

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: S20001**

**Product name: SULFURMAX**

**Chemical active substance:**

**sulphur, 4g/L**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(New application)**

**Applicant: Evergreen Garden Care France SAS**

**Date: 26/12/2019**

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## **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 SULFURMAX (product code: S20001), containing 4g/L sulphur as a fungicide for non-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).

Appendix 3 of this document contains a copy of the letter(s) of access.

#### **1.1 Application background**

The present registration report concerns the evaluation of Evergreen Garden Care France SAS's application to market SULFURMAX (S20001) 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 MSs of the Southern zone.

The present application (2018-3404) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009<sup>1</sup>, the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs Southern zone for field uses, taking into account the worst-case uses ("risk envelope approach")<sup>2</sup>. 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 SULFURMAX (S20001) have been made using endpoints agreed in the EU peer review of sulphur. It also includes assessment of data and information related to SULFURMAX (S20001) 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 546/2011<sup>3</sup>, 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 SULFURMAX (S20001).

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<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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

Available upon request.

## 1.3 Justification for submission of tests and studies

According to the applicant: “All tests and studies were prepared and submitted in support of the assessment as required according to 284/2013 EU”.

## 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of SULFURMAX (S20001), 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	S20001.
Product name in MS	SULFURMAX.
Authorisation number	2190874
Low risk (article 47)	No.
Function	Fungicide.
Applicant	Evergreen Garden Care France SAS.
Active substance(s) (incl. content)	4g/L Sulphur
Formulation type	Other liquids to be applied undiluted [code: AL].
Packaging	HDPE (0.8 L; 1 L ; 1.2 L); HDPE (2.5 L; 3 L; 5 L); PET (0.8 L – 1 L). All containers with a trigger spray. HDPE (2.5 L ; 5 L) with a pre pressure spray. Non-professional user .
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 SULFURMAX (S20001) 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:	No classification regarding human health.
Hazard pictograms:	-
Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
	Given the diversity of species and varieties of ornamental crops, it is advisable to test the phytotoxicity of SULFURMAX (S20001) on some plants of the same variety, and at the same stage of development, before using the product on a larger scale.
	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction [EUH208].

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.
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### 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<sup>4</sup> 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;
- 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

<sup>4</sup> 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 <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte>

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 26 March 2014<sup>5</sup> provides that:

- an authorisation granted for a “reference” crop applies also for “linked” crops, unless formally stated in the Decision
- the “reference” and “linked” 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<sup>6</sup> 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.

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	
	Do not dispose of unused spray in the sink, gutter or any other water point.
	Do not treat when bees are visiting the area
Other specific restrictions	
Re-entry period	Wait for complete drying of the treated area

### 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.

<sup>5</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo>

<sup>6</sup> SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

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## 2.6 Intended uses (only NATIONAL GAP)

**Please note:** The GAP Table below reports the intended uses proposed by the applicant, 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.

GAP rev. 1, date: 2019-12-26

PPP (product name/code): SULFURMAX (S20001)

Formulation type: AL <sup>(a, b)</sup>

Active substance 1: sulphur

Conc. of a.s. 1: 4g/L <sup>(c)</sup>

Applicant: Evergreen Garden Care France SAS

Professional use: ☐

Zone(s): Southern Zone <sup>(d)</sup>

Non-professional use: ☒

Verified by MS: Yes

Field of use: Fungicide

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/synergis 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)	L product/m² a) max. rate per appl. b) max. total rate per crop/season	g a.s./m² 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	All woody ornamentals and ornamental shrubs (roses and flowers), for example: NNNZG; NNNZA; NNNGB; NNNZT; ROSXM; ROSSS	Fn	Rose black spot ( <i>Diplocarpon rosae</i> DIPCRO)	Foliar sprayer: covering both sides of leaves of infected plants	During vegeta- tion growth (April to Sep- tember) BBCH 15-93	a) 1  b) 6	7	a) 0.1  b) 0.6	a) 0.4  b) 2.4	Ready- to-use product, no dilution required	n.a.	Acceptable
2	FR	All woody ornamentals and ornamental shrubs (roses and flowers), for example: NNNZG; NNNZA; NNNGB; NNNZT; ROSXM; ROSSS	Fn	Rusts including but not limited to examples: <i>Phragmidium mucronatum</i> [PHRAMU], <i>P. tuberculatum</i> [PHRATU]	Foliar sprayer: covering both sides of leaves of infected plants	During vegeta- tion growth (April to Sep- tember) BBCH 15-93	a) 1  b) 6	7	a) 0.1  b) 0.6	a) 0.4  b) 2.4	Ready- to-use product, no dilution required	n.a.	Not acceptable (Lack of efficacy data)



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3	FR	All non-woody ornamentals, for example: NNNZD; NNNZA; NNNGB; NNNZI; NNNZT	Fn	Rusts including but not limited to examples: <i>P. mucronatum</i> [PHRAMU], <i>P. tuberculatum</i> [PHRATU]	Foliar sprayer: covering both sides of leaves of infected plants	During vegetation growth (April to September) BBCH 14-69	a) 1 b) 6	7	a) 0.1 b) 0.6	a) 0.4 b) 2.4	Ready-to-use product, no dilution required	n.a.	<b>Not acceptable</b> (Lack of efficacy data)
4	FR	All woody ornamentals and ornamental shrubs (roses and flowers), for example: NNNZG; NNNZA; NNNGB; NNNZT; ROSXM; ROSSS	Fn	Powdery mildews including but not limited to examples: <i>Sphaerotheca pannosa</i> [SPHRPA], <i>Erysiphe</i> sp. [ERYSSP]	Foliar sprayer: covering both sides of leaves of infected plants	During vegetation growth (April to September) BBCH 15-93	a) 1 b) 6	7	a) 0.1 b) 0.6	a) 0.4 b) 2.4	Ready-to-use product, no dilution required	n.a.	Acceptable
5	FR	All non-woody ornamentals, for example: NNNZD; NNNZA; NNNGB; NNNZI; NNNZT	Fn	Powdery mildews including but not limited to examples: <i>S. pannosa</i> [SPHRPA], <i>Erysiphe</i> sp. [ERYSSP]	Foliar sprayer: covering both sides of leaves of infected plants	During vegetation growth (April to September) BBCH 14-69	a) 1 b) 6	7	a) 0.1 b) 0.6	a) 0.4 b) 2.4	Ready-to-use product, no dilution required	n.a.	Acceptable

**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.
- (c) 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.

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<b>Remarks</b> <b>columns:</b>	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 <sup>3</sup> 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 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)**

SULFURMAX (S20001) is a ready-to-use liquid suspension, classified as an “other liquid to be applied undiluted” (AL). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a white liquid, with no distinctive odour. It is not explosive, has no oxidising properties and is not flammable. No self-ignition temperature could be determined. Neat, it has a pH value of 7.45 at 20°C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0°C and 14 days at 54°C, neither the active substance content nor the technical properties were significantly changed. The spray characteristics were also not altered by storage. A long-term stability study must be provided as a post-authorisation requirement to confirm the expected shelf life of two years at ambient temperature when stored in HDPE or PET.

The technical characteristics are acceptable for an “other liquid” formulation.

The formulation is not classified for the physico-chemical aspect.

#### **3.2 Efficacy (Part B, Section 3)**

Considering the data submitted:

#### **3.3 Efficacy data**

Given the insufficient data and the absence of possible extrapolation for uses on rusts (on woody and non-woody ornamentals) and on foliar spot diseases (on ornamental trees and shrubs), the evaluation of the efficacy of SULFURMAX (S20001) for these uses cannot be finalised. The efficacy level of SULFURMAX (S20001) is considered acceptable for the other uses.

##### **3.3.1 Information on the occurrence or possible occurrence of the development of resistance**

The risk of resistance developing or appearing to sulphur does not require monitoring for the requested uses.

##### **3.3.2 Adverse effects on treated crops**

The phytotoxicity level of SULFURMAX (S20001) is considered acceptable for all the requested uses.

Precautions for use: given the diversity of species and varieties of ornamental crops, it is advisable to test the phytotoxicity of SULFURMAX (S20001) on some plants of the same variety, and at the same stage of development, before using the product on a larger scale.

### 3.3.3 Observations on other undesirable or unintended side-effects

The risk of adverse effects on succeeding crops is considered negligible. The risk of adverse effects on adjacent crops is considered acceptable.

## 3.4 Methods of analysis (Part B, Section 5)

### 3.4.1 Analytical method for the formulation

An analytical method for the determination of the active substance in the formulation is available and validated. As the active substance sulphur does not contain any relevant impurity, no pertinent analytical method is required.

### 3.4.2 Analytical methods for residues

Considering the intended uses (ornamental plants), and as no MRL is required for, analytical methods for the determination of its residues in plants and foodstuffs of animal origin are not necessary.

## 3.5 Mammalian toxicology (Part B, Section 6)

### Endpoints used in risk assessment

Active substance: <b>sulphur</b>			
ADI	N/A.		EFSA 2008
ARfD	N/A.		
AOEL	Replaced by average sulphur background intake value: 26 mg/kg body weight/day*		
AAOEL	N/A.		
Dermal absorption	Based on the Peer review of the pesticide assessment of the active substance sulphur (EFSA Scientific Report (2008) 221, 1-70):		
		Concentrate (used in formulation) 4g/L	Spray dilution (used in formulation – product applied undi- luted) 4g/L
	<b>Dermal absorption end- points %</b>	<b>10</b>	<b>10</b>
Oral absorption (%)			<b>100</b>

\*average sulphur background intake value was 26 mg/kg body weight/day [overall intake: 1.6 g/person/day, US National Academy of Medicine].

### 3.5.1 Acute toxicity

SULFURMAX (S20001), containing 4g/L sulphur, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

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### 3.5.2 Operator exposure

Summary of critical use patterns:

Crop type	F/G <sup>7</sup>	Equipment <i>Application method</i>	Maximum application rate (product) [g a.s./ha]	Minimum volume water (L/ha)
1-5 All woody and non-woody ornamentals and ornamental shrubs (roses and flowers)	F	Foliar sprayer	Sulphur 4g/L (0.4 g /ha)	Ready-to-use

Considering the proposed home garden use, operator systemic exposure was estimated using the French study from UPJ 2009-2010, EFSA<sup>8</sup> and UK models:

Crop	Equipment		PPE and/or working coverall	% of average sulphur background intake value: [26 mg/kg bw/d; substitute for AOEL]
		AOEM: EFSA model		
Ornamentals	Foliar sprayer		-	0.74
		UPJ: French model		
Rose-bush-like plants	Foliar sprayer		-	0.03
Flower bed, vegetable crop (< 60 cm)	Foliar sprayer		-	0.05
Hedges and high crops (> 60 cm)	Foliar sprayer		-	0.05
		UK model: trigger spray surface treatment		
-	Foliar sprayer		-	0.0

According to the model calculations, it may be concluded that the risk for the non-professional using SULFURMAX (S20001) is acceptable without personal protective equipment.

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

<sup>7</sup> Open field or glasshouse.

<sup>8</sup> AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874).

Refill container (2.5L ; 3L ; 5L) were not acceptable for non-professional user.

In summary, compliance with the provisions of French Decree No. 2010-1755 of 30 December 2010 and Orders of 30 December 2010 relating to the use of certain plant protection products by non-professional users, is considered to be finalised.

### **3.5.3 Worker exposure**

SULFURMAX (S20001) 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 of the product. It will be necessary to ensure complete drying of the treated area or of treated plants before handling them.

### **3.5.4 Bystander and resident exposure**

Recreational (resident) exposure was assessed according to the EFSA model. Exposure is estimated to be 2.59% and 0.78% of the substitute AOEL of sulphur for children and adults, respectively. It may be concluded that there is no unacceptable risk anticipated for recreational exposure.

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

## **3.6 Residues and consumer exposure (Part B, Section 7)**

Not relevant – use on non-comestible plants only.

## **3.7 Environmental fate and behaviour (Part B, Section 8)**

The fate and behaviour in the environment of S20001 has been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate predicted environmental concentrations (PECs) 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 values of sulphur in surface water and groundwater have been assessed according to FOCUS guidance documents, and the endpoints established in the EU review or agreed in the assessment based on new data provided.

The intended uses of the product SULFURMAX (S20001) are limited to amateur home-garden uses (no professional uses), therefore PEC<sub>soil</sub> calculations are not required in this specific case.

The results for PEC<sub>sw</sub> and PEC<sub>sed</sub> values for sulphur are used for the ecotoxicological risk assessment.

PEC<sub>gw</sub> values for sulfates do not exceed the trigger of 250mg/L (Directive 98/83/CE<sup>9</sup>). Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

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<sup>9</sup> Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

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

### **3.8 Ecotoxicology (Part B, Section 9)**

#### **3.8.1 Effects on terrestrial vertebrates**

Applicable for packaging other than ready-to-use trigger sprayer:

The TER<sub>A</sub> values at the first-tier exceed the trigger value of 10, indicating that SULFURMAX (S20001) applied according to the intended use poses an acceptable acute risk to birds.

No long-term assessment for birds exposed to S20001 was performed. The long-term risk to birds can be considered acceptable, since available acute and short-term toxicity studies demonstrate the low toxicity of sulphur to birds.

No risk assessment of secondary poisoning via the terrestrial and aquatic food chain is required for S20001, since Sulphur bio-accumulation is not expected. There is no risk expected for birds exposed to the active substance through consumption of contaminated water.

For terrestrial vertebrates other than birds, no risk assessment was performed, given the home-garden (amateur) uses and since the formulation is used as a foliar spray.

For this product in a ready-to-use sprayer, considering the packaging type and the application method, exposure of terrestrial vertebrates to active substance is considered negligible. Consequently, no risk assessment for terrestrial vertebrate wildlife is deemed necessary.

#### **3.8.2 Effects on aquatic species**

For the same reasons as terrestrial vertebrates, exposure of the surface water compartment to active substance is considered negligible. Consequently, no risk assessment for aquatic organisms is deemed necessary.

For packaging other than ready-to-use trigger sprayer, no unacceptable risk is expected for aquatic organisms for the intended uses.

#### **3.8.3 Effects on bees**

An acceptable acute and chronic risk for adult honeybees is expected from the use of S20001 according to the intended uses.

Sufficient data on the effects of S20001 on honeybee development including emergence of honeybee larvae are not available. Thus the chronic risk for honeybee larvae cannot be finalised.

#### **3.8.4 Effects on other arthropod species other than bees**

No risk assessment was performed given the home and garden (amateur) uses.

### **3.8.5 Effects on soil organisms**

No risk assessment was performed given the home and garden (amateur) uses.

### **3.8.6 Effects on non-target terrestrial plants**

No risk assessment was performed given the home and garden (amateur) uses.

### **3.8.7 Effects on other terrestrial organisms (Flora and Fauna)**

Not required.

## **3.9 Relevance of metabolites (Part B, Section 10)**

Not relevant.

## **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**

None.



## Appendix 1 Copy of the product authorisation



### 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 **SULFURMAX***

*de la société **Evergreen Garden Care France SAS***

*enregistrée sous le **n°2018-3404***

*Vu les conclusions de l'évaluation de l'Anses du 8 novembre 2019,*

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 ses annexes.

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.



Informations générales sur le produit	
Nom du produit	SULFURMAX
Type de produit	Produit de référence
Titulaire	Evergreen Garden Care France SAS 21 chemin de la Sauvegarde 69130 ECULLY France
Formulation	Autre liquide (AL)
Contenant	4 g/L - soufre
Numéro d'intrant	755-2018.01
Numéro d'AMM	2190874
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 2021.

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.

**Attention : à compter du 01/01/2019, la mise sur marché, la délivrance, l'utilisation et la détention des produits de la gamme d'usages « amateur » sont exclusivement réservées aux utilisateurs professionnels, en application de l'article L. 253-7-III du Code rural et de la pêche maritime, à l'exception des produits de la gamme amateurs inscrits sur la liste des produits de biocontrôle, des produits utilisables en agriculture biologique ou des produits à faible risque. Cette interdiction ne s'applique pas aux traitements et mesures nécessaires à la destruction et à la prévention de la propagation des organismes nuisibles mentionnés à l'article L. 251-3, en application de l'article L. 251-8 du même Code.**

A Maisons-Alfort le,

26 DEC. 2019

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





## ANNEXE I : Modalités d'autorisation du produit

<b>Vente et distribution</b>	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Bouteilles en polyéthylène haute densité avec pulvérisateur à gâchette	800 mL ; 1 L ; 1,2 L
Bouteilles en polyéthylène téréphtalate avec pulvérisateur à gâchette	800 mL ; 1 L
Bidons en polyéthylène haute densité avec pulvérisateur à gâchette	2,5 L ; 3 L ; 5 L
Bidons en polyéthylène haute densité avec pulvérisateur à pression préalable	2,5 L ; 5 L

Les bidons « recharge » de 2,5 L, 3 L, et 5 L en polyéthylène haute densité sont refusés car ils ne permettent pas de garantir une exposition minimale de l'utilisateur.

<b>Classification du produit</b>
La classification retenue est la suivante : Sans classement.
Pour les phrases P se référer à la réglementation en vigueur.
EUH208 : Contient de la 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique.
<b>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.</b>



### 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 arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
<b>14053204</b> Arbres et arbustes*Trt Part.Aer.* Oïdium(s)	100 mL/m <sup>2</sup>	6/an	entre les stades BBCH 15 et BBCH 93	Non applicable	-	-	-
Intervalle minimum entre les applications : 7 jours.							
<b>17403202</b> Cultures florales et plantes vertes*Trt Part.Aer.* Oïdium(s)	100 mL/m <sup>2</sup>	6/an	entre les stades BBCH 14 et BBCH 69	Non applicable	-	-	-
Intervalle minimum entre les applications : 7 jours.							
<b>17303201</b> Rosier*Trt Part.Aer.* Maladies des taches noires	100 mL/m <sup>2</sup>	6/an	entre les stades BBCH 15 et BBCH 93	Non applicable	-	-	-
Intervalle minimum entre les applications : 7 jours.							
<b>17303203</b> Rosier*Trt Part.Aer.* Oïdium(s)	100 mL/m <sup>2</sup>	6/an	entre les stades BBCH 15 et BBCH 93	Non applicable	-	-	-
Intervalle minimum entre les applications : 7 jours.							

SULFURMAX  
AMM n°2190874





Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
<b>14053200</b> Arbres et arbustes*Trt Part.Aer.*Maladies diverses	100 mL/m <sup>2</sup>	6/an	Non applicable
<b>Motivation du refus :</b> L'usage est refusé en raison d'un manque de données efficacité.			
<b>14053203</b> Arbres et arbustes*Trt Part.Aer.*Rouille(s)	100 mL/m <sup>2</sup>	6/an	Non applicable
<b>Motivation du refus :</b> L'usage est refusé en raison d'un manque de données efficacité.			
<b>17403203</b> Cultures florales et plantes vertes*Trt Part.Aer.*Rouille(s)	100 mL/m <sup>2</sup>	6/an	Non applicable
<b>Motivation du refus :</b> L'usage est refusé en raison d'un manque de données efficacité.			
<b>17303210</b> Rosier*Trt Part.Aer.*Rouille(s)	100 mL/m <sup>2</sup>	6/an	Non applicable
<b>Motivation du refus :</b> L'usage est refusé en raison d'un manque de données efficacité.			

SULFURMAX  
AMM n°2190874

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## 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 de bidon non utilisés.

#### **Protection de la faune**

- Ne pas appliquer en présence d'insectes pollinisateurs (abeilles, bourdons).

## Recommandations relatives à l'étiquette du produit

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

- Préciser les conditions d'utilisation sur cultures ornementales afin de prévenir tout risque éventuel de phytotoxicité.

S20001/SULFURMAX  
Part A - National Assessment  
FRANCE version

## 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.





## SOUFRE LIQUIDE

*Maladies des rosiers et plantes ornementales*

SulfurMax est un fongicide (anti-maladies) idéal pour les rosiers, les plantes fleuries et ornementales. Il élimine de nombreuses maladies telles que l'oïdium (dit "blanc"), les taches noires et la rouille. Il permet aussi de prévenir l'apparition de nouvelles maladies.

### COMMENT L'UTILISER ?

- **AGITER TRÈS VIGOREUSEMENT (30 SEC.) AVANT UTILISATION.**
- Appuyer sur le dessus de la tête du pulvérisateur pour débloquent l'embout et le faire pivoter en position jet large.
- Pulvériser en mouillant bien tout le feuillage et les rameaux y compris le dessous des feuilles.
- Après utilisation, remettre l'embout sur STOP.
- Pour minimiser le risque pour les abeilles, pulvériser tôt le matin (7-9h) ou le soir (18h-20h), quand les abeilles sont moins actives.

### QUAND L'UTILISER ?

J	F	M	A	M	J	J	A	S	O	N	D
---	---	---	---	---	---	---	---	---	---	---	---

Oïdium et rouille	Dès l'apparition de la maladie et renouveler 7-10 jours plus tard jusqu'à disparition de la maladie. 6 applications max par an.
Taches noires	Tous les 7-10 jours dès l'apparition de la maladie. Si les rosiers ont été infectés durant la saison précédente, pulvériser dès le bourgeonnement et réappliquer régulièrement. 6 applications max par an.

**Nom homologué :** SULFURMAX. **AMM n°** XXXXXX de Evergreen Garden Care France SAS (69). **Emploi autorisé dans les jardins.** **Composition :** 4 g/L (0,4% p/p) de soufre. **Formulation :** AL – Liquide prêt à l'emploi. **Type d'action :** fongicide de contact. **Usages en traitement des parties aériennes et doses homologués :** Plantes >50cm : 1L/10m<sup>2</sup> - Plantes <50cm : 600mL/10m<sup>2</sup> - **Rosier, Cultures ornementales, cultures florales et plantes vertes, arbres et arbustes :** Oïdium(s), Rouille(s), Maladies des taches foliaires. **EUH401 :** Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement. • **P101 :** En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette. • **P103 :** Lire l'étiquette avant utilisation. • **P270 :** Ne pas manger, boire ou fumer en manipulant ce produit. **P501 :** Éliminer le contenu et récipient dans une déchetterie ou par un organisme agréé. • **SP1 :** Ne pas polluer l'eau avec le produit ou son emballage. **En cas d'urgence, appeler le 15 ou un centre anti-poison.** SulfurMax a été testé sur de nombreuses variétés de plantes. Pour éviter tout effet indésirable, il est toutefois recommandé de tester le produit sur une petite partie de la plante avant de généraliser le traitement.

0 805 090 036 Service & support produits

VOLUME NET

800 mL

**FSOL1800**

EMB 27108

Evergreen Garden Care France SAS  
21, chemin de la Sauvegarde  
69130 ECULLY

**EMPLACEMENT**  
**GENCOD TRONQUÉ**  
**IMPRESSION NOIRE**  
**N°3121970172744**



### **Appendix 3 Letter of Access**

Provided upon request.