FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: **ORKAN 350 SL**

Product name: **ORKAN 350 SL, SPRINTER 350 SL**

Chemical active substances:

Glyphosate, 260 g/L
MCPA, 90 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(renewal of authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: 04/2020

MS Finalisation date: 09/2020**;** 11.2021

Version history

When	What
09/2020	Assessment by expert
11/2021	Evaluation after commenting period - RR

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10 Relevance of metabolites in groundwater

Evaluator's Comments:	The submitted justification was accepted. The MCPA metabolite 2C4M was added by evaluator. Based on PECgw assessment for metabolites concentration in groundwater were below the trigger value of 0.1 µg/L.

10.1 General information

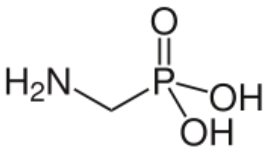
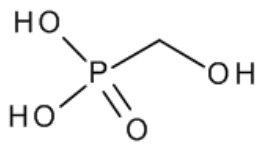
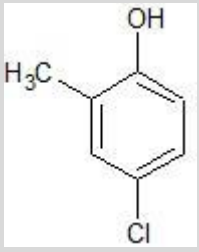
The metabolites of glyphosate (i.e. AMPA and HMPA) are predicted to occur in groundwater at concentrations below 0.1 µg/L (see dRR Part B section 8).

~~There are no relevant metabolites of MCPA.~~

The metabolite of MCPA – 4C2M was also considered, and is predicted to occur in groundwater at concentrations below 0.1 µg/L (see dRR Part B section 8).

Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.
General information on the metabolites are provided in Table 10.1-1.

Table 10.1-1: General information on the metabolites

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessmnent	
Glyphosate	AMPA		Max PEC_{gw} Based on:	< 0.1 µg/L each scenario; calculated with PEARL 4.4.4 PELMO 5.5.3
Glyphosate	HMPA		Max PEC_{gw} Based on:	< 0.1 µg/L EFSA Journal 2015;13(11):4302
MCPA	4C2M		Max PEC_{gw} Based on:	< 0.1 µg/L

10.2 Relevance assessment of AMPA and HMPA

Summary:

The groundwater metabolite AMPA and HMPA, are considered as non-relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10, since their predicted concentration in the groundwater do not exceed the concentration of 0.1 µg/L. Studies supporting PEC_{gw} data are evaluated in Section 8 (Environmental fate and behaviour).

Glyphosate

According to EFSA Journal 2015;13(11):4302 Peer review of the pesticide risk assessment of the active substance glyphosate:

" Metabolism in animals: Poorly metabolised with the only biotransformation product aminomethylphosphonic acid (AMPA) accounting for up to 1 % of the total excreted amount (probably resulting from bacterial metabolism in the gut)"

"Aminomethylphosphonic acid (AMPA, metabolite in glyphosate tolerant GM plants and in soil and water:

Rat & mice LD50 oral > 5000 mg/kg bw, Rat LD50 dermal > 2000 mg/kg bw; Skin sensitisation: negative (M&K test);

90-day, rat: NOAEL: 400 mg/kg bw per day based on bw gain↓, urothelial hyperplasia (bladder) and gastrointestinal clinical signs; 90-day, dog: NOAEL 263 mg/kg bw per day, the highest dose tested.

Genotoxicity: consistently negative in Ames tests, mammalian cell gene mutation and UDS tests in vitro and in micronucleus assays in vivo.

Rat developmental toxicity: No evidence of teratogenicity, maternal NOAEL 150 mg/kg bw per day, based on clinical signs, bw gain/food consumption↓, developmental NOAEL 400 mg/kg bw per day, based on mean foetal wt↓; AMPA presents a similar toxicological profile as glyphosate and the reference values of the latter apply to its metabolite AMPA. Therefore AMPA is considered as toxicologicaly non-relevant

MCPA

According MCPA SANCO/4062/2001-rev. 5 07 April 2005

" 70 - 90 % as unchanged MCPA in the urine; 2-7% HMCPA (hydroxymethyl- derivative); traces of glycine conjugate in rats, 30 % unchanged MCPA, 6,5% HMCPA 12-38% glycine conjugates in dogs. In humans high level of conjugation may occur (56-73 % conjugates in a volunteer) " Metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

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

Appendix 2 Additional information

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