

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: 2018/12/19

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PART A

RISK MANAGEMENT

1 Details of the application

The company Azufrera y Fertilizantes Pallarés, S.A. (AFEPASA) 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.

Appendix 4 of this document is the list of data considered for national authorisation

1.1 Application background

The present registration report concerns the evaluation of Azufrera y Fertilizantes Pallarés, S.A. (AFEPASA)'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) 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 are based and is not intended to show the assessment in detail.

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

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

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in **Erreur ! Source du renvoi introuvable..**

2 Details of the authorisation decision

2.1 Product identity

Product code	Sulphur 80% WG
Product name in MS	AZUMO JARDIN
Authorisation number	N/A
Low risk (article 47)	No
Function	Fungicide
Applicant	Azufrera y Fertilizantes Pallarés, S.A. (AFEPASA)
Active substance(s) (incl. content)	Sulphur, 800 g/kg
Formulation type	Water-dispersible granule (WG)
Packaging	Aluminum PE bag (4 kg, 1.5 kg, 1 kg, 750 g, 500 g, 400 g, 100 g, 50 g and 20 g) Not acceptable for non professional users
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 AZUMO JARDIN (Sulphur 80% WG) resulted in the decision to

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

refuse 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 2017⁴ provides that:

- 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

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

appendix 3 of the above-mentioned French Order.

Finally, the French Order of 26 March 2014⁵ 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 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.

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

According to French order of 30 december 2010 the packaging should minimize operator exposure when non-professional uses are intended. Considering that proposed packaging do not allow to minimize operator exposure, the product cannot be registered in France.

2.5.1 Restrictions linked to the PPP

N/A : no authorisation in France

2.5.2 Specific restrictions linked to the intended uses

N/A : no authorisation in France

⁵ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

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

2.6 Intended uses (only NATIONAL GAP)

Please note:

When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

PPP (product name/code): 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 situation (crop destination / 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/ syner- gist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (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	See 2.5
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	a) 6 b) 6	10-14	a) 2 b) 12	a) 1.6 b) 19.2	0.04-0.10	3	See 2.5
3	South /EU	Pome fruits: Apple, pear, quince	Fn	Powdery mildew: <i>Podo- sphaera leucotricha</i>	Overall spray- ing directed on the plant	1 st applica- tion 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	NP	See 2.5

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4	South /EU	Stone fruits: Peach, nectarine and apricot	Fn	Powdery mildew: <i>Sphaerotheca pannosa</i>	Overall spray- ing directed on the plant	1 st applica- tion 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	NP	See 2.5
5	South /EU	Sugar beet	Fn	Powdery mildew <i>Erysiphe betae</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	0.03	14	See 2.5
Minor uses according to Article 51 (zonal uses)													
6	South /EU	Ornamentals: roses, flowers and green plants, interior and balcony plants, trees and shrubs	Fn	Powdery mildew: <i>Sphaerotheca pannosa</i> and others	Overall spray- ing directed on the plant	1 st applica- tion at onset of disease	5	10	a) 0.3 b) 1.5	a) 0.24 b) 1.2	0.045-0.15	n.a.	See 2.5
7	South /EU	Avocados, man- goes, papayas	Fn	Powdery mildew	Overall spray- ing directed on the plant	1 st applica- tion 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	See 2.5
8	South /EU	Chicory	Fn	Powdery mildew <i>Erysiphe sp</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	0.03	3	See 2.5
9	South /EU	Pepper	Fn	Powdery mildew (<i>Leveillula</i> sp.)	Overall spray- ing directed on the plant	1 st applica- tion 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	See 2.5
10	South /EU	Salsifies	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	See 2.5
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	See 2.5
12	South /EU	Blackcurrant Raspberry	Fn	Powdery mildew (<i>Sphaerotheca mors- uvae</i> ; <i>Sphaerotheca</i> <i>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-	See 2.5
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.	See 2.5

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14	South/EU	Beetroot Garden beet	Fn	Powdery mildew Erysiphe sp	Overall spray- ing directed on the plant	1st 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	See 2.5
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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**4 Further information to permit a decision to be made or to support
a review of the conditions and restrictions associated with the
authorisation**

N/A : no authorisation in France.

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 l'arrêté du 30 décembre 2010 relatif aux conditions d'emballage des produits phytopharmaceutiques pouvant être employés par des utilisateurs non professionnels,

*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°2017-2617

Vu les conclusions de l'évaluation de l'Anses du 22 octobre 2018,

Considérant que les emballages du produit ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel, conformément à l'article 1 de l'arrêté du 30 décembre 2010,

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.



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	<table border="1"> <tr> <td>Nom commercial</td><td>VISUL GD 80</td></tr> <tr> <td>N° AMM</td><td>9700114</td></tr> </table>	Nom commercial	VISUL GD 80	N° AMM	9700114
Nom commercial	VISUL GD 80				
N° AMM	9700114				
Numéro d'intrant	928-2017.01				
Numéro d'AMM	-				
Fonction	Fongicide				
Gamme d'usage	Amateur / emploi autorisé dans les jardins				

A Maisons-Alfort le,

19 DEC. 2018

Françoise WEBER

Directrice générale déléguée

en charge du pôle produits réglementés

Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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	
Cèleri-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	---	

Pulvériser avec soin le dessus et le dessous des feuilles ainsi que l'extrémité des rameaux

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.

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 :

Appendix 3 Letter of Access

Not applicable.

