

REGISTRATION REPORT

Part A

Risk Management

Product code: CF950

Product name(s): SULFSHIELD

Chemical active substance(s):

Sulfur, 600 g/L

Potassium phosphonates, 300 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: Ceradis Crop Protection B.V.

Date: 2023/08/11

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PART A

RISK MANAGEMENT

1 Details of the application

The company Ceradis Crop Protection B.V. has requested a marketing authorisation in France for the product SULFSHIELD (formulation code: CF950), containing 600 g/L of Sulphur and 300 g/L of Potassium phosphonates as a fungicide 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 Ceradis Crop Protection B.V.'s application submitted on 01/04/2022 to market SULFSHIELD (CF950) 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 (2022-0339) 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 the Southern zone, 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 SULFSHIELD (CF950) has been made using endpoints agreed in the EU peer reviews of sulfur and potassium phosphonates. It also includes assessment of data and information related to SULFSHIELD (CF950) 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 SULFSHIELD (CF950).

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

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1.2 Letters of Access

The applicant has provided letters 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 product SULFSHIELD (CF950) is a new formulation: physical and chemical properties, analytical method, efficacy studies and (eco)toxicity studies are submitted with this application. ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of SULFSHIELD (CF950), 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	CF950
Product name in MS	SulfShield
Authorisation number	N/A : no marketing authorisation granted
Kind of use	Professional use
Low risk product (article 47)	No
Function	Fungicide
Applicant	Ceradis Crop Protection B.V.
Active substance(s) (incl. content)	Sulphur, 600 g/l Potassium phosphonates 300 g/L
Formulation type	Suspension Concentrate (SC)
Packaging	N/A : no marketing authorisation granted
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 SULFSHIELD (CF950) resulted in the decision **to refuse** 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

N/A : no marketing authorisation granted.

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

N/A : no marketing authorisation granted

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.

Moreover, 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”

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>

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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.

Finally, the French Order of 20 November 2021⁷ 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 crop⁸ 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

N/A : no marketing authorisation granted

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.

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.

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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, 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. Cerasulfur, date 05/2023

PPP (name/product code): SulfShield / CF950

Formulation type: SC

Active substance 1: Sulfur

Conc. of as 1: 600 g/L

Active substance 2: Potassium phosphonates

Conc. of as 2: 300 g/L

Applicant: Ceradis Crop Protection BV (company)

Professional use:

Zone(s): Southern zone

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 destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/synergist per ha (0)
					Method / Kind	Timing / Growth stage of crop & sea- son	Max. number a) per use b) per crop/ season	Min. inter- val between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

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GAP rev. Cerasulfur, date 05/2023

PPP (name/product code):	SulfShield / CF950	Formulation type:	SC
Active substance 1:	Sulfur	Conc. of as 1:	600 g/L
Active substance 2:	Potassium phosphonates	Conc. of as 2:	300 g/L
Applicant:	Ceradis Crop Protection BV (company)	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Southern zone	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes		

Field of use: Fungicide

Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Apple <i>Malus domestica</i> (MABSD)	F	Apple scab (<i>Venturia inaequalis</i>)	Spraying/ Foliar ap- plication	From BBCH 51 onwards	a) 6 b) 6	10	a) 2.75	a) 1.65 kg S, 0.825 kg K-HPO ₃ b) 9.9 kg S; 4.95 kg HPO ₃	1000	32	Not acceptable (MRL, bees, non-target ar- thropods)
2	FR	Grapevine <i>Vitis vinifera</i> (VITVI)	F	Downy mildew (<i>Plasmopara viticola</i>)	Spraying/ Foliar ap- plication	BBCH 16-79	a) 6 b) 6	10	a) 4.0	a) 2.4 kg S, 1.2 kg K-HPO ₃ b) 14.4 kg S; 7.2 kg HPO ₃	200-1000	15	Not acceptable (workers, MRL, bees, non-target arthropods, soil macroorganisms, efficacy)

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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 3-8263-3151.99-4), 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 intervals (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)

Packaging claimed (national data and section 1,2&4): HDPE bottle (1L), HDPE container (5, 10, 20L), HDPE tank (220 L and 1000L)

Claimed packaging are made of HDPE. As no information is provided on the technical possibility to homogenize the product before sampling when stored in large containers (>20L), a mitigation measure is proposed: the preparation should be shaken before use.

The preparation is a suspension concentrate (SC). 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 an off white liquid with a characteristic odour. The preparation is not classified for explosive and oxidising properties. CF950 did not ignite under the temperature of 600°C, therefore it is not considered highly flammable. In aqueous solution, it has a pH value around 6.2 at 22.1 °C. 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 changed consistently. Its technical characteristics are acceptable for a SC formulation, and a shelf life of 2 years is considered acceptable when stored in HDPE. This needs to be confirmed by a stability study at room temperature in the commercial packaging, which is ongoing and required in post-authorisation. The intended concentration of use is 0.275% to 2% (v/v). The formulation is not classified for the physico-chemical aspect.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

The efficacy level of SULFSHIELD (CF950) is considered acceptable for the requested use on *Venturia inaequalis*.

The efficacy level of SULFSHIELD (CF950) is considered variable and partial for the requested use on *Plasmopara viticola*. **However, the benefits of sulphur in association has not been demonstrated on downy mildew of grapevine (*Plasmopara viticola*). Sulphur is known to have intrinsic activity on powdery mildew of grapevine (*Erysiphe necator*). Nevertheless, the intrinsic activity of sulphur on *Plasmopara viticola* has not been demonstrated. Consequently, the evaluation cannot be finalized for the requested use on *Plasmopara viticola*.**

The phytotoxicity level of S SULFSHIELD (CF950) is considered acceptable for the requested uses.

The risk of negative impact quality is considered acceptable.

The risks of negative impact on yield, propagation, wine-making, cider-making and adjacent crops are considered negligible.

The risk of resistance development or appearance to sulphur and to potassium phosphonates is considered low and does not require a monitoring for the requested uses.

3.3 Methods of analysis (Part B, Section 5)**3.3.1 Analytical method for the formulation**

Analytical methods for the determination of active substances in the formulation are available and validated. As no relevant impurities are specified, no analytical method for the determination of relevant impurities in the formulation is necessary.

3.3.2 Analytical methods for residues

Due to the compound, analytical methods for the determination of residues of sulphur in plants, foodstuff of animal origin, body fluids and tissues, soil, water and air are not necessary.

Analytical methods are available in the DAR and in this dossier and validated for the determination of residues of potassium phosphonates in plants (high water, acidic crops), food of animal origin, soil, water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

Product	SULFSHIELD (CF950)	
Formulation Type	Suspension concentre (SC)	
Active substance (s)	SULPHUR 600.0 g/L	POTASSIUM PHOSPHONATES 300.0 g/L
AOELsystemic (RVNAS)	26 mg/kg/day	5 mg/kg/day
Inhalation absorption	100%	100%
Oral absorption	100%	60%
Dermal absorption	Concentrate : 10% Dilution: 50% Default values (EFSA Journal 2017; 15(6):4873)	Concentrate : 10% Dilution : 50% Default values (EFSA Journal 2017; 15(6):4873)

3.4.1 Acute toxicity

SULFSHIELD (CF950) containing 600 g/L Sulphur and 300 g/L of potassium phosphonates, has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the eye and it is irritating to skin and is not a skin sensitiser.

3.4.2 Operator exposure

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

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Apple					
		Sulphur		Potassium phosphonates	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops					
Application rate		1.65 kg a.s./ha		0.825 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.504	1.94	0.269	5.40
	Work wear (arms, body and legs covered) M/L and A + gloves	0.187	0.72	0.094	1.90
Grapes					
		Sulphur		Potassium phosphonates	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops					
Application rate		2.4 kg a.s./ha		1.2 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.709	2.73	0.378	7.57
	Work wear (arms, body and legs covered) M/L and A + gloves	0.271	1.04	0.137	2.74

Conclusion : According to the EFSA model calculations, it can be concluded that the risk for the operator using SULFSHIELD (CF950) is below the AOEL without PPEs for the both active substances.

3.4.3 Worker exposure

Estimation of worker exposure was calculated according to AOEM model. Exposure is summarized in table below:

Apple			
		Sulphur	Potassium phosphonates

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Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Searching, reaching, picking Outdoor Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 days					
Number of applications and application rate		6 x 1.65 kg a.s./ha		6 x 0.825 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	5.398	20.76	2.699	53.99
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	2.699	10.38	1.349	26.99

Conclusion : According to the EFSA model calculations, it can be concluded that the risk for the worker using SULFSHIELD (CF950) is below the AOEL without PPEs for both active substances.

Grapes					
		Sulphur		Potassium phosphonates	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Hand harvesting Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 days					
Number of applications and application rate		6 x 2.4 kg a.s./ha		6 x 1.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000 cm ² /person/h	52.351	201.35	26.175	523.51
	Work wear (arms, body and legs covered) TC:10100 cm ² /person/h	17.624	67.79	8.812	176.25

Conclusion: According to the EFSA model calculations, it can be concluded that the risk for the worker using SULFSHIELD (CF950) is above the AOEL of Potassium phosphonates, even when adequate work wear and gloves are worn.

3.4.4 Bystander exposure

According to EFSA Guidance on the assessment of exposure of operators, work-ers, 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 ef-fects after a single exposure. Exposure in this case will be determined by average exposure

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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 resi-dents also covers bystander exposure.”

Conclusion : No AAOEL has been set for both active substances. Thus, for these active substances, resident exposure assessment covers bystander exposure.

3.4.5 Resident exposure

Residential exposure was assessed according to EFSA model with mitigation measures (with drift reduction technology and a buffer zone of 10 meters).

Apple					
		Sulphur		Potassium phosphonates	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to high crops Buffer zone: 10 m Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 days					
Number of applications and application rate		6 x 1.65 kg a.s./ha		6 x 0.825 kg a.s./ha	
Resident child Body weight: 10 kg	Sum (mean)	0.532	2.05	0.265	5.32
Resident adult Body weight: 60 kg	Sum (mean)	0.288	1.11	0.144	2.88
Grapes					
		Sulphur		Potassium phosphonates	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to high crops Buffer zone: 10 m Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 days					
Number of applications and application rate		2 x 2.4 kg a.s./ha		2 x 1.2 kg a.s./ha	
Resident child Body weight: 10 kg	Sum (mean)	1.145	4.41	0.573	11.46
Resident adult Body weight: 60 kg	Sum (mean)	0.632	2.43	0.316	6.33

Conclusion : According to the EFSA model calculations, it can be concluded that the risk for the resident is below the AOEL for both active substances.

3.4.6 Combined exposure

Apple		
Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators – tractor mounted application	Cumulative risk operators (HI)	0.07
Workers – Searching, reaching, picking	Cumulative risk workers (HI)	0.75
Resident - child	Cumulative risk resident – child (HI)	
	Sum of all pathways	0.08
Resident - adult	Cumulative risk resident – adult (HI)	
	Sum of all pathways	0.04

Conclusion: The Hazard Index is < 1. Thus, combined exposure to both active substances in SULFSHIELD (CF950) is not expected to present a risk for operators, workers, bystanders and residents.

Grapes		
Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators – tractor mounted application	Cumulative risk operators (HI)	0.11
Workers – hand-harvesting	Cumulative risk workers (HI)	2.44
Resident - child	Cumulative risk resident – child (HI)	
	Sum of all pathways	0.15
Resident - adult	Cumulative risk resident – adult (HI)	
	Sum of all pathways	0.08

Conclusion for Grapes :

- The Hazard Index is < 1. Thus, combined exposure to both active substances in SULFSHIELD (CF950) is not expected to present a risk for operators, workers, bystanders and residents.
- **The Hazard Index is > 1 for worker. Thus, combined exposure to both active substances in SULFSHIELD (CF950) is expected to present a risk for workers.**

3.5 Residues and consumer exposure (Part B, Section 7)**3.5.1 Residues**

The data available are considered not sufficient for risk assessment.

Sulphur is included in Annexe IV to 396/2005/EC regulation, which includes those active substances where no MRL are required.

In the absence of magnitude residues trials with potassium phosphonates in apples and grapevines,

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the intended uses on apples and grapevines are considered as not sufficiently supported.

In the framework of the Peer Review, the setting of an acute reference dose (ARfD) and an acceptable daily dose (ADI) was not deemed necessary for sulphur. The assessments of the chronic and the short-term intakes of sulphur are therefore not necessary.

Since the setting of an ARfD was not deemed necessary for potassium phosphonates, no acute risk assessment was performed in the framework of this dossier.

Due to the lack of residue trials on apples and grapes, the estimation of consumer chronic intakes of potassium phosphonate residues could not be performed.

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

Information on SULFSHIELD (CF950) (KCA 6.8)

Crop	PHI for SULFSHIELD (CF950) proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for SULFSHIELD (CF950) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Sulphur	Potassium phosphonates		
Grapes	15	Yes	No	-	Use not recommended
Apples	32	Yes	No	-	Use not recommended

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).

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 substances and 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 active substances and 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 PEC_{sw} derived for the active substances and metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PEC_{gw} values for sulfates do not exceed the drinking water limit of 250 mg/L set in the Drinking Water Directive 98/83/EC⁹. PEC_{gw} for phosphonic acid do not occur at levels exceeding those mentioned in

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

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 review for 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 additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, mammals, earthworms, micro-organisms and non-target terrestrial plants are acceptable for the intended uses.

Mitigation measures are required for aquatic organisms.

For bees, the evaluation of the risk (acute and chronic screening / Tier-1 risk assessments) for bees and larvae was also performed in accordance with the “EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp.) and solitary bees, Journal 2013; 11(7):3295.

The results of the screening step show that all the calculated HQ/ETR values of acute contact and oral toxicities for adult bees fall below the trigger values of 42 and 0.2, respectively, indicating an acceptable acute contact and oral risks to bees following application of SULFSHIELD (CF950) at the proposed label rate.

Calculated ETR values of chronic oral toxicity for adult honeybee for sulfur and SULFSHIELD (CF950) , and calculated ETR value of chronic oral toxicity for honeybee larvae for SULFSHIELD (CF950) exceed the trigger values indicating that a refinement is needed.

The results of the Tier 1 risk assessment for sulfur show that the ETR values of chronic oral toxicity for adult honeybee fall below the trigger value of 0.03, indicating low chronic oral risk to adult honeybee following application of SULFSHIELD (CF950) at the proposed label rates, except for scenario “risk from foraging on the treated crop” at BBCH 40-69 in apples and at BBCH 10-69 in vines.

The results of the Tier 1 risk assessment for SULFSHIELD (CF950) show that the ETR values of chronic oral toxicity for adult honeybee fall below the trigger value of 0.03 for all scenarios except “risk from foraging on the treated crop”, “risk from foraging on weeds in the treated field” and “risk from foraging on next crop”, and the ETR values of chronic oral toxicity for honeybee larvae fall below the trigger value of 0.2 for all scenarios except “risk from foraging on the treated crop” and “risk from foraging on weeds in the treated field”, indicating that a refinement is needed.

Concerning chronic toxicity of sulfur to adult honeybees and honeybee larvae, a semi-field study is available to address the risk assessment. Thus, the risk assessment for the active substance sulfur is considered as finalized for all intended uses of SULFSHIELD (CF950).

Following the higher tier risk assessment, for the product SULFSHIELD (CF950), chronic toxicity on adult honey-bees and honeybee larvae the risk is still considered as not finalized as no new data was provided.

The oral and contact acute risks to bumblebees are performed as described in the EFSA guidance document for bees (EFSA, 2013; revised July 2014). Hazard quotients for contact toxicity and exposure toxicity ratios (ETR) for oral toxicity for bumblebees following the screening step for contact toxicity and following the Tier 1 for oral toxicity are lower than trigger values of 7 and 0.036, respectively, indicating

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acceptable risk to bumblebees following application of SULFSHIELD (CF950) at the proposed label rates, for all scenarios except for “risk from foraging on the treated crop”. No higher-tier risk assessment is provided to address the risk for bumble bees. Thus, it is not possible to finalize the risk assessment for bumble bees foraging on the treated crop for all the intended uses of SULFSHIELD (CF950).

Overall, the risk for bees is regarded as not finalized for the product SULFSHIELD (CF950) and further data are needed to refine the chronic risk for adult bees and larvae foraging in treated crop, on weeds and on next crop.

For bumble bees the risk is not finalized for the product SULFSHIELD (CF950) for bumble bees foraging on treated crop for uses on apples for BBCH stages 40 to 69 and vines for BBCH stages 10 to 69 following the application of the product SULFSHIELD (CF950).

For non-target arthropods, the in-field risk assessment, based on the extended laboratory data, the HQ in-field are above the trigger value of 1 for *A. rhopalosiphi*, *T. pyri*, *C. carnea* and *T. cacoeciae* indicating an unacceptable risk to in-field non-target arthropods for the intended uses on apples and vines of SULFSHIELD (CF950). Further data are needed to conclude to an in-field acceptable risk for the requested uses of SULFSHIELD (CF950).

No further data was provided by the applicant to refine the in-field risk assessment for the product SULFSHIELD (CF950). Furthermore, it is zRMS' opinion that the risk assessment cannot be refined using data from the active substance sulfur only. **Therefore, it is not possible to finalise the in-field risk assessment for all the intended uses of SULFSHIELD (CF950).**

The assessment of the off-field risk for SULFSHIELD (CF950) for apples and vines for *A. rhopalosiphi* and *T. cacoeciae* lead to an unacceptable risk, indicating that risk mitigation measures should be implemented. A 30 m unspray buffer zone is needed for early applications on apples; or a 20 m unspray buffer zone with 50% drift reduction nozzle; a 15 m unspray buffer zone with 75% drift reduction nozzle or a 5 m unspray buffer zone with 90% drift reduction nozzle. For late applications a 15 m unspray buffer zone is needed or a 10 m unspray buffer zone with 50% drift reduction nozzle; a 5 m unspray buffer zone with 75% drift reduction nozzle or a 3 m unspray buffer zone with 90% drift reduction nozzle.

For vines, a 5 m unspray buffer zone or a 3 m unspray buffer zone with 75% drift reduction nozzle; is needed for early application and a 10 m unspray buffer zone or a 5 m unspray buffer zone with 50% drift reduction nozzle; or a 3 m unspray buffer zone with 75% drift reduction nozzle is needed for late applications.

The long-term risk of SULFSHIELD (CF950) to earthworms and other non-target soil organisms (meso- and macrofauna) was assessed from long-term toxicity exposure ratios (TERs) between the selected toxicity endpoints for the active substances, the formulated product, and the respective maximum soil PECs. For phosphonic acid and the product SULFSHIELD (CF950), the long-term TER values are higher than the trigger value of 5, indicating an acceptable risk to earthworms and other non-target soil organisms (meso- and macrofauna) following application of SULFSHIELD (CF950) for the proposed uses on apples and vines.

For sulfur, the TERLT values are above the trigger value of 5 for long-term exposure of *Eisenia fetida* and *Hypoaspis aculeifer* for the intended uses of SULFSHIELD (CF950) on apple and vines, indicating an acceptable risk for these uses. For *Folsomia candida*, the TERLT is above the trigger value for the intended use of CF950 on apple. The TERLT is below the trigger for the intended use of SULFSHIELD (CF950) on vines.

Further data for collembola are needed to conclude about the requested use of SULFSHIELD (CF950) on vines. However, no additional data or higher-tier study is available to address the risk for collembola.

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Therefore, it is not possible to finalize the risk for collembola following the application of SULFSHIELD (CF950) on vines.

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

The active substances are 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:

- The final report of the stability study of the product at ambient temperature in its commercial packaging

Appendix 1 Copy of the product authorisation

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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 **SULFSHIELD***

*de la société CERADIS
enregistrée sous le n° 2022-0339*

Vu les conclusions de l'évaluation de l'Anses du 14 juin 2023,

Considérant qu'il existe un risque de dépassement des limites maximales de résidus de la substance phosphonates de potassium,

Considérant qu'un risque d'effet inacceptable pour les arthropodes non-cibles, lié à l'utilisation du produit, ne peut être exclu,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

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Informations générales sur le produit	
Nom du produit	SULFSHIELD
Type de produit	Produit de référence
Titulaire	CERADIS CROP PROTECTION B.V. Agro Business Park 10 6708PW WAGENINGEN Pays-Bas
Formulation	Suspension concentrée (SC)
Contenant	600 g/L - soufre 300 g/L - phosphonates de potassium
Numéro d'intrant	156-2022.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 11/08/2023

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)

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ANNEXE : Conditions de mise sur le marché demandées

Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12603203 Fruits à pépins*Trt Part.Aer.*Tavelure(s)	2,75 L/ha	6/an	32
	Motivation du refus : L'usage est refusé : <ul style="list-style-type: none"> - car en l'absence d'essais résidus, le respect des limites maximales de résidus de phosphonates de potassium ne peut être vérifié et une évaluation du risque pour le consommateur ne peut être effectuée, - car, les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les arthropodes non-cibles et les macroorganismes du sol, - car l'intérêt de l'association des substances actives dans le produit n'est pas justifié. 		
12703203 Vigne*Trt Part.Aer.*Mildiou(s)	4 L/ha	6/an	15
	Motivation du refus : L'usage est refusé : <ul style="list-style-type: none"> - en raison d'un risque d'effet nocif pour les travailleurs, - car en l'absence d'essais résidus, le respect des limites maximales de résidus de phosphonates de potassium ne peut être vérifié et une évaluation du risque pour le consommateur ne peut être effectuée, - car, les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les arthropodes non-cibles et les macroorganismes du sol, - car l'intérêt de l'association des substances actives dans le produit n'est pas justifié. 		

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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.

Partie "Visible"


SULFSHIELD

FONGICIDE BIOCONTROLE

Pour le traitement du mildiou de la vigne et de la tavelure du pommier
Suspension concentrée (SC) contenant 600 g/L (40% p/p) de soufre et 300 g/L (20 % p/p) de phosphonates de potassium

Fongicide réservé à un usage exclusivement professionnel
Mode d'action FRAC: Groupe M02 pour le soufre et P07 pour le phosphonates de potassium

Volume net: x Litres

<p>SULFSHIELD</p> <p>AMM n° xx dérivé le xx</p> <p>UFI: 9W10-W0TR-D00E-74TQ</p> <p>Contient : 600 g/L de soufre (40% p/p) 300 g/L de phosphonates de potassium (20% p/p)</p> <p>INDICATIONS DE DANGER: H 315. Provoque une irritation cutanée.</p> <p>CONSEILS DE PRUDENCE: P264. Laver les mains soigneusement après manipulation P280. Porter des gants et un vêtement de protection P302+352. EN CAS DE CONTACT AVEC LA PEAU: Laver abondamment à l'eau et au savon P321. Traitement spécifique (voir indications sur cette étiquette). P332+313. En cas d'irritation cutanée: consulter un médecin. P362+364. Enlever les vêtements contaminés et les laver avant réutilisation. P501. Eliminer le contenu/récipient conformément à la réglementation locale/nationale</p> <p>EUH401. Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.</p> <p>SP1. Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.</p> <p>Spe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau.</p> <p>Spe 3 (pour applications tardives sur pommiers): Pour protéger les arthropodes non cibles, respecter une zone non traitée de 10 m par rapport à la zone non cultivée adjacente OU respecter une zone non traitée de 5 m par rapport à la zone non cultivée adjacente si des mesures de réduction de la dérive de 50% sont appliquées OU respecter une zone non traitée de 3 m par rapport à la zone non cultivée adjacente si des mesures de réduction de la dérive de 75% sont appliquées.</p>	 ATTENTION
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Spe 3 (pour applications tardives sur vignes): Pour protéger les arthropodes non cibles, respecter une zone non traitée de 5 m par rapport à la zone non cultivée adjacente OU respecter une zone non traitée de 3 m par rapport à la zone non cultivée adjacente si des mesures de réduction de la dérive de 75% sont appliquées

Spe8 : Pour protéger les abeilles et autres insectes pollinisateurs, ne pas appliquer durant la floraison

Spe8 : Ne pas appliquer lorsque des adventices en fleur sont présentes

Délai de rentrée dans les cultures (DRP) : 24 heure

EN CAS D'URGENCE:
Composer le 15 ou le 112, ou contacter le Centre Antipoison le plus proche

Puis signaler vos symptômes au réseau Phyt'attitude, N° vert 0800 887 887
(appel gratuit depuis un poste fixe)

PREMIERS SOINS

S'éloigner de la zone dangereuse.

En cas de contact cutané : enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet avec du savon.

En cas de projection dans les yeux : rincer immédiatement pendant 15 sous un filet d'eau paupières ouvertes. Retirer les lentilles de contact après quelques minutes et rincer abondamment de nouveau. Consulter un spécialiste.

En cas d'inhalation : déplacer la victime et l'amener à l'air frais. Si la victime ne respire plus, la placer sous respiration artificielle. Contacter le secours.

En cas d'ingestion : rincer immédiatement la bouche avec de l'eau si la victime est consciente. Contacter sans délai les secours : le 15, le 112 ou un centre antipoison.

Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité.

En cas d'intoxication animale, contactez votre vétérinaire.

Fiche de Données de Sécurité disponible sur : www.quickfifs.com » ou en contactant le numéro de l'entreprise:

Ceradis Crop Protection B.V.
www.ceradis.com
N°: 0031317843791

N° de lot et date de fabrication : Voir sur l'emballage
Bien lire l'étiquette avant toute utilisation et respecter les précautions d'emploi
Réemploi de l'emballage interdit

Code Barre:

Code EAN

Homologué par : Ceradis Crop Protection B.V.
Agro Business Park 10
6708 PW Wageningen
The Netherlands
info@ceradis.com
www.ceradis.com



Consulter ce livret avant toute utilisation

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Partie "Livret"

DESRIPTIF DU PRODUIT

SULFSHIELD est un fongicide biocontrôle efficace pour lutter contre le mildiou de la vigne (*Plasmopara viticola*) et la tavelure du pommier (*Vennaria inaequalis*). C'est un fongicide à la fois de contact (soufre) et systémique (phosphonates de potassium), à action préventive.

Tableau des usages autorisés : pour un traitement des parties aériennes

Culture	Dose maximum d'emploi	Nombre maximum d'applications	Stade d'application / conditions d'emploi	Décalavant récolte (jours)	Zone non traitée aquatique (mètres)	Si pertinent, Spéc. précautions environnementales
Pommier * Tr. Part. Aer. * Tavelure	2,75 L/ha	6 / an	A partir de BBCH 51	32	5 m	Spe3 Spe8
Vigne * Tr. Part. Aer. * Mildiou	4 L/ha	6 / an	BBCH 16-79	15	5 m	Spe3 Spe8

Intervalle minimum entre les applications : 10 jours

Le soufre est inscrit à l'annexe IV du règlement CE 396/2005 qui regroupe les substances pour lesquelles il n'est pas nécessaire de fixer de limites maximales de résidus (LMR).

Pour les phosphonates de potassium, se reporter aux LMR européennes du Fosetyl-AI.

Mode d'action

Le soufre agit par contact et par effet vapeur. Il présente un mode d'action multi sites prévenant l'apparition de résistances, en agissant sur le champignon ciblé à différents niveaux de la cellule :

- Inhibition de la chaîne respiratoire, synthèse protéique et d'acides nucléiques.

Les phosphonates de potassium est systémique, il circule dans la plante après avoir pénétré les feuilles lors de l'application. Il est reconnu comme élicitant les défenses naturelles des plantes. Il a aussi une action directe sur les champignons.

RECOMMANDATIONS D'EMPLOI

- Conditions d'application

IMPORTANT : lire attentivement les instructions de cette section afin de garantir une utilisation sûre et efficace de ce produit.

- Précautions d'emploi

SulfShield doit être appliqué en préventif. Se reporter aux préconisations des chambres d'agriculture locales pour commencer les traitements.

Sur pommiers

Commencer les traitements lors de l'apparition des premiers symptômes durant la période d'émergence de l'inflorescence foliaire.

SulfShield peut être utilisé seul, quelque soit la pression maladie.

Le volume d'eau à utiliser lors de l'application dépend du stade de développement des arbres. Le volume d'eau utilisé doit permettre de couvrir convenablement la culture.

Ne pas utiliser en cas de fort ensoleillement, de températures élevées (>30°C) et de périodes sèches prolongées. Dans certaines situations climatiques, le produit peut provoquer des brûlures sur feuilles.

Pour assurer l'effet contact préventif du soufre contenu dans SulfShield, réappliquer le produit si pluies lessivants survenues lors ou peu après l'application.

Sur vignes

Commencer les traitements lors de l'apparition des premiers symptômes durant la période de développement des feuilles.

SulfShield peut être utilisé seul uniquement lorsque la pression maladie est faible, ou assez modérée. En cas de pression maladie élevée, il est recommandé d'alterner les applications de SulfShield avec des fongicides chimiques conventionnels.

Le volume d'eau à utiliser lors de l'application dépend du stade de développement de la vigne. Le volume d'eau utilisé doit permettre de couvrir convenablement la culture.

Pour assurer l'effet contact préventif du soufre contenu dans SulfGuard, réappliquer le produit si pluies lessivants survenues lors ou peu après l'application.

- Mélanges extemporanés

Les mélanges extemporanés doivent être mis en œuvre conformément à la réglementation en vigueur. Nous consulter pour tout mélange avec d'autres produits phytopharmaceutiques.

- Préparation de la bouillie

Bien agiter le bidon avant utilisation.

PREVENTION ET GESTION DE LA RESISTANCE

L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, l'utilisateur doit raisonner en premier lieu les pratiques agronomiques et respecter les conditions d'emploi du produit. Il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation. En dépit du respect de ces règles, on ne peut pas exclure une altération de l'efficacité de cette préparation liée à ces phénomènes de résistance. De ce fait, Ceradis Crop Protection B.V. décline toute responsabilité quant à d'éventuelles conséquences qui pourraient être dues à de telles résistances.

SulfGuard étant composé de deux substances actives multi-sites et pour lesquelles le risque de résistances est faible, son utilisation est peu soumise aux risques d'apparition de résistances.

MISE EN ŒUVRE RÉGLEMENTAIRE ET BONNES PRATIQUES

- Recommandations de stockage

Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart des aliments et boissons, y compris ceux pour animaux. Conserver hors de la portée des enfants et des personnes non autorisées.

- Équipements de protection individuelle: Protection de l'opérateur et du travailleur

Se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée.

Ne pas manger, boire, téléphoner ou fumer lors de l'utilisation du produit.

Il convient de rappeler que l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention comme les risques professionnels, avant la mise en place de protections complémentaires comme les protections individuelles.

En tout état de cause, le port de combinaison de travail dédiée ou d'équipement de protection individuelle (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. Se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée. Ne pas manger, boire, téléphoner ou fumer lors de l'utilisation du produit.

Pour protéger l'opérateur et les travailleurs, porter les protections individuelles préconisées ci-dessous, dans le cadre d'une application par épandage de SULFSHIELD:

Pendant le chargement du matériel d'épandage

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

Pendant l'épandage

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

Pendant le nettoyage du matériel d'épandage

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

Pendant la récolte manuelle (en cas de contact avec la culture traitée)

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Des gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1-A1 (type A) (uniquement pour travailleurs en culture de vignes)

Rapporter les équipements de protection individuelle (EPI) usagés dans un sac translucide, à votre distributeur partenaire ECO EPI ou faire appel à une entreprise habilitée pour la collecte et l'élimination de produits dangereux.

-Nettoyage du pulvérisateur et gestion des fonds de cuve

A la fin de la période d'application du produit, l'intégralité de l'appareil (cuve, rampe, circuit, buses...) doit être rincée à l'eau claire. Le rinçage du pulvérisateur, l'épandage ou la vidange du fond de cuve et l'élimination des effluents doivent être réalisés conformément à la réglementation en vigueur.

-Élimination du produit, de l'emballage

Réemploi de l'emballage interdit.

Pour les bidons jusqu'à 25 L, lors de l'utilisation du produit, bien vider et rincer le bidon à l'eau claire (rinçage manuel à 3 reprises en agitant le bidon rempli au 1/3 ou rinçage mécanique d'une durée minimale de 30 secondes) en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur.

Apporter les emballages ouverts, rincés et égouttés à votre distributeur partenaire d'A.D.I.VA.LOR ou à un autre service de collecte spécifique. Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Interroger votre distributeur partenaire d'A.D.I.VA.LOR ou faites appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux.

Pour les fûts plastiques au-delà de 25L et ce jusqu'à 300 L, apporter les emballages vidés et fermés à votre distributeur partenaire d'A.D.I.VA.LOR ou à un autre service de collecte spécifique.

Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Interroger votre distributeur partenaire d'A.D.I.VA.LOR ou faites appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux.

-En cas de versement accidentel

Se protéger (EPI) et sécuriser la zone. Prévenir les pompiers (18 ou 112) en cas de danger immédiat pour l'environnement que vous ne pouvez gérer avec vos propres moyens.

Collecter tout ce qui a pu être en contact avec le produit, terre souillée incluse. Nettoyer le site et le matériel utilisé, en prenant soin de confiner les effluents générés par l'opération de nettoyage. Les éliminer selon la réglementation en vigueur.



AVERTISSEMENT

Toute reproduction totale ou partielle de cette étiquette est interdite

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte, sous la responsabilité de l'utilisateur, de tous les facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...

Le fabricant garantit la qualité du produit vendu dans son emballage d'origine et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les autorités compétentes françaises. Pour les dernières issues de cultures protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.