

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: SAP09I

Product name: VOLKETE MAX

Chemical active substance:

Spinosad, 480 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New product authorization according to article 34 of Regulation (EC) 1107/2009)

Applicant(s): Albaugh TKI d.o.o.

Submission date: January 2025

MS Finalisation date: 12/2025

Version history

When	What
January 2025	V0 – Original dRR version from applicant Albaugh TKI d.o.o. for submission to zRMS Poland in the frame of a new authorization according to Article 33/34 of Regulation (EC) No. 1107/2009.

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10 Relevance of metabolites in groundwater

10.1 General information

Please refer to the reference product Dossier of SPINTOR 480 SC in Poland registered since 2003 (permit of the Ministry of Agriculture and Rural Development No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018.

10.2 Relevance assessment of metabolite

Please refer to the reference product Dossier of SPINTOR 480 SC in Poland registered since 2003 (permit of the Ministry of Agriculture and Rural Development No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018.

10.2.1 STEP 1: Exclusion of degradation products of no concern

Please refer to the reference product Dossier of SPINTOR 480 SC in Poland registered since 2003 (permit of the Ministry of Agriculture and Rural Development No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018.

10.2.2 STEP 2: Quantification of potential groundwater contamination

Please refer to the reference product Dossier of SPINTOR 480 SC in Poland registered since 2003 (permit of the Ministry of Agriculture and Rural Development No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.2.3.1 STEP 3, Stage 1: screening for biological activity

Please refer to the reference product Dossier of SPINTOR 480 SC in Poland registered since 2003 (permit of the Ministry of Agriculture and Rural Development No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

Please refer to the reference product Dossier of SPINTOR 480 SC in Poland registered since 2003 (permit of the Ministry of Agriculture and Rural Development No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018.

10.2.3.3 STEP 3, Stage 3: screening for toxicity

Please refer to the reference product Dossier of SPINTOR 480 SC in Poland registered since 2003 (permit of the Ministry of Agriculture and Rural Development No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

Please refer to the reference product Dossier of SPINTOR 480 SC in Poland registered since 2003 (permit of the Ministry of Agriculture and Rural Development No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018.

10.2.5 STEP 5: Refined risk assessment

Please refer to the reference product Dossier of SPINTOR 480 SC in Poland registered since 2003 (permit of the Ministry of Agriculture and Rural Development No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018.

Appendix 1 Lists of data considered in support of the evaluation

Please refer to the reference product Dossier of SPINTOR 480 SC in Poland registered since 2003 (permit of the Ministry of Agriculture and Rural Development No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018.

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
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	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
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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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	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

Please refer to the reference product Dossier of SPINTOR 480 SC in in Poland registered since 2003 (permit of the Ministry of Agriculture and Rural Development No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018.

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