

FINAL REGISTRATION REPORT

Part B

Section 10

**Assessment of the relevance of metabolites in
groundwater**

Detailed summary of the risk assessment

Product code: CHR/H/ETO 500 SC

Product name(s): BITT 500 SC, BETRON 500 SC, ETONAL
500 SC

Chemical active substance(s):

Ethofumesate, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: June 2021

MS Finalisation date: 14/01/2022

Version history

When	What
06/2021	Dossier sent for evaluation to Merit Mark (PL)
11/2021	zRMS finalised evaluation
01/2022	Final version prepared by zRMS after Commenting period

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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

10 Relevance of metabolites in groundwater

In the following document, data for active substance ethofumesate was described during its renewal process in 2016. Where reference to active substance data in the current risk assessment has been made, it was based on the data presented by Bayer.

In June 14th, 2018r Kemiron Koncentrat 500SC product has been renewed in Poland thus according to the art. 59 reg. 1107/2009, data protection for mentioned data expired 30 months from date of first renewal of authorisation of product containing that active substance (in this case December, 14th 2020).

Considering analogous arguments (art. 59 reg 1107/2009) – data protection of studies presented by UPL for renewal of product Bettix Combi 500 SC (renewal of authorisation granted in Poland 14.02.2019 r.) expires August 14th, 2021.

Taking into account that some data was presented by others Notifiers, Applicant would like to emphasise that unprotected Bayer's endpoints and input parameters accepted during renewal of active substance, should be treated as an equivalent matching data in cases where any of endpoints might be protected.

10.1 General information

Evaluator's Comments:	The submitted justification was accepted. Based on PEC _{gw} assessment for metabolites, their concentration in groundwater was below the trigger value of 0.1 µg/L. Therefore, the relevance assessment of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is not required.
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No metabolites exceed trigger value 0.1 µg/L.

Appendix 1 Lists of data considered in support of the evaluation

Appendix 2 Additional information