therefore concluded that the threshold of concern 0.75 µg/L is not exceeded.

2,4-D

The metabolites of 2,4-D (i.e. 2,4-DCP and 2,4-DCA) are predicted to occur in groundwater at concentrations below 0.1 µg/L

The groundwater metabolite 2,4-DCP and 2,4-DCA are considered as non-relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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 |
|------------|-----------|------|---|----------------------------|-------|
| - | - | - | - | - | - |

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 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 |
|-------------------|------------------|-------------|--|-------------------------------------|--------------|
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Appendix 2 Additional information

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|-------------------|--|
| Comments of zRMS: | Comment on statement; acceptable or not. |
|-------------------|--|