

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: AG-F8-250 CS

Chemical active substance:

Flurochloridone, 250 g/L

Central Zone

Member State: Poland

CORE ASSESSMENT

(authorization)

Sponsor: ADAMA Agan Ltd

Applicant: Country organisation/representative of
ADAMA Agan Ltd. as reported in Part A

Submission date: January 2020

MS Finalisation date: October 2020 (initial Core Assessment)

March 2021 (final Core Assessment)

Version history

When	What
January 2020	dRR submitted by the Applicant
October 2020	<p>Initial zRMS assessment</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.</p>
March 2021	<p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow.</p> <p>No comments after the commenting period.</p>

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ZRMS general remarks:

No toxicological information is available on the metabolite R42819 that may be found in groundwater at levels above the threshold value of 0.1 µg/L according to environmental models; Considering the classification proposal as **H360Df for the parent***, this metabolite is considered as relevant according to the Guidance document on assessment of the relevance of metabolites in groundwater (European Commission, 2003) and a critical area of concern can be identified. (see EFSA Journal 2010;8(12):1869; point 2, p.8)

However, metabolites R42819 is considered as relevant (see our comment above), based on current assessment metabolite R42819 is not predicted to occur in groundwater at concentrations above 0.1 µg/L at tier 2 (see dRR Part B8 Point 8.8). Further assessment and refinements are therefore not required.

Metabolite R406639 is not predicted to occur in groundwater at concentrations above 0.1 µg/L tier 1 (see dRR Part B8 Point 8.8). Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

*The Reviewer points out that the **H360Df classification has been accepted by the ECHA/RAC committee (opinion CLH-O-0000001412-86-242/F adopted 30 November 2018)**, although there is no formal EC decision regarding the harmonized classification of the parent substance yet, however, due to the teratogenic potential of Flurochloridone, one should bear in mind the risk resulting from potential leaching of the above-mentioned metabolite to groundwater.

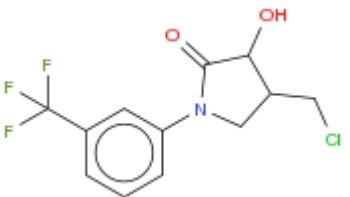
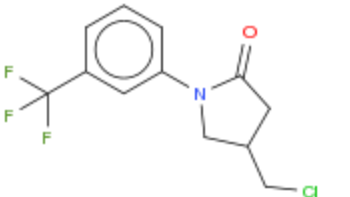
10 Relevance of metabolites in groundwater

10.1 General information

The metabolites R42819 and R406639 are not predicted to occur in groundwater at concentrations above 0.1 µg/L at tier 2 and tier 1, respectively (see dRR Part B8 Point 8.8). 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 code	Structural formula	Trigger for relevance assessment	
Flurochloridone	R406639		Max PEC _{gw} Based on:	0.018 µg/L PELMO, Okehampton scenario
Flurochloridone	R42819		Max PEC _{gw} Based on:	Tier 1: 0.611 µg/L (PEARL, Okehampton) Tier 2: 0.003 µg/L (PELMO, Okehampton)

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

None.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

None.

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
-	-	-	-	-	-