REGISTRATION REPORT

Part A

Risk Management

Product code: AG-E1-500 SC1

Product name(s): ETHOSAT SC

Chemical active substance(s):

Ethofumesate, 500 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: ADAMA France s.a.s

Date: 11/08/2022

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PART A
RISK MANAGEMENT

1 Details of the application

The company ADAMA France s.a.s has requested a marketing authorisation in France for the product ETHOSAT SC (AG-E1-500 SC1) (formulation code: SC), containing 500 g/L Ethofumasate[1] as a herbicide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

1.1 Application background

The present registration report concerns the evaluation of ADAMA France s.a.s's application submitted on 03/05/2021 to market ETHOSAT SC (AG-E1-500 SC1) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone

The present application (2021-1268) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[2], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[3]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of ETHOSAT SC (AG-E1-500 SC1) has been made using endpoints agreed in the EU peer review of Ethofumasate. It also includes assessment of data and information related to ETHOSAT SC (AG-E1-500 SC1) where those data have not been considered in the EU peer review process.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

1.2 Letters of Access

The applicant has provided letters of access for active substance. These letters of access are available upon request.

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1 Commission implementing regulation (EU) 2016/1426 of 25 August 2016 renewing the approval of the active substance ethofumesate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

2 Regulation (EC) no 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

3 SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

1.3 Justification for submission of tests and studies

According to the applicant: « All reports submitted are needed for the first registration of AG-E1-500 SC1 in accordance to the data requirements laid down in Regulation (EC) No. 284/2013. ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of ETHOSAT SC (AG-E1-500 SC1), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	AG-E1-500 SC1
Product name in MS	ETHOSAT SC
Authorisation number	2220656
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	ADAMA France s.a.s
Active substance(s) (incl. content)	ethofumesate; 500 g/L
Formulation type	Suspension concentrate [SC]
Packaging	HDPE bottle 1L, HDPE container 5-10-15-20L
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for ETHOSAT SC (AG-E1-500 SC1) resulted in the decision **to grant** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	 GHS09
Signal word:	Warning
Hazard statement(s):	H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the existing legislation***
Additional labelling phrases:	EUH 208 : Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water.Avoid contamination via drains from farmyards and roads.
	For other restrictions refer to 2.5

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017[4] provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

[4] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Moreover, the French Order of 12 April 2021[5] provides that:
- an authorisation granted for a "reference" crop applies also for "related" crops, unless formally stated in the Decision
- the "reference" and "related" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "related" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those "related" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

Finally, the French Order of 20 November 2021[7] on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive culture[8] when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific Spe 8 may include reference to this order.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Bystander and resident protection :	
	Respect an unsprayed zone of 3 meters from the extremity of the boom and : - areas where bystanders are present during treatment - areas where residents could be present.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	

5 https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456
6 SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9
7 https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734
8 List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

SPe 1	To protect groundwater, following an application on beet, do not apply this or any other product containing ethofumesate more than every other year.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 20 metres with a 5-metres permanent planted buffer strip to surface water bodies for uses on sugar beet and fodder beet, and inedible MAPP
SPe 3	To protect non-target plants, respect an unsprayed buffer zone of 5 metres to non-agricultural land for the uses on inedible MAPP.
Other specific restrictions	
Re-entry period	6 hours.
Storage	-
Risk mitigation measures	Do not grow root vegetables in case of crop failure.
Agricultural recommendations	None

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2022-08

PPP (product name/code):	ETHOSAT SC / AG-E1-500 SC1	Formulation type:	SC [a, b]
Active substance 1:	Ethofumasate	Conc. of a.s. 1:	500 g/L [c]
Active substance 2:	/	Conc. of a.s. 2:	/
Active substance 3:	/	Conc. of a.s. 3:	/
Applicant:	ADAMA France s.a.s	Professional use:	☒
Zone(s):	Southern Zone [d]	Non-professional use:	☐
Verified by MS:	Yes		
Field of use:	Herbicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Red beet BEAVD	F	annual dicot weeds and annual grass weeds	foliar spraying, overall	BBCH 10-37 spring	a) 5 b) 5	5	a) 0.65 L/ha b) 2 L/ha	a) 325 b) 1000	80-200	F	**Acceptable**
2	FR	Sugar beet BEAVA Fodder beet BEAVC Seed Production (sugar beet and fodder beet) *	F	annual dicot weeds and annual grass weeds	foliar spraying, overall	BBCH 10-37 spring	a) 5 b) 5	5	a) 0.65 L/ha b) 2 L/ha	a) 325 b) 1000	80-200	F	**Acceptable**

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FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application** Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	**Application rate** kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max	**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
3	FR	Herbal infusions (from leaves and flowers)	F	weeds	spraying	BBCH 10-37	a) 1 b) 2	5	a) 1 L/ha b) 2 L/ha	a) 500 b) 1000	80-200	35	**Not acceptable (MRL)**
4	FR	Herbs and edible flowers	F	weeds	spraying	BBCH 10-37	a) 1 b) 2	5	a) 1 L/ha b) 2 L/ha	a) 500 b) 1000	80-200	50	**Not acceptable (MRL)**
5	FR	Inedible MAPP	F	weeds	spraying	BBCH 10-37	a) 1 b) 2	5	a) 1 L/ha b) 2 L/ha	a) 500 b) 1000	80-200	n.a.	**Acceptable**

* As some standards may have undergone changes, it is the responsibility of the applicant to update the references.

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 authorisation 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

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

Packaging claimed: HDPE bottle 1L, HDPE container 5-10-15-20L
The preparation does not contain compounds classified H304.

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a homogeneous white liquid. It is not explosive, has no oxidising properties. The product has a flash point of >90 °C. It has a self-ignition temperature of 480°C. The pH value of the neat formulation is 7.7 at ambient temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the content of the active ingredient nor the technical properties were changed. The 2 years shelf life study is on-going at the time of submission of this dossier. Interim results after one-year storage are provided. Based on these results and on the accelerated storage stability study, the shelf life is expected to be at least 2 years when stored at ambient temperature in HDPE commercial containers. **Final report of the shelf life study is required in post authorisation**. Its technical characteristics are acceptable for a SC formulation.

The intended concentration of use is 0.25-1.25 % v/v

3.2 Efficacy (Part B, Section 3)

The level of efficacy of ETHOSAT SC (AG-E1-500 SC1) applied post-emergence for the control of broadleaf weeds is considered satisfactory for industrial and fodder beets, herbs, infusions and inedible AMPP.
The level of selectivity of the product ETHOSAT SC (AG-E1-500 SC1) in post-emergence application is considered to be satisfactory for all the claimed uses escept on red beet.
Given the absence of data on red beet, the evaluation of the level of selectivity of the product ETHOSAT SC (AG-E1-500 SC1) in post-emergence application for this use cannot be finalized.
The risks of negative impact on yield, quality, and multiplication are considered negligible.
The risk of negative impact on the replacing crops is considered acceptable.
In the absence of data, the risk assessment on adjacent crops could not be finalized. Particular attention should therefore be paid to the conditions of application of the product near adjacent crops.
The risk of the appearance or development of resistance to ethofumesate does not require monitoring for all the claimed uses.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substance and the relevant impurities (EMS and iBMS) in the formulation are available and validated. **However, specificity of the method for the determination of relevant impurities in the current composition of the preparation ETHOSAT SC (AG-E1-500 SC1) should be provided in post registration.**

3.3.2 Analytical methods for residues

Analytical methods are available in the RAR of the active substance and validated for the determination of residues of ethofumesate in plants (high water content), food of animal origin, soil, water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Agreed EU endpoints	
Active substance	**Ethofumesate**
AOEL systemic	2.5 mg/kg bw/day
AAOEL	Not derived, not necessary
Oral absorption	> 80%
Vapour pressure	3.6 x 10^{-4} Pa at 20°C (99.9%) DAR 1998 6.5 x 10^{-4} Pa at 25°C (99.9%) DAR 1998 4.0 x 10^{-3} Pa at 40°C (99.9%) DAR 1998
Reference	Peer review of the pesticide risk assessment of the active substance ethofumesate, EFSA Journal 2016;14(1):4374 SANTE/10119/2016 Rev. 3
Dermal absorption (EFSA default values 2017)	Concentrate: 10 % Dilution: 50 %

3.4.1 Acute toxicity

ETHOSAT SC (AG-E1-500 SC1) containing 500 g/L ethofumesate has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.4.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model[9]:

Model data		**Ethofumesate**
	Level of PPE	**% AOEL**
Application : Outdoor downward spraying, vehicle mounted, to leaf vegetables and fresh herbs		
Application rate: 2 applications, 1 L ETHOSAT SC/ha (spray interval of 5 days)		2x0.5 kg Ethofumesate/ha (spray interval 5 days)
Spray ap-plication (AOEM; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	0.28

[9] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

According to the model calculations, it can be concluded that the risk for the operator using ETHOSAT SC (AG-E1-500 SC1) is acceptable with a working coverall and gloves during mixing/loading and application.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.4.3 Worker exposure

Workers may have to enter into treated areas after treatment for crop inspection/irrigation activities. Therefore, estimation of worker exposure was calculated according to AOEM model.

Model data		**Ethofumesate**
	Level of PPE	**%AOEL**
Activity: Inspection, irrigation Outdoor downward spraying, vehicle mounted, to leaf vegetables and fresh herbs Work rate: 2 hours/day Number of applications : 2 Interval between treatments: 5 days		
DT50:		30 days
DFR:		3 µg/cm^2/kg a.s./ha
Application rate (kg as/ha)		2x0.5 kg Ethofumesate/ha
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 1400 cm2/person/h	2.65

There is no unacceptable risk anticipated for the worker reentering into treated crops.

For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

3.4.4 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[10].
Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*."

3.4.5 Resident exposure

Resident exposure was assessed according to EFSA model without mitigation measures (i.e. without drift reduction technology and a buffer zone of 3 meters).

[10] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

Model data		Ethofumesate
		% AOEL
Scenario: Buffer zone: 3 (m) Drift reduction technology: no Number of applications : 2 Interval between treatments: 5 days		
DT_{50}		30 days
DFR		3 µg/cm²/kg a.s./ha
Resident (children) Body weight: 10 kg	Spray drift (75th percentile)	3.36
	Vapour (75th percentile)	0.04
	Surface deposits (75th percentile)	0.31
	Entry into treated crops (75th percentile)	3.19
	All pathways (mean)	4.66
Resident (adults) Body weight: 60 kg	Spray drift (75th percentile)	0.80
	Vapour (75th percentile)	0.01
	Surface deposits (75th percentile)	0.13
	Entry into treated crops (75th percentile)	1.77
	All pathways (mean)	1.90

An acceptable risk was determined for resident (adult and/or child).

3.4.6 Combined exposure

Not relevant. The product contains only one active substance.

3.5 Residues and consumer exposure (Part B, Section 7)

Inedible MAPP will not be consumed by humans or livestock. Residue trials for MRL setting or for consumer risk assessment are therefore not needed.

An exceedance of the current MRLs on sugar beet, fodder beet and red beet for ethofumesate as laid down in Commission Regulation (EU) 2017/1016 of 14 June 2017 amending Reg. (EC) No 396/2005 is not expected. **However, an exceedance of the current MRL on herbal infusion, herbs and edible flowers cannot be excluded due to insufficient data.**

The chronic and the short-term intakes of ethofumesate residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, the zRMS agrees with the authorization of the intended uses.

Summary for AG-E1-500 SC1

Table : Information on AG-E1-500 SC1 (KCA 6.8)

Crop	PHI for AG-E1-500 SC1 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for AG-E1-500 SC1 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Ethofumesate		
Sugar beet	F**	Yes	F	
Fodder beet	F**	Yes	F	
Herbs and edible flowers	50	No	Insufficient residue trials	
Herbal infusions (leaves and flowers)	35	No	Insufficient residue trials	
Inedible MAPP	F**	NR	NR	

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for AG-E1-500 SC1
Crop group	Led by ethofumesate	
Root vegetables	/	Do not grow root vegetables in case of crop failure

3.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substance and its metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of ethofumesate and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC soil and PECsw derived for the active substance and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw for ethofumesate and its metabolites do not occur at levels exceeding those mentioned in regulation EU No 546/2011 for the intended use on herbs for applications every year and for the intended use on sugar beet for applications every other year. Therefore, no unacceptable risk of groundwater contamination is expected in these conditions of use.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substances and their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when addi-tional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, aquatic organisms, mammals, other non-target arthropods, earthworms, other soil macro- and micro-organisms and terrestrial non-target plants are acceptable for the intended uses. Risk mitigations are required for aquatic organisms and non-target terrestrial plants.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to 3.6 for conclusion on the risk of groundwater contamination.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substance ethofumesate is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- Final report of the shelf life study,

- Specificity of the method for the determination of relevant impurities in the current composition of the preparation ETHOSAT SC (AG-E1-500 SC1).

Appendix 1 Copy of the product authorisation

RÉPUBLIQUE FRANÇAISE
Liberté
Égalité
Fraternité

anses

Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique ETHOSAT SC

de la société *ADAMA FRANCE SAS*

enregistrée sous le *n°2021-1268*

Vu les conclusions de l'évaluation de l'Anses du 30 juin 2022,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et son annexe.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

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Informations générales sur le produit	
Nom du produit	ETHOSAT SC
Type de produit	Produit de référence
Titulaire	ADAMA FRANCE SAS 33 rue de Verdun 92156 SURESNES France
Formulation	Suspension concentrée (SC)
Contenant	500 g/L - éthofumesate
Numéro d'intrant	365-2021.01
Numéro d'AMM	2220656
Fonction	Herbicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 octobre 2032.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le 11/08/2022

DocuSigned by:
Charlotte Grastilleur
AE281AB55A42454...

Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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ANNEXE : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	**Contenance**
Bouteilles en polyéthylène haute densité	1 L
Bidons en polyéthylène haute densité	5 L ; 10 L ; 15 L ; 20 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
EUH208 : Contient 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique. Pour les phrases P se référer à la règlementation en vigueur. **Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.**	

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Liste des usages autorisés
En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
15055911 Betterave industrielle et fourragère*Désherbage	**2 L/ha**	**1/an**	entre les stades BBCH 10 et BBCH 37	F (BBCH 37)	20 (dont DVP 5)	-	-	Non concerné
	Fractionnement obligatoire en 3 à 5 applications, à la dose maximale de 0,65 L/ha par application, sans dépasser 2 L/ha et avec un intervalle de 5 jours entre les applications.							
16175901 Betterave potagère*Désherbage	**2 L/ha**	**1/an**	entre les stades BBCH 10 et BBCH 37	F (BBCH 37)	20 (dont DVP 5)	-	-	Non concerné
	Fractionnement obligatoire en 3 à 5 applications, à la dose maximale de 0,65 L/ha par application, sans dépasser 2 L/ha et avec un intervalle de 5 jours entre les applications.							
00607008 Porte graine - Betterave industrielle et fourragère*Désherbage	**2 L/ha**	**1/an**	entre les stades BBCH 10 et BBCH 37	F (BBCH 37)	20 (dont DVP 5)	-	-	Non concerné
	Fractionnement obligatoire en 3 à 5 applications, à la dose maximale de 0,65 L/ha par application, sans dépasser 2 L/ha et avec un intervalle de 5 jours entre les applications.							

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19335901 PPAM - non alimentaires*Désherbage	**1 L/ha**	**2/an**	entre les stades BBCH 10 et BBCH 37	Non applicable	20 (dont DVP 5)	-	5	Non concerné
	Intervalle minimum entre les applications : 5 jours.							

DVP : Dispositif Végétalisé Permanent.

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
19155901 Fines Herbes*Désherbage	2 L/ha	1/an	50
	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus.		

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
00517053 Infusions*Désherbage	2 L/ha	1/an	35
	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus.		

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles ;
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage) ;
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;

• pendant l'application

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

Pour le travailleur, porter

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1.

Délai de rentrée en application de l'arrêté du 4 mai 2017 :

- 6 heures.

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Protection des personnes présentes et des résidents (au sens du règlement (UE) N°284/2013)

Respecter une distance d'au moins 3 mètres entre la rampe de pulvérisation et :
- l'espace fréquenté par les personnes présentes lors du traitement ;
- l'espace susceptible d'être fréquenté par des résidents.

Respect des limites maximales de résidus (LMR)

- Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

- Afin d'éviter la présence de résidus dans les cultures suivantes, ne pas implanter de cultures de racines.

Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.
- SPe 1 : Pour protéger les eaux souterraines, suite à une utilisation sur betterave, ne pas appliquer ce produit ou tout autre produit contenant de l'éthofumesate plus d'une année sur deux.

Protection de la faune

- Spe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau.

Protection de la flore

- SPe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente pour l'usage "PPAM - non alimentaires".

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
- Fournir les résultats de l'étude en cours de réalisation, concernant la stabilité au stockage pendant 2 ans, à température ambiante.	24	-

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- Pour prévenir tout risque éventuel de phytotoxicité, préciser les conditions optimales d'application sur betterave potagère ainsi que par rapport aux cultures adjacentes.

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

1G.1 - Projet d'étiquette - ETHOS