

REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: AG-E1-500 SC1

Product name: Ethosat 500 SC

Chemical active substances:

Ethofumesate, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Sponsor: ADAMA Agan Ltd.

Applicant: ADAMA Polska Sp. z o.o.

Submission date: March 2021

MS Finalisation date: January 2022 (initial Core Assessment)

June 2022 (final Core Assessment)

Version history

When	What
March 2021	dRR version 1 submitted by applicant
January 2022	<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>
June 2022	<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 received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded.</p>

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application under article 33 of regulation 1107/2009 submitted by the applicant in March 2021 is for first authorisation of the product AG-E1-500 SC1 (containing 500 g/L ethofumesate) follows the data requirements of

- Regulation (EC) No. 283/2013 for the active substance ethofumesate, and
- Regulation (EC) No. 284/2013 for the plant protection product AG-E1-500 SC1.

Any deviation from this is justified in the relevant parts of the dossier.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Northern zone	Sweden	Denmark Finland Lithuania
Central zone	Germany	Austria Belgium Czech Republic The Netherlands
Central zone	Poland	Hungary Slovakia
Southern zone	France	Croatia Italy Spain
Inter-zonal	Not applicable	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Ethofumesate

Table 0.1-2: Summary of regulatory history of CAS No: 26225-79-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	<p>Commission Directive 2002/37/EC of 03 May 2002 amending Council Directive 91/414/EEC</p> <p>Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011</p> <p>Commission Implementing Regulation (EU) 2016/950 of 15 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods</p> <p>Commission Implementing Regulation (EU) 2016/1426 of 25 August 2016 renewing the approval of the active substance in accordance with Regulation (EC) No 1107/2009</p>
RMS	Austria (The original RMS was Sweden)
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.11.2016
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.01.2017 (Art. 43)
Date of final Commission (re-registration) deadline (Step 2)	-
Current expiration of approval	31.10.2031
Low risk substance or Candidate for Substitution?	-

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States:

- shall pay particular attention to the risk to aquatic organisms.

Conditions of use shall include risk mitigation measures, where appropriate.

Table 0.1-3: Information on minimum purity of ethofumesate

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
970 g/kg	975 g/kg Equivalence report available: Y (Austria) for details refer to Part C

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The ADAMA Agan Ltd. source of ethofumesate has been confirmed for being equivalent by the Rapporteur Member State (RMS) Austria in November 2014. The equivalence report is published on CIRCA. Details on this are provided in PART C.

The Renewal report for ethofumesate (SANTE/10119/2016 Rev. 3) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. However an EFSA Scientific Report was made available on 19/01/2016 (EFSA Journal 2016;14(1):4374). The list of endpoints from this EFSA Scientific Report is considered in this submission.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints:

No such table is provided here.

Information on deviating endpoints, where relevant, will be specified in the respective Part B documents.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

Authorisation of the product AG-E1-500 SC1 is recommended for the use in sugar beet in Hungary, Slovakia and in Poland, and for the fodder beet in Hungary. In Slovakia, the authorization of the use in fodder beet will depend on that cMS's decision, whereas in Poland it may be only authorized following art. 51 of the 1107/2009.

Uses to be considered safe on the basis of EU methodology:

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses to be considered non-safe on the basis of EU methodology:

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

See column 15 of the GAP table presented in Appendix 1 of this document.

All uses/ GAPs are covered by established MRLs.

Appendix 1 ALL intended uses

GAP rev. 2, date: **June** ~~January~~ 2022

PPP (product name/code): AG-E1-500 SC1 Formulation type: SC
Active substance 1: ethofumesate Conc. of as 1: 500 g/L
Safener: not relevant Conc. of safener: not relevant
Synergist: not relevant Conc. of synergist: not relevant
Applicant: ADAMA Agan Ltd. Professional use: ☒
Zone(s): central Non professional use: ☐
Verified by MS: **yes** ~~no~~ Formulation type: SC
Field of use: herbicide Conc. of as 1: 500 g/L

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15						
Use- No. (e)	Me- mbe r state (s)	Crop and/ or situa- tion (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha (f)	Overall conclusions						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica- tions (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. (^e)	Me- mbe r state (s)	Crop and/ or situa- tion (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha (^f)	Overall conclusions							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica- tions (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	HU	Sugar beet BEAVA Fodder beet BEAVC	F	annual dicot weeds and annual-grass weeds	foliar spraying, overall	BBCH 10-18/ spring	a) 2 b) 2	a) 5 b) 5	a) 1 L/ha b) 2 L/ha	a) 500 b) 1000	100-400	n.a.	Max. rate of active must not exceed 1.0 kg/ha every 3 years (from all used products with ethofumesate).	A	A	A	A	R Triennial application Maximum cumulative rate of ethofumesate on the treated field from all used products with this substance is 1000 g a.s. every three years	R Aquatic species scenario R3 A Aquatic species scenarios D3, D4, R1 R NTTP A Remaining species	A	A
2	SK	Sugar beet BEAVA Fodder beet BEAVC	F	annual dicot weeds and annual-grass weeds	foliar spraying, overall	BBCH 10-18/ spring	a) 2 b) 2	a) 5 b) 5	a) 1 L/ha b) 2 L/ha	a) 500 b) 1000	100-400	n.a.	Max. rate of active must not exceed 1.0 kg/ha every 3 years (from all used products with ethofumesate).	A	A	A	A	R Triennial application Maximum cumulative rate of ethofumesate on the treated field from all used products with this substance is 1000 g a.s. every three years	R Aquatic species scenario R3 A Aquatic species scenarios D3, D4, R1 R NTTP A Remaining species	A	A e
3	PL	Sugar beet BEAVA Fodder beet BEAVC	F	annual dicot weeds and annual-grass weeds	foliar spraying, overall	BBCH 10-18/ spring	a) 3 b) 3	a) 5 b) 5	a) 0.6 L/ha b) 1.8 L/ha	a) 300 b) 900	100-400	n.a.	Max. rate of active must not exceed 1.0 kg/ha every 3 years (from all used products with ethofumesate).	A	A	A	A	R Triennial application Maximum cumulative rate of ethofumesate on the treated	R Aquatic species scenario R3 A Aquatic species scenarios D3, D4, R1	A	A (sugar beet)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15								
Use- No. (e)	Me- mber state (s)	Crop and/ or situa- tion (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha (f)	Overall conclusions								
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica- tions (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy	
													At each time can be applied in tankmix: AG- E1-50 SC1 0.5 L/ha + Goltix Titan 565 SC 1.5 L/ha + Atpolan BIO-80 EC 1.0 L/ha						field from all used products with this substance is 1000 g a.s. every three years	A Remaining species		N (fodder beet - possible author- iz. under art. 51)

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
 (c) g/kg or g/l

(d) Select relevant
 (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
 (f) No authorization possible for uses where the line is highlighted in grey. Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
 2 Use official codes/nomenclatures of EU Member States
 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
 8 The maximum number of application possible under practical conditions of use must be provided.
 9 Minimum interval (in days) between applications of the same product
 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
 13 PHI - minimum pre-harvest interval
 14 Remarks may include: Extent of use/economic importance/restrictions
 15 Overall conclusions - explanation for the column 15 is below*

* Explanation for column 15 "Overall conclusions"

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use