

REGISTRATION REPORT

Part A

Risk Management

Product code: E00001

Product name(s): SULFUR ULTRA

Chemical active substance(s):

Sulphur, 200 g/L

Southern Zone

Zonal and Interzonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: Evergreen Garden Care France SAS

Date: december 2021

Table of Contents

1	Details of the application	4
1.1	Application background	4
1.2	Letters of Access	5
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims	5
2	Details of the authorisation decision	5
2.1	Product identity	5
2.2	Conclusion	6
2.3	Substances of concern for national monitoring	6
2.4	Classification and labelling	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011	7
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	7
2.5	Risk management	7
2.5.1	Restrictions linked to the PPP	8
2.5.2	Specific restrictions linked to the intended uses	8
2.6	Intended uses (only NATIONAL GAP)	9
3	Background of authorisation decision and risk management	12
3.1	Physical and chemical properties (Part B, Section 2)	12
3.2	Efficacy (Part B, Section 3)	12
3.3	Methods of analysis (Part B, Section 5)	12
3.3.1	Analytical method for the formulation	12
3.3.2	Analytical methods for residues	12
3.4	Mammalian toxicology (Part B, Section 6)	12
3.4.1	Acute toxicity	13
3.4.2	Operator exposure	13
3.4.3	Bystander exposure	14
3.4.4	Resident exposure	14
3.4.5	Combined exposure	14
3.5	Residues and consumer exposure (Part B, Section 7)	15
3.6	Environmental fate and behaviour (Part B, Section 8)	15
3.7	Ecotoxicology (Part B, Section 9)	15
3.8	Relevance of metabolites (Part B, Section 10)	15
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	16
5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation	16
5.1.1	Post-authorisation monitoring	16

5.1.2	Post-authorisation data requirements	16
Appendix 1	Copy of the product authorisation	17
Appendix 2	Copy of the product label	23

PART A

RISK MANAGEMENT

1 Details of the application

The company Evergreen Garden Care France SAS has requested a marketing authorisation in France for the product SULFUR ULTRA (formulation code: E00001), containing 200 g/L Sulphur as a fungicide for amateur 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 Evergreen Garden Care France SAS's application submitted on 23/11/2020 to market SULFUR ULTRA (E00001) in France (product uses described under point 2.3). France acted as a zonal and interzonal 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 Europe.

The present application (2020-3909) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009¹, the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of Europe, taking into account the worst-case uses ("risk envelope approach")². 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 SULFUR ULTRA (E00001) has been made using endpoints agreed in the EU peer review of Sulphur. It also includes assessment of data and information related to SULFUR ULTRA (E00001) 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.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011³, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of SULFUR ULTRA (E00001).

¹ 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

² 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](#)

³ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

1.2 Letters of Access

The applicant has provided a letter of access for active substance and PPP data. This letter of access is available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: « The following tests have been submitted: product data on physical and chemical properties, analytical methods, toxicology (only skin sensitization) and efficacy as SULFUR ULTRA (E00001) is a new product ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of SULFUR ULTRA (E00001), 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	E00001
Product name in MS	SULFUR ULTRA
Authorisation number	2210939
Kind of use	Fungicide
Low risk product (article 47)	No
Function	Fungicide
Applicant	Evergreen Garden Care France SAS
Active substance(s) (incl. content)	200 g/L Sulphur
Formulation type	Suspension Concentrate [Code: SC]

Packaging	HDPE Flatbram 140 mL HDPE Flatbram 280 mL HDPE Flatbram 540 mL HDPE Flatbram 1000 mL HDPE Bettix 125 mL HDPE Bettix 250 mL HDPE Bettix 500 mL HDPE Bettix 1000 mL f-HDPE Bettix 125 mL f-HDPE Bettix 250 mL f-HDPE Bettix 500 mL f-HDPE Bettix 1000 mL PET Bormioli 20 mL HDPE YOGI 250 mL-drainback cap HDPE YOGI 500 mL-drainback cap HDPE YOGI 1000 mL-drainback cap HDPE YOGI 250 mL-Luna system HDPE YOGI 500 mL- Luna system HDPE YOGI 1000 mL- Luna system HDPE Unidose Tube 20 mL Other packagings proposed by the applicant are not accepted by zRMS for non-professional users : - HDPE/PET Bormioli 100 mL - HDPE/PET Levington 0,1 L, 0,25 L, 0,5 L, 1 L with dosing cap above a non dosing cap
Coformulants of concern for national authorisations	--
Restrictions related to identity	--
Mandatory tank mixtures	--
Recommended tank mixtures	--

2.2 Conclusion

The evaluation of the application for SULFUR ULTRA (E00001) 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:	Not classified for human health Not classified for the environment
Hazard pictograms:	-

Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	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

	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 2017⁴ 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.

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.

Finally, the French Order of 12 April 2021⁵ 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 extrapolation⁶ 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.

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/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

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

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.
Integrated pest management (IPM)/sustainable use:	
-	
Environmental protection	
	To protect aquatic organisms do not apply at least 5 meters away from any surface water bodies (well, pond, stream, river, etc.).
	Do not discharge into the sink, gutter or any other water hole the non-used container leftovers and the sprayer washing water.
	Do not apply in the presence of pollinating insects or auxiliaries (bees, bumblebees, ladybugs, chrysopes, hoverflies...).
Other specific restrictions	
Re-entry period	Wait until the treated zone or plants have dried.
Storage	-
Risk mitigation measures	-
Agricultural recommendations	Specify the conditions of use on ornamental crops to prevent any possible risk of phytotoxicity.

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 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as izRMS. 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.

PPP (product name/code):	E00001	Formulation type:	Suspension concentrate [Code: SC]
Active substance 1:	Sulphur	Conc. of as 1:	200 g/L
Active substance 2:	--	Conc. of as 2:	--
Safener:	--	Conc. of safener:	--
Synergist:	--	Conc. of synergist:	--
Applicant:	Evergreen Garden Care France SAS	Professional use:	<input type="checkbox"/>
Zone(s):	Southern/Europe	Non-professional use:	<input checked="" type="checkbox"/>
Verified by MS:			

Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: zRMS conclusion
					Method / Kind	Timing / Growth stage of crop & sea- son	Max. number a) per use b) per crop/ season	Min. interval between appli- cations (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		
Southern Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	All woody ornamentals and ornamental shrubs (Roses and Flowers), for example: NNNZG; NNNZA; NNNGB; NNNZT; ROSXM; ROSSS	Fn Gn	Rose black spot (<i>Diplocarpon rosae</i> DIPCRO)	Foliar sprayer: Covering both sides of leaves of infested plants	During vegetation growth (April to September) BBCH 15-93	a) 6 b) 6	Interval min 7 days	a) 20 L product/ha b) 120 L product / ha	a) Sulphur 4 kg/ha b) Sulphur 24 kg/ha	Treatment to run-off point depending on vegetation (max 1000 L/ha)	n.a.	Acceptable
2	FR	All woody ornamentals and ornamental	Fn Gn	Rusts including but not limited to examples:	Foliar sprayer: Covering both	During vegetation growth	a) 6 b) 6	Interval min 7 days	a) 20 L product/ha	a) Sulphur 4 kg/ha	Treatment to run-off	n.a	Not acceptable (efficacy)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: zRMS conclusion
					Method / Kind	Timing / Growth stage of crop & sea- son	Max. number a) per use b) per crop/ season	Min. interval between appli- cations (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		
		shrubs (Roses and Flowers), for exam- ple: NNNZG; NNNZA; NNNGB; NNNZT; ROXXM; ROSSS		<i>Phragmidium mucrona- tum</i> [PHRAMU], <i>Phrag- midium tuberculatum</i> [PHRATU]	sides of leaves of infested plants	(April to Sep- tember) BBCH 15-93			b) 120 L product / ha	b) Sulphur 24 kg/ha	point de- pending on vegetation (max 1000 L/ha)		
3	FR	All non woody orna- mentals, for exam- ple: NNNZD; NNNZA; NNNGB; NNNZI; NNNZT	Fn Gn	Rusts including but not limited to examples: <i>Phragmidium mucrona- tum</i> [PHRAMU], <i>Phrag- midium tuberculatum</i> [PHRATU]	Foliar sprayer: Covering both sides of leaves of infested plants	During vegeta- tion growth (April to Sep- tember) BBCH 15-93	a) 6 b) 6	Interval min 7 days	a) 20 L product/ ha b) 120 L product / ha	a) Sulphur 4 kg/ha b) Sulphur 24 kg/ha	Treatment to run-off point de- pending on vegetation (max 1000 L/ha)	n.a.	Not acceptable (efficacy)
4	FR	All woody ornamen- tals and ornamental shrubs (Roses and Flowers), for exam- ple: NNNZG; NNNZA; NNNGB; NNNZT; ROXXM; ROSSS	Fn Gn	Powdery mildews includ- ing but not limited to ex- amples: <i>Sphaerotheca pannosa</i> [SPHRPA], <i>Erysiphe</i> sp. [ERYSSP]	Foliar sprayer: Covering both sides of leaves of infested plants	During vegeta- tion growth (April to Sep- tember) BBCH 15-93	a) 6 b) 6	Interval min 7 days	a) 20 L product/ ha b) 120 L product / ha	a) Sulphur 4 kg/ha b) Sulphur 24 kg/ha	Treatment to run-off point de- pending on vegetation (max 1000 L/ha)	n.a.	Acceptable
5	FR	All non woody orna- mentals, for exam- ple: NNNZD; NNNZA; NNNGB; NNNZI; NNNZT	Fn Gn	Powdery mildews includ- ing but not limited to ex- amples: <i>Sphaerotheca pannosa</i> [SPHRPA], <i>Erysiphe</i> sp. [ERYSSP]	Foliar sprayer: Covering both sides of leaves of infested plants	During vegeta- tion growth (April to Sep- tember) BBCH 15-93	a) 6 b) 6	Interval min 7 days	a) 20 L product/ ha b) 120 L product / ha	a) Sulphur 4 kg/ha b) Sulphur 24 kg/ha	Treatment to run-off point de- pending on vegetation (max 1000 L/ha)	n.a.	Acceptable

Home and garden use

20 mL/L application rate (4 g/10m²)

e.g: Plant height <50 cm: 600 L/ha of treated surface , Plant height >50 cm: 1000 L/ha of treated surface

E00001 / SULFUR ULTRA

Part A - National Assessment

FRANCE DEPR version

Page 11/24

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(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	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	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.	12	If water volume range depends on application equipment (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)

SULFUR ULTRA (E00001) is a suspension concentrate (SC) formulation type. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The product is homogenous and free flowing white-cream opaque liquid with no signs of separation, sedimentation or suspended solids. It is not considered explosive or oxidising. The product is not flammable. No flashpoint was observed up to a 100 °C. It has a self-ignition temperature of 269°C. In aqueous solution (1%), it has a pH value around 6.48 (HDPE) and 6.50 (PET). 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 active ingredient content nor the technical properties were changed when stored in HDPE or PET. Other claimed packaging are also acceptable considering the formulation type. Its technical characteristics are acceptable for a Suspension Concentrate formulation, except for persistence of foam where no data was provided.

3.2 Efficacy (Part B, Section 3)

The efficacy level of SULFUR ULTRA (E00001) is considered acceptable for the requested uses, except for the use on black spot on woody and not woody plants and rusts.

Considering the insufficient data and the absence of possible extrapolation for all uses on black spot on woody and not woody crops and on rusts, the evaluation of the level of efficacy of the product SULFUR ULTRA (E00001) for these uses can't be considered as acceptable.

The phytotoxicity level of SULFUR ULTRA (E00001) is considered acceptable for the requested uses.

The risk of negative impact on succeeding crops and adjacent crops are considered negligible.

The risk of development resistance or appearance to sulphur used in home garden should not be increased in comparison with the professional uses.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

A validated analytical method for the determination of the active substance in the preparation is available. As it contains no relevant impurity, no analytical method is required.

3.3.2 Analytical methods for residues

As no residue definition has been set for this active substance, no analytical method is required.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment:

Active substance(s) (incl. content)	Sulphur 200 g/L
AOEL systemic	AOEL not applicable ⁷ background level: 26 mg/kg bw/day
AAOEL	None
Inhalation absorption	100%
Oral absorption	100%
Vapour pressur	9.8 x 10 ⁻⁵ Pa at 20°C
Dermal absorption	Concentrate: 10% Dilution: 50% (Default value)

3.4.1 Acute toxicity

SULFUR ULTRA (E00001) containing 200 g/L/kg sulphur has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the skin or eye and is not a skin sensitizer.

3.4.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using EFSA model⁸ and the French UPJ model 2009-2010⁹ dedicated to non-agricultural areas :

		Sulphur	
Model data	Level of PPE	Total absorbed dose	% of systemic AOEL
EFSA model			
Manual-Knapsack, down-ward spraying	Potential	2.06 mg kg bw/day	7.91
Manual-Knapsack, up-ward spraying	Potential	0.76 mg kg bw/day	2.93
UPJ model (Garden exposure model v3_6) Trigger sprayer Application rate: 20 mLproduct / 10m² min. water volume Plant height <50 cm = 0.06 L/m² min. water volume Plant height >50 cm = 0.1 L/m²			
Rosebush like plants	Without gloves	8990 µg/kg bw/day	0.58
Flower bed, vegetable crop (<60 cm)	Without gloves	11467 µg/kg bw/day	0.74

⁷ Review report of Sulphur SANCO/2676/08 – final 13 July 2012

⁸ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

⁹ Studies and models that can be used to estimate operator exposure during the use of plant protection products in non- agricultural areas. Report from expert group « produits phytosanitaires : substances et préparations chimiques » Working group "évaluation de l'exposition des utilisateurs de produits phytopharmaceutiques en zones non agricoles" - June 2011

Hedges and high crops (>60 cm)	Without gloves	8990 µg/kg bw/day	0.58	
-----------------------------------	----------------	-------------------	-------------	--

According to the model calculations, it can be concluded that the risk for the operator using SULFUR ULTRA (E00001) is acceptable without personal protective equipment.

The proposed packaging has been described in sufficient detail, and its compliance can therefore be finalised.

In summary, compliance with the provisions of French regulation relating to the conditions of authorisation of plant protection products by non-professional users is considered to be finalised only for the following packaging:

- Bottle HDPE with dosing cap (0.125 L, 0.14 L, 0.25 L, 0.28 L, 0.5 L, 0.54 L, 1 L)
- Unidose tube HDPE (20 mL)
- Bottle unidose PET (20 mL)

Other packaging proposed by the applicant are not accepted by zRMS for non-professional users:

- Bottle HDPE/PET Bormioli 100 mL
- Bottle HDPE/PET Levington (0.1 L, 0.25 L, 0.5 L, 1 L) with dosing cap above a non dosing cap. Worker exposure

SULFUR ULTRA (E00001) is intended to be used by amateurs during home garden application. In this case of the non-professional user, the worker is also the user. Therefore, the assessment of worker exposure is covered by the operator exposure. It will be necessary to ensure complete drying of the treated area or of treated plants before handling them.

3.4.3 Bystander exposure

In the context of use by non-professionals, the assessment for bystanders is considered to be covered by that for the operator (user).

3.4.4 Resident exposure

Resident exposure was assessed according to the EFSA model, considering recreational exposure, without mitigation measures.

EFSA model – Recreational exposure Application rate: 6 x 4 kg as./ha*		
	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Child	2.40	9.25
Adult	1.01	3.89

* Covers all claimed uses

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

3.4.5 Combined exposure

Not relevant. The product contains only one active substance.

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

As trees and shrubs, roses, flowering crops and green plants are not intended for food or feed use, the assessment of residue levels and consumer risk is not relevant.

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 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 sulphur 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 or specific approaches for home and garden uses, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC soil, PEC_{sw} and PEC_{sed} derived for the active substance are used for the ecotoxicological risk assessment.

PEC_{gw} for sulphates do not occur at levels exceeding those mentioned in regulation EU No 546/2011. Therefore, no unacceptable risk of groundwater contamination 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 substance were used 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 risk to birds is considered acceptable for the intended uses. For aquatic organisms, the risk can be considered as acceptable, with following mitigation:

For bees, the risk assessment provided by the applicant is based on the EFSA Guidance Document¹⁰.

The risk to bees is not acceptable at Tier 1 for all intended uses and no higher-tier studies were available at the time of evaluation. Therefore, the risk assessment for bees cannot be finalised.

3.8 Relevance of metabolites (Part B, Section 10)

No assessment according to the SANCO/221/2000 guidance document was needed. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

¹⁰ EFSA Journal 2013;11(7):3295 EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)

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

The active substance sulphur 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 following data would have been required to update the dossier:
results of the study being conducted on the storage stability for 2 years at room temperature.

Appendix 1 Copy of the product authorisation

DocuSign Envelope ID: 89A6279C-A9A2-43E8-9FF2-D91F7045BFEC



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 réglementaire,

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique **SULFUR ULTRA***

de la société EVERGREEN GARDEN CARE FRANCE SAS

enregistrée sous le n°2020-3909

Vu les conclusions de l'évaluation de l'Anses du 25 octobre 2021,

Vu les éléments complémentaires transmis par la direction en charge de l'évaluation des produits réglementés de l'Anses le 9 décembre 2021,

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.

DocuSign Envelope ID: 89A6279C-A9A2-43E8-9FF2-D91F7045BFEC



Informations générales sur le produit	
Nom du produit	SULFUR ULTRA
Type de produit	Produit de référence
Titulaire	EVERGREEN GARDEN CARE FRANCE SAS 4 allée des Séquoias 69760 LIMONEST France
Formulation	Suspension concentrée (SC)
Contenant	200 g/L - soufre
Numéro d'intrant	1033-2020.01
Numéro d'AMM	2210939
Fonction	Fongicide
Gamme d'usage	Amateur / emploi autorisé dans les jardins

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 décembre 2023.

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 28/12/2021

DocuSigned by:

AE281A955A42454...

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

DocuSign Envelope ID: 89A6279C-A9A2-43E8-9FF2-D91F7045BFEC



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 munies d'un bouchon doseur ou d'un système auto-doseur	125 mL ; 140 mL ; 250 mL ; 280 mL ; 500 mL ; 540 mL ; 1 L
Bouteilles en polyéthylène haute densité fluoré munies d'un système auto-doseur	125 mL ; 250 mL ; 500 mL ; 1 L
Bouteilles unidoses en polyéthylène téréphtalate	20 mL
Tubes unidoses en polyéthylène haute densité	20 mL

Les bouteilles en polyéthylène téréphtalate/polyéthylène haute densité de 100 mL avec seringue doseuse et les bouteilles en polyéthylène téréphtalate/polyéthylène haute densité de 100 mL, 250 mL, 500 mL et 1 L munies d'un capot doseur par-dessus le bouchon non doseur sont refusées au motif que ces emballages ne permettent pas de garantir une exposition minimale de l'utilisateur non-professionnel.

Classification du produit
La classification retenue est la suivante : Sans classement.
Pour les phrases P se référer à la réglementation 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.

DocuSign Envelope ID: 89A6279C-A9A2-43E8-9FF2-D91F7045BFEC

**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)	Mention abeilles
14053204 Arbres et arbustes* Trt Part.Aer.*Oidium(s)	20 mL/L	6/an		Non applicable	5	-	-	-
Egalement autorisé sous abri. Applications entre avril et septembre. Intervalle minimum entre les applications : 7 jours.								
17403202 Cultures florales et plantes vertes* Trt Part.Aer.*Oidium(s)	20 mL/L	6/an		Non applicable	5	-	-	-
Egalement autorisé sous abri. Applications entre avril et septembre. Intervalle minimum entre les applications : 7 jours.								
17303201 Rosier* Trt Part.Aer.* Maladies des taches noires	20 mL/L	6/an		Non applicable	5	-	-	-
Egalement autorisé sous abri. Applications entre avril et septembre. Intervalle minimum entre les applications : 7 jours.								
17303203 Rosier* Trt Part.Aer.* Oidium(s)	20 mL/L	6/an		Non applicable	5	-	-	-
Egalement autorisé sous abri. Applications entre avril et septembre. Intervalle minimum entre les applications : 7 jours.								

DocuSign Envelope ID: 89A6279C-A9A2-43E8-9FF2-D91F7045BFEC



Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
00002019 Arbres et arbustes*Trt Part.Aer.* Maladies des taches foliaires	20 mL/L	6/an	Non applicable
Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas de déterminer l'efficacité du produit.			
14053203 Arbres et arbustes*Trt Part.Aer.* Rouille(s)	20 mL/L	6/an	Non applicable
Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas de déterminer l'efficacité du produit.			
17403203 Cultures florales et plantes vertes*Trt Part.Aer.* Rouille(s)	20 mL/L	6/an	Non applicable
Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas de déterminer l'efficacité du produit.			
17303210 Rosier*Trt Part.Aer.* Rouille(s)	20 mL/L	6/an	Non applicable
Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas de déterminer l'efficacité du produit.			

DocuSign Envelope ID: 89A6279C-A9A2-43E8-9FF2-D91F7045BFEC



Conditions d'emploi du produit

Délai de rentrée :

- Attendre le séchage complet de la zone traitée.

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

- Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds d'emballages non utilisés et les eaux de lavage du pulvérisateur.

Protection de la faune

- Pour protéger les organismes aquatiques, ne pas appliquer à moins de 5 mètres d'un point d'eau (puits, bassin, mare, ruisseau, rivière, fossé...)
- Ne pas appliquer en présence d'insectes pollinisateurs ou auxiliaires (abeilles, bourdons, coccinelles, chrysopes, syrphes...).

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 :

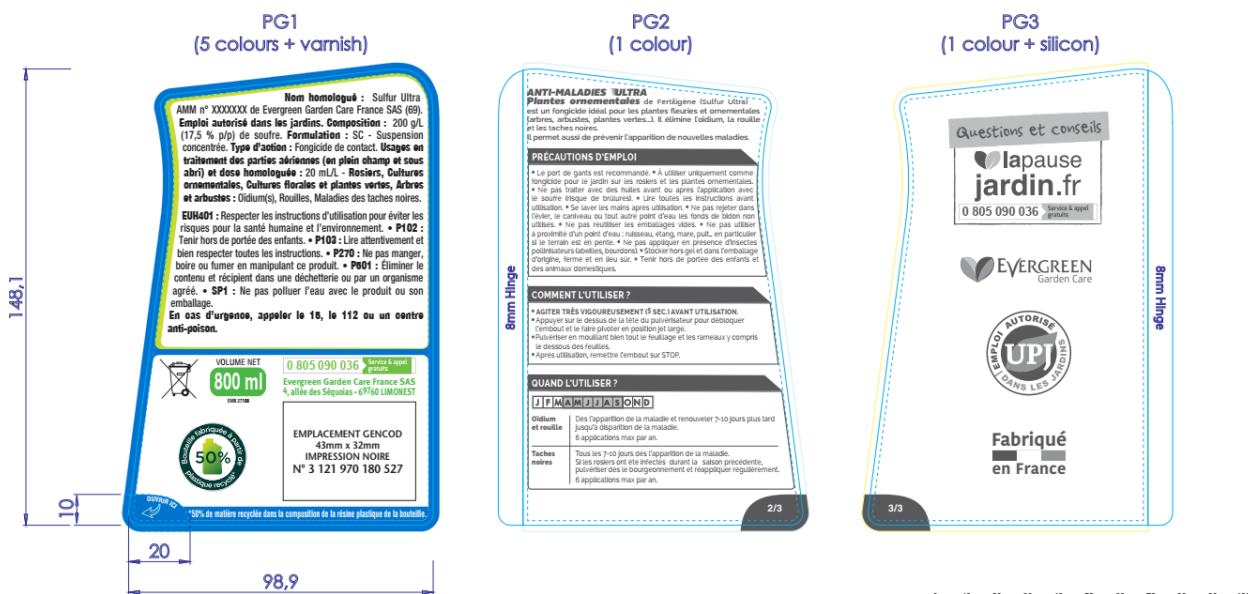
- Contient de la 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique.
- Préciser les conditions d'utilisation sur cultures ornementales afin de prévenir tout risque éventuel de phytotoxicité.

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.




 CREATIVE BRAND AGENCY 159, rue Gallieni - 92100 Boulogne-Billancourt - France T : +33 (0)1 53 70 75 00 - www.hotshop.fr	Client : FERTILIGÈNE Exe : Fertiligène Anti-Maladies Ultra_800ml FSUPAL800_Recto Dossier : 8CQ200107	Impression : 5 couleurs <div> <div> Cyan</div> <div> Magenta</div> <div> Yellow</div> <div> Noir</div> </div> <div> <div> PMS 285 C</div> </div>
	Imprimeur : -	
Date : 19/10/2020 Relecture : 03 Livraison EXE le :	Logiciels : Illustrator CC - Photoshop CC Infographiste : PV	
Impression : <input type="radio"/> Offset <input type="radio"/> Flexo <input type="radio"/> Helio <input type="radio"/> Autre Support : <input checked="" type="radio"/> Blanc <input type="radio"/> Transparent <input type="radio"/> Aluminisé		Couleurs composées : <div> <div> M.16% Y.100%</div> <div> C.50% Y.100%</div> <div> C.25% - Y.98% (Cible PMS 381 C)</div> </div>
Commentaires : Une étape de photogravure est indispensable. Import HD.		Logo FERTILIGÈNE : <div> <div> Magenta 80% à 100% en surimpression du cyan à 100%</div> <div> Ombres N.50% en surimpression</div> </div> <div> <div> C.100% M.20% Y.100%</div> <div> À réaliser par le photographe : C.100% + M.20% en surimpression sur le PMS 381C.</div> </div>



Print Guidelines

1. Maximum number of colours shown above each relevant page
2. Colour used on inner pages must be the same on all pages, and must include the adhesive-kill area in the corner
3. Colour used on inner pages must also be one of the colours used on Page 1

[illegible]



CREATIF BRAND AGENT

Couleur : ENVOI GREEN

Exe : Fertiliser

Art-Matériau : Plastiki_B001

Art-Matériau : Verre

Couleur : BCG002H1

Impression : -

Impression : 5 couleurs

☒ Cyan **PMS 286 C**

☐ Magenta

☐ Yellow

☐ Noir

☐ Noir 85
(Pages Intérieures)

Date : 27/10/2020 Rétrochec : 3

Livraison EXKE le :

Impression : ☐ Offset ☐ Flexo ☐ Helix ☐ Autre

Support : ☒ Stanc ☐ Transparent ☐ Humidifié

Commentaires :

Une Etape de photogravure est indispensable.

ATTENTION : Ce document est un document d'éducation et non un document prêt à l'envoi. Les recouvrements, suppressions de couleurs et calage doivent être notés à l'arrivée sur le matériel.