

REGISTRATION REPORT
Part A
Risk Management

Product code: Sulphur 80% WG
Product name(s): AZUMO JARDIN
Chemical active substance(s):
Sulphur, 800 g/kg

Southern Zone
Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
For non professional uses
(new application)

**Applicant: Azufrera y Fertilizantes Pallarés, S.A.
(AFEPASA)**
Date: 2021/04/07
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PART A

RISK MANAGEMENT

1 Details of the application

The company Azufrera y Fertilizantes Pallarés, S.A. (AFEPPASA) has requested marketing authorisation in France for the product AZUMO JARDIN (formulation code: Sulphur 80% WG), containing 800 g/kg sulphur for use as a fungicide for non-professional uses.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to AZUMO JARDIN (Sulphur 80% WG) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of AZUMO JARDIN (Sulphur 80% WG) have been made using endpoints agreed in the EU peer review of sulphur.

This document describes the specific conditions of use and labelling required for France for the registration of AZUMO JARDIN (Sulphur 80% WG).

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

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

Appendix 3 of this document is a copy of the letter(s) of Access.

1.1 Application background

The present registration report concerns the evaluation of Azufrera y Fertilizantes Pallarés, S.A. (AFEPPASA)'s application to market AZUMO JARDIN (Sulphur 80% WG) in France as a fungicide (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 (2017-2617 and 2020-0549) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")¹ – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009², implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations

¹ 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](#)

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

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are based and is not intended to show the assessment in detail.

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

1.2 Letters of Access

Not necessary.

1.3 Justification for submission of tests and studies

According to the applicant: All conducted studies are necessary for evaluation and authorisation of the amateur uses of the PPP against powdery mildew in the above mentioned crops.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of AZUMO JARDIN (Sulphur 80% WG), 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	Sulphur 80% WG
Product name in MS	AZUMO JARDIN
Authorisation number	2210283
Low risk (article 47)	No
Function	Fungicide
Applicant	Azufrrera y Fertilizantes Pallarés, S.A. (AFEPASA)
Active substance(s) (incl. content)	Sulphur, 800 g/kg
Formulation type	Water-dispersible granule (WG)
Packaging	Bags in paper/Al/LDPE ⁴ (0.02 kg, 0.05 kg, 0.1 kg, 0.4 kg, 0.5 kg, 0.75 kg, 1 kg, 1.5 kg) containing a measuring spoon Bags in paper/LDPE ⁵ (1 kg, 1.5 kg) containing a measuring spoon
Coformulants of concern for national authorisations	-
Restrictions related to identity	-

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

⁴ Paper /Aluminum / Low density polyethylene

⁵ Paper / Low density polyethylene

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Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for AZUMO JARDIN (Sulphur 80% WG) resulted in the decision **to grant** the authorization.

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

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

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

refer to 2.5

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

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4th May 2017⁶ provides that:

⁶ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjutants visés à l'article L. 253-1 du code rural et de la pêche maritime

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- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally 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, drift 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 2014⁷ 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 “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁸ 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

Operator protection:	
-	-
Worker protection:	
-	-
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
	Do not discharge into the sink, gutter or any other water hole the non-used container leftovers and the sprayer washing water.
	To protect aquatic organisms do not apply at least 5 meters away from any surface water bodies (well, pond, stream, river,...).

⁷ <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGR1632554A/jo/texte>

⁸ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

⁸ 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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	Do not treat when beneficial organisms or pollinators are visiting the area.
Other specific restrictions	
Re-entry period	Ensure complete drying of the treated area or of treated plants before handling them.

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 **Erreur ! Source du renvoi introuvable.** (mandatory labelling):

None.

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2.6 Intended uses (only NATIONAL GAP)

Please note:

PPP (product name/code):	Sulphur 80% WG AZUMO JARDIN			Formulation type: WG
Sulphur:	sulphur			Conc. of as 1: 800 g/kg
Applicant:	AFEPASA			Home and garden use:
Zone(s):	southern			Non professional use: yes
Verified by MS:	Yes			

Field of use: fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Member state(s)	Crop and/or sit- uation (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syn- ergist per ha	
					Method / Kind	Timing / Growth stage of crop & sea- son	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	g product/m ² a) max. rate per appl. b) max. total rate per crop/season	g as/m ² a) max. rate per appl. b) max. total rate per crop/season	Water L/m ² min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	South /EU	Grapes	Fn	Powdery mildew <i>Erysiphe necator</i>	Overall spray- ing directed on the plant	1 st applica- tion BBCH 15-18	a) 8 b) 8	7	a) 1.25 b) 10	a) 1 b) 8	0.05-0.10	5	Acceptable
2	South /EU	Tomato Aubergine (= Eggplant)	Fn	Powdery mildew <i>Leveillula</i> spp.	Overall spray- ing directed on the plant	1 st applica- tion at onset of disease From BBCH 10-51	a) 6 b) 6	10-14	a) 2 b) 12	a) 1.6 b) 19.2	0.04-0.10	3	Acceptable

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3	South /EU	Pome fruits: Apple, pear, quince	Fn	Powdery mildew: <i>Podosphaera leucotricha</i>	Overall spraying directed on the plant	1 st application at onset of disease BBCH 01-60 and from BBCH 69	a) 6 b) 6	10-14	a) 0.75 b) 4.5	a) 0.6 b) 3.6	0.07-0.10	NP	Acceptable
4	South /EU	Stone fruits: Peach, nectarine and apricot	Fn	Powdery mildew: <i>Sphaerotheca pannosa</i>	Overall spraying directed on the plant	1 st application at onset of disease From BBCH 69	a) 6 b) 6	10-14	a) 0.75 b) 4.5	a) 0.6 b) 3.6	0.07-0.10	NP	Acceptable
5	South /EU	Sugar beet	Fn	Powdery mildew <i>Erysiphe betae</i>	Overall spraying directed on the plant	1 st application at onset of disease From BBCH 15-39	a) 3 b) 3	10	a) 0.75 b) 2.25	a) 0.6 b) 1.8	0.03	14	Acceptable
Minor uses (zonal uses)													
6	South /EU	Ornamentals: roses, flowers and green plants, interior and balcony plants, trees and shrubs	Fn	Powdery mildew: <i>Sphaerotheca pannosa and others</i>	Overall spraying directed on the plant	1 st application at onset of disease	5	10	a) 0.3 b) 1.5	a) 0.24 b) 1.2	0.045-0.15	n.a.	Acceptable
7	South /EU	Avocados, mangoes, papayas	Fn	Powdery mildew	Overall spraying directed on the plant	1 st application at onset of disease	a) 6 b) 6	10-14	a) 0.75 b) 4.5	a) 0.6 b) 3.6	0.07-0.10	n.a	Acceptable
8	South /EU	Chicory	Fn	Powdery mildew <i>Erysiphe sp</i>	Overall spraying directed on the plant	1 st application at onset of disease	a) 3 b) 3	10	a) 0.75 b) 2.25	a) 0.6 b) 1.8	0.03	3	Acceptable
9	South /EU	Pepper	Fn	Powdery mildew (<i>Leveillula sp.</i>)	Overall spraying directed on the plant	1 st application at onset of disease	a) 6 b) 6	10-14	a) 0.20 b) 1.2	a) 0.16 b) 0.96	0.04-0.10	3	Acceptable
10	South /EU	Salsifies	Fn	Powdery mildew (<i>Erysiphe sp.</i>)	Overall spraying directed on the plant	1 st application at onset of disease	a) 3 b) 3	10	a) 0.75 b) 2.25	a) 0.6 b) 1.8	0.03	3	Acceptable

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11	South /EU	Celery	Fn	Powdery mildew	Overall spray-ing directed on the plant	1 st applica-tion at onset of disease	a) 3 b) 3	10	a) 0.75 b) 2.25	a) 0.6 b) 1.8	0.03	3	Acceptable
12	South /EU	Blackcurrant Raspberry	Fn	Powdery mildew (<i>Sphaerotheca mors-uvae</i> ; <i>Sphaerotheca macularis</i>)	Overall spray-ing directed on the plant	1 st applica-tion at onset of disease	a) 3 b) 3	10	a) 0.75 b) 2.25	a) 0.6 b) 1.8	0.07-0.10	n.a-	Acceptable
13	South/EU	Grapes	Fn	Erinose (<i>Colomeris vitis</i>)	Overall spray-ing directed on the plant	BBCH 05	a) 1 b) 1	-	a) 2.0 b) 2.0	a) 1.6 b) 1.6	0.05-0.10	n.a.	Acceptable
14	South/EU	Beetroot Garden beet	Fn	Powdery mildew <i>Erysiphe</i> sp	Overall spray-ing directed on the plant	1 st applica-tion at onset of disease	a) 3 b) 3	10	a) 0.75 b) 2.25	a) 0.6 b) 1.8	0.03	3	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
 International Technical Monograph n°2, 6th Edition Revised May 2008
 (c) g/kg or g/l

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

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

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

3 Background of authorisation decision and risk management

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

AZUMO JARDIN (Sulphur 80% WG) is a water dispersible granules formulation. 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 a brown powder with weak odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self- ignition temperature higher than 236 °C. In 1% aqueous solution, it has a pH value of 9.8 at 22°C. There is no effect of low and high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in aluminium/LDPE. Its technical characteristics are acceptable for a water dispersible granules formulation. The formulation is not classified for the physico-chemical aspect.

3.2 Efficacy (Part B, Section 3)

The efficacy level of AZUMO JARDIN (Sulphur 80% WG) is considered as acceptable for the claimed uses. The claimed doses of 0,2 g/m² (e.g.1600 g/ha sulphur) on tomato, eggplant and pepper and of 0,3 g/m² (e.g. 2400 g/ha sulphur) on roses are inferior to that usually claimed on these crops but can be considered as acceptable in case of low to moderate infestation. The preparation achieves however a low efficacy in trials with high infestation levels.

The phytotoxicity level of AZUMO JARDIN (Sulphur 80% WG) is considered as acceptable for the claimed uses.

The risks of negative impact of AZUMO JARDIN (Sulphur 80% WG) on yield and quality and are considered as negligible.

The risk of negative impact of AZUMO JARDIN (Sulphur 80% WG) on propagation is considered as negligible.

The risks of negative impact of AZUMO JARDIN (Sulphur 80% WG) on succeeding and adjacent crops are considered as negligible.

The risk of resistance apparition or development to sulphur does not require any monitoring.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical method for the determination of the active substance in the formulation is available and validated. As no relevant impurity is specified in the active substance sulphur, no analytical method for the determination of relevant impurities in the preparation is required.

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3.3.2 Analytical methods for residues

Considering the low toxicity of sulphur, analytical methods for the determination of residues of this active substance in plants, foodstuffs of animal origin, soil, water and air are not necessary. Nevertheless, analytical methods for the determination of residues are available in the Draft Assessment Report and validated for the determination of residues of sulfur in plants (grape fruits, tomatoes and sugar beets). The active substance is neither toxic nor very toxic hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active Substance: Sulphur			
ADI	Not applicable	Efsa (2008)	
ARfD	Not applicable		
AOEL	Not applicable Background level 26 mg/kg/day		
Dermal absorption	Based on default values according to EFSA sulphur conclusions on dermal absorption (Efsa 2008) *: Dermal absorption endpoints %	Concentrate (used in formulation)	Spray dilution (used in formulation)
		10 %	10 %

* No studies were performed with the representative formulations, Sulfur 80% WG products and Sulfur 98.5 % DP. A default value of 10 %, as the worst case based on the physical/chemical properties of Sulfur, was proposed by EFSA for all formulations.

3.4.1 Acute toxicity

AZUMO JARDIN (Sulphur 80% WG) containing 800 g/kg Sulphur has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitizer.

AZUMO JARDIN (Sulphur 80% WG) is a water dispersible granules formulation for non-professional users with attrition (94%) and particle size (40.3% <10µm). The proposed packaging has been described in sufficient detail, and its compliance **can therefore** be accepted.

Indeed, the proposed packaging do ensure the minimal exposure of amateur users except 4kg bags.

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 for bags in paper/Al/LDPE⁹ (0.02 kg, 0.05 kg, 0.1 kg, 0.4 kg, 0.5 kg, 0.75 kg, 1 kg, 1.5 kg) containing a measuring spoon and bags in paper/LDPE¹⁰ (1 kg, 1.5 kg) containing a measuring spoon. However, it is considered not acceptable for 4kg bags

⁹ Paper /Aluminum / Low density polyethylene

¹⁰ Paper / Low density polyethylene

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3.4.2 exposure

Summary of critical use patterns (worst cases):

Crop	F/G ¹¹	Equipment	Application rate kg as/ha	Spray dilution (L/ha)	Model
Grapes	Fn	Manual-Knapsack - Upward spraying	16	50-100	EFSA
Fruiting vegetables		Manual-Knapsack - Upward spraying	1.6	40-100	EFSA
Low berry and other small fruits		Manual-Knapsack - Upward spraying	6	70-100	EFSA
Ornamentals		Manual-Knapsack - Upward spraying	2.4	45-150	EFSA
Pome fruits		Manual-Knapsack - Upward spraying	6	70-100	EFSA
Root and tuber vegetables		Manual-Knapsack - Upward spraying	6	30	EFSA
Stone fruits		Manual-Knapsack - Upward spraying	6	70-100	EFSA

¹¹

Open field or glasshouse

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Tier I: Considering proposed uses, operator systemic exposure was estimated using the EFSA model adapted to amateur uses:

Crop	Equipment	PPE and/or working cover-all	% AOEL Sulfur
Grapes	Manual-Knapsack - Upward spraying	No PPE*	0.91
Fruiting vegetables	Manual-Knapsack - Upward spraying	No PPE*	0.11
Low berry and other small fruits	Manual-Knapsack - Upward spraying	No PPE*	0.36
Ornamentals	Manual-Knapsack - Upward spraying	No PPE*	0.16
Pome fruits	Manual-Knapsack - Upward spraying	No PPE*	0.36
Root and tuber vegetables	Manual-Knapsack - Upward spraying	No PPE*	0.36
Stone fruits	Manual-Knapsack - Upward spraying	No PPE*	0.36

* no PPE: Operator wearing work wear (arms, body and legs covered)

EFSA model (worst case: grapes): Operator exposure is estimated below 0.91 of the AOEL of Sulfur without PPE.

Tier II:

UPJ model (worst case: grapes): Operator exposure is estimated below 0.56 of the AOEL of Sulfur without PPE.

Conclusion:

According to the model calculations, it can be concluded that the risk for the operator (non-professional) using AZUMO JARDIN (Sulphur 80% WG) is acceptable.

3.4.3 Worker exposure

AZUMO JARDIN (Sulphur 80% WG) 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.

3.4.4 Bystander and resident exposure

In the context of use by non-professionals, it is considered that the assessment for bystanders is covered by that of the operator.

Residential exposure was assessed according to EFSA model.

Crop		Sum (all pathways) % AOEL Sulfur
<u>Grapes</u>	Resident child Body weight: 10 kg	9.99
	Resident adult Body weight: 60 kg	5.43
<u>Fruiting vegetables</u>	Resident child Body weight: 10 kg	0.89
	Resident adult Body weight: 60 kg	0.48
<u>Low berry and other small fruits</u>	Resident child Body weight: 10 kg	3.33
	Resident adult Body weight: 60 kg	1.81
<u>Ornamentals</u>	Resident child Body weight: 10 kg	0.52
	Resident adult Body weight: 60 kg	0.70
<u>Pome fruits</u>	Resident child Body weight: 10 kg	3.66
	Resident adult Body weight: 60 kg	1.91
<u>Root and tuber vegetables</u>	Resident child Body weight: 10 kg	3.33
	Resident adult Body weight: 60 kg	1.81
<u>Stone fruits</u>	Resident child Body weight: 10 kg	3.66
	Resident adult Body weight: 60 kg	1.91

Conclusion:

EFSA model: Exposure is estimated below 9.99 and 5.43 % of the AOEL of Sulfur for children and adults, respectively.

It is concluded that there is no unacceptable risk to the resident exposed to AZUMO JARDIN (Sulphur 80% WG).

EFSA model (Golf course, turf or other sports lawns): Recreational exposure is assessed according to EFSA model. Exposure is estimated to 1.02% and 0.31 % of the AOEL of Sulfur for children and adults, respectively. It is concluded that there is no unacceptable risk anticipated for recreational exposure.

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

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation AZUMO JARDIN (Sulphur 80% WG) are presented in **Erreur ! Source du renvoi introuvable.**. They have been selected from the individual GAPs in the Southern zone. A list of all intended uses within the zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment.

Sulphur is included in Annex IV of Regulation (EC) No 396/2005 containing a list of active substances for which maximum residue levels (MRLs) are not required. Therefore, an exceedance of the current MRL for sulphur as laid down in Reg. (EU) 396/2005 is not expected.

According to DAR (2007), elemental sulphur applied to the target plants would amount only as a small supplement to the reservoir of sulphur that already exists in the plant. Based on this outcome, the chronic and the short-term intakes of sulphur residues are unlikely to present a public health concern.

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

According to available data, no specific mitigation measures should apply.

Data gaps

None.

Summary of the evaluation

The preparation AZUMO JARDIN (Sulphur 80% WG) is composed of sulphur (800 g/kg).

Toxicological reference values for the dietary risk assessment of sulphur

Reference value	Source	Year	Value	Study relied upon	Safety factor
ADI	EFSA Scientific report (2008) 221,39-70	2008	None allocated	--	--
ARfD	EFSA Scientific report (2008) 221,39-70	2008	None allocated	--	--

EFSA, 2009

“Since sulfur is an essential element, and considering its wide range of background exposure, its low acute and short-term toxicity and its lack of genotoxic potential, long-term toxicity, carcinogenicity- and reproductive toxicity studies were not performed, neither they were required. Likewise, it was agreed not to propose an ADI, AOEL and ARfD.

Subsequent to the EU review of sulphur it was reported in the EFSA Review Report (EFSA Scientific Report (2008) 221, December 2008) that a residue definition for monitoring was not necessary nor an MRL

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for elemental sulphur. Subsequently Annex IV of Council Regulation (EC) No 369/2005 has been amended in accordance with the recommendation (see Commission Regulation (EU) No 459/2010).

Summary for sulphur

Summary for sulphur

Use- No.*	Crop	Plant metab- olism cov- ered?	Sufficient residue tri- als?	PHI suffi- ciently sup- ported?	Sample storage covered by stabil- ity data?	MRL com- pliance	Chronic risk for consumers identified?	Acute risk for con- sumers identified?
1	Grapes	Yes	NR	NR	NR	No MRL required	No	No
2	Tomato Aubergine							
3	Pome fruits: Apple, pear, quince							
4	Stone fruits: Peach, nect- ararine and apricot							
5	Beetroot							
6	Ornamen- tals: roses, flowers and green plants, interior and balcony plants, trees and shrubs	Yes	NR	NR	NR	No MRL required	No	No
7	Avocados, mangoes, papayas							
8	Chicory							
9	Pepper							
10	Salsifies							
11	Celery							
12	Blackcurrant Raspberry							
13	Grapes							

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

NR: not relevant

Sulphur is a naturally occurring element of soil and plants. It is therefore difficult to make the distinction between sulphur coming from the exogenous application and naturally occurring sulphur.

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The data presented below, available in the DAR of sulphur (2007), have been evaluated as sufficient to support the authorisation of sulphur as active ingredient. It is important to note that sulphur fulfils criteria of Annex VI of Regulation 2229/2004. Furthermore, sulphur is included in Annex IV of Regulation 396/2005. This annex includes substances for which no MRL is required to be set.

Summary for AZUMO JARDIN (Sulphur 80% WG)**Information on AZUMO JARDIN (Sulphur 80% WG)**

Use-No.*	Crop	PHI for AZUMO JARDIN (Sulphur 80% WG) proposed by applicant	PHI/ Withholding period* sufficiently supported for sulphur	PHI for AZUMO JARDIN (Sulphur 80% WG) proposed by zRMS	zRMS Comments (if different PHI proposed)
1	Grapes	5	NR	n.n.	-
2	Tomato Aubergine	3	NR	n.n.	-
3	Pome fruits: Apple, pear, quince	NP	NR	n.n.	PHI not required.
4	Stone fruits: Peach, nectarine and apricot	NP	NR	n.n.	PHI not required.
5	Beetroot	14	NR	n.n.	-
6	Ornamentals: roses, flowers and green plants, interior and balcony plants, trees and shrubs	n.a.	NR	n.a.	Not assessed: non-food/non-feed use
7	Avocados, mangoes, papayas	n.a.	NR	n.n.	PHI not required.
8	Chicory	3	NR	n.n.	-
9	Pepper	3	NR	n.n.	-
10	Salsifies	3	NR	n.n.	-
11	Celery	3	NR	n.n.	-
12	Blackcurrant Raspberry	3	NR	n.n.	-
13	Grapes	n.a.	NR	n.n.	-

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).

n.n.: not necessary

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Waiting periods before planting succeeding crops

Not relevant.

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

The fate and behaviour in the environment of the formulation has been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate 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 of sulfur in soil, surface water and groundwater has 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 results for PEC soil and PECsw and PECsed for the active substance are used for the eco-toxicological risk assessment.

PECgw for sulfur do not exceed the trigger of 250 mg/L (Directive 98/83/CE). Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

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.

3.7 Ecotoxicology (Part B, Section 9)

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

Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms are acceptable for the intended uses in home and garden.

3.8 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 of 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.

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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 **AZUMO JARDIN***

de la société AFEPASA (AZUFRERA Y FERTILIZANTES PALLARES SA)
enregistrée sous le n°2020-0549

Vu les conclusions de l'évaluation de l'Anses du 4 mars 2021,

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

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

Avertissement :

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

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Informations générales sur le produit

Nom du produit	AZUMO JARDIN	
Type de produit	Deuxième gamme	
Titulaire	AFEPASA (AZUFRERA Y FERTILIZANTES PALLARES SA) Av. De Europa, 1-7 Pol. Ind. De Constanti 43120 CONSTANTI (Tarragona) Espagne	
Formulation	Granulé dispersable (WG)	
Contenant	800 g/kg - soufre	
Produit de référence	Nom commercial	VISUL GD 80
	N° AMM	9700114
Numéro d'intrant	168-2020.01	
Numéro d'AMM	2210263	
Fonction	Fongicide et acaricide	
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 2022.

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. L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit de référence.

A Maisons-Alfort, le

07 AVR. 2021

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)

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**ANNEXE I : Modalités d'autorisation du produit****Vente et distribution**

Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :

Emballage	Contenance
Sacs en papier / aluminium / polyéthylène basse densité	20 g ; 50 g ; 100 g ; 400 g ; 500 g ; 750 g ; 1 kg ; 1,5 kg
Sacs en polyéthylène basse densité / papier	1 kg ; 1,5 kg

Les emballages de 4 kg sont refusés car ils ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel.

Classification du produit

La classification retenue est la suivante :

Sans classement.

Pour les phrases P se référer à la réglementation en vigueur.

Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.

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Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée anthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
14053204 Arbres et arbustes* ^T tr Part.Aer.* Oridium(s)	0,3 g/m²	5/an						
Intervalle minimum entre les applications : 10 jours.								
00803003 Avocatier* ^T tr Part.Aer.* Oridium(s)	0,75 g/m²	6/an						
Intervalle minimum entre les applications : 10 jours.								
15053202 Bitterave industrielle et fourragère* ^T tr Part.Aer.* Maladies du feuillage	0,75 g/m²	3/an	entre les stades BBCH 15 et BBCH 39	-	5	-	-	
Intervalle minimum entre les applications : 10 jours.								
16173204 Bitterave potagère* Tr part.aer. * ^T ridium(s)	0,75 g/m²	3/an	entre les stades BBCH 15 et BBCH 39	-	5	-	-	
Intervalle minimum entre les applications : 10 jours.								
12153202 Cassisier* ^T tr Part.Aer.* Oridium(s)	0,75 g/m²	3/an			5	-	-	
Intervalle minimum entre les applications : 10 jours.								
01123004 Céleri-branche* ^T tr Part.Aer.* Oridium(s)	0,75 g/L	3/an			5	-	-	
Intervalle minimum entre les applications : 10 jours.								

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	Déai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
16353204 Chicorées - Production de racines*Ttr Part.Aer.*Oridium(s)	0,75 g/m²	3/an	-	-	5	-	-	-
			Intervalle minimum entre les applications : 10 jours.					
17403202 Cultures florales et plantes vertes*Ttr Part.Aer.*Oridium(s)	0,3 g/m²	5/an	-	-	5	-	-	-
			Intervalle minimum entre les applications : 10 jours.					
12353204 Framboisier*Ttr Part.Aer.*Oridium(s)	0,75 g/m²	3/an	-	-	5	-	-	-
			Intervalle minimum entre les applications : 10 jours.					
00810005 Mangouier*Ttr Part.Aer.*Oridium(s)	0,75 g/m²	6/an	-	-	5	-	-	-
			Intervalle minimum entre les applications : 10 jours.					
01271004 Papayer*Ttr Part.Aer.*Oridium(s)	0,75 g/m²	6/an	-	-	5	-	-	-
			Intervalle minimum entre les applications : 10 jours.					
12553224 Pêcher*Ttr Part.Aer.*Oridium(s)	0,75 g/m²	6/an	à partir de BBCH 69	-	5	-	-	-
			Intervalle minimum entre les applications : 10 jours.					
16863203 Poivron*Ttr Part.Aer.*Oridium(s)	0,2 g/m²	6/an	-	-	5	-	-	-
			Intervalle minimum entre les applications : 10 jours.					

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Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
12603202 Pommier*Trit Part.Aer.* Oridium(s)	0,75 g/m ²	6/an	entre les stades BBCH 01 et BBCH 60 puis à partir de BBCH 69	-	5	5	5	-
Intervalle minimum entre les applications : 10 jours.								
17303203 Rosier*Trit Part.Aer.* Oridium(s)	0,3 g/m ²	5/an	-	-	5	-	-	-
Intervalle minimum entre les applications : 10 jours.								
16903201 Salsifis*Trit Part.Aer.* Oridium(s)	0,75 g/m ²	3/an	-	-	5	-	-	-
Intervalle minimum entre les applications : 10 jours.								
16953206 Tomate*Trit Part.Aer.* Oridium(s)	0,2 g/m ²	6/an	entre les stades BBCH 10 et BBCH 51	-	5	-	-	-
Intervalle minimum entre les applications : 10 jours.								
12703115 Vigne*Trit Part.Aer.*Erimose	2 g/m ²	1/an	à partir du stade BBCH 05	-	5	-	-	-
Intervalle minimum entre les applications : 7 jours.								
12703204 Vigne*Trit Part.Aer.*Oridium(s)	1,25 g/m ²	8/an	à partir du stade BBCH 15	-	5	-	-	-

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Conditions d'emploi du produit

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

- 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 et les eaux de lavage du pulvérisateur.

Protection de la faune

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

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Appendix 2 Copy of the product label

AZUMO JARDIN

Autorisation de Mise sur le Marché n° XXXXXX
Détenteur: AFEPASA Pol. Ind. De Constanti, Av. De Europa, 1-7, 43120 Constanti Espagne

FONGICIDE, granulé dispersable contenant 80% de soufre

Usages autorisés:

Cultures/Organisme nuisible	Dose	Délai avant récolte (jours)	Application
Vigne / Oïdium	12,5 g/l	5	
Tomate, aubergine, poivron / Oïdium	2 g/l	5	
Betterave industrielle et fourragère / Maladies du feuillage	7,5 g/l	14	
Arbres fruitiers à noyaux (pêcher, abricotier, nectarine, Mango, avocado) / Oïdium	7,5 g/l	---	
Arbres fruitiers à pépins (pommier, Poirier, Cognassier, Nèfles, Nashi, Pommette, papaye) / Oïdium	7,5 g/l	---	
Ornementales (rosier, fleurs et plantes vertes, plantes d'intérieur et de balcon, arbres et arbustes)	2,4 g/l	--	
Chicorées – production de racines	7,5 g/l	3	
Salsifis, scorsonère	7,5 g/l	3	
Céleri-branche, fenouil, rhubarbe	7,5 g/l	3	
Framboisier, mûres, mûres des haies	7,5 g/l	--	
Cassissier, myrtillier, groseillier, sureau noir, airelle, cynorodon, azerolier	7,5 g/l	--	
Vigne / Erinose	20 g/l	---	

Respectez une zone non traitée de 5 mètres par rapport aux points d'eaux.

Traiter à partir du stade BBCH 15-18 sur vigne et à partir du début de l'apparition de la maladie sur tous les autres cultures.

Mode d'action: Le soufre est un produit minéral dont l'action sur l'oïdium est connue depuis très longtemps. Le soufre peut provoquer des brûlures en conditions défavorables et plus particulièrement à températures élevées. En traitement préventif : lorsque les conditions climatiques ont été favorables au développement des oïdiums, à savoir après une période de température douce (15 à 20°C) et de forte humidité.

En traitement curatif : Pulvériser dès l'apparition des premières taches blanches d'oïdium, en période de haut risque, traiter tous les 10 à 15 jours et renouveler le traitement après une forte pluie.

Mode d'emploi: Azumo jardin s'utilise en pulvérisation sur le feuillage. Remplir la cuve du pulvérisateur au ¾ du volume d'eau nécessaire. Verser lentement les granules dispersables dans l'eau du pulvérisateur, puis agiter pour mélanger la préparation, la formulation en granules dispersables assure une dissolution instantanée. Compléter avec de l'eau jusqu'au volume final.

Les limites maximales en résidus sont consultables à l'adresse suivante: <http://e-phy.agriculture.gouv.fr>

La fiche de sécurité est disponible sur demande ou sur internet sous : www.afepasa-agro.fr

N.B. « Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé.

Emballages vides: Réemploi de l'emballage interdit. Ne pas jeter dans les poubelles ménagères, mais éliminer l'emballage avec ou sans produit en déchèterie ou par un organisme agréé.

Précautions d'emploi

Lors de la préparation du pulvérisateur : Ne préparer que la quantité de bouille nécessaire au traitement.

Lors de l'application : Ne pas traiter en cas de fortes chaleurs (+28°C) ou par temps venté. Préférer un traitement tôt le matin ou tard le soir. Sur arbres fruitiers, une sensibilité variétale peut survenir (ex. abricotier Bergeron). Espacer de 8 à 10 jours les traitements au soufre et ceux à base de produits huileux (risque de brûlure).

Après l'application : l'eau de rinçage du pulvérisateur (rincé 3 fois lors de la dernière utilisation) doit être pulvérisée à nouveau sur la zone traitée. Ne jamais la vider près d'un point d'eau. **Bien refermer le sachet après usage, en utilisant l'autocollant situé dans le rabat de la boîte.** Conserver le produit dans son emballage d'origine, à l'abri de l'humidité entre 0°C et +40°C.

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Contient 80% de soufre micronisé
P102 : Tenir hors de portée des enfants
P270 : Ne pas manger, boire ou fumer en manipulant ce produit
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 des systèmes d'évacuation des eaux à partir des cours de ferme ou des routes).
SPe3 Pour protéger les organismes aquatiques respecter une zone non traitée de 5 mètres par rapport aux points d'eau.
EUH401 : Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

Détenteur: AFEPASA Pol. Ind. De Constanti, Av. De Europa, 1-7, 43120 Constanti Espagne

REMARQUES : Respectez les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage, qui ont été déterminés en fonction des caractéristiques et des applications pour lesquelles le produit est préconisé. Conduisez, sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous 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 de ces produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise sur le marché du Ministère de l'Agriculture. La société ne sera pas responsable des pertes ou des dégâts occasionnés par une utilisation non conforme à ses recommandations. L'utilisateur assume tous les risques associés à un tel usage, non conforme à ces recommandations.

N° DE LOT : voir sur emballage

POIDS NET :

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Appendix 3 Letter of Access

Not applicable.