

REGISTRATION REPORT

Part A

Risk Management

Product code: 1 40011 01

Product name(s): FAETON JARDIN

Chemical active substance:

Sulphur, 800 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: PHYTEUROP SA

Date: 7 November 2024

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PART A

RISK MANAGEMENT

1 Details of the application

The company PHYTEUROP SA has requested a marketing authorisation in France for the product FAETON JARDIN (product code: 1 40011 01), containing 800 g/L sulphur¹ as a fungicide for non-professional uses.

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

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

1.1 Application background

The present registration report concerns the evaluation of PHYTEUROP SA's application submitted on 02/08/2022 to market FAETON JARDIN (1 40011 01) 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).

The present application (2022-3036) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs, taking into account the worst-case uses ("risk envelope approach")³. 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 FAETON JARDIN (1 40011 01) has been made using endpoints agreed in the EU peer review of sulphur . It also includes assessment of data and information related to FAETON JARDIN (1 40011 01) 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 546/2011⁴, 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 FAETON JARDIN (1 40011 01).

¹ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances

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

³ 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](#)

⁴ 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 a letter of access for the active substance. This letter of access is available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: « Studies are submitted in accordance with Regulation 284/2013 and current Guidelines.».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of FAETON JARDIN (1 40011 01), 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	1 40011 01
Product name in MS	FAETON JARDIN
Authorisation number	2240385
Kind of use	Non-professional use
Low risk product (article 47)	No
Function	Fungicide
Applicant	PHYTEUROP SA
Active substance(s) (incl. content)	Sulphur, 800 g/L
Formulation type	Suspension concentrate [SC]
Packaging	HDPE Bottles with integrated dosing chamber (125 mL, 250 mL, 500 mL, 1L). HDPE Bottles with measuring cap (275 mL, 500 mL, 750 mL, 1 L) Other packagings proposed by the applicant are not accepted by zRMS for non-professional users : HDPE Bottle with a non-dosing cap and without dosing system (0.120 L, 0.275 L, 0.550 L, 1 L, 1.1 L)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

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The evaluation of the application for FAETON JARDIN (1 40011 01) resulted in the decision **to grant** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008 :

Hazard class(es), categories:	-
Hazard pictograms:	-
Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	EUH 208 : Contains 1, 2-benzisothiazole-3(2H)-one and reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction.

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

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

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
	For other restrictions refer to 2.5

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

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017⁵ provides that:

⁵ 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/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

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- 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 2021⁶ provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁷ 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 2021⁸ 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 crop⁹ 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

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	

⁶ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

⁷ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

⁸ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

⁹ 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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	Do not discharge into the sink, gutter or any other water source the non-used container leftovers and the sprayer washing water..
	To protect aquatic organisms apply at least 5 meters away from any surface water bodies (well, pond, stream, river...).
	Do not apply when pollinating and/or beneficials such as bees, bumble bees, ladybirds etc. are present.
Other specific restrictions	
Re-entry period	Not applicable.Wait until the treated zone or plants have dried.
Storage	-
Risk mitigation measures	

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.

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2.6 Intended uses (only NATIONAL GAP)

GAP rev. 3, date: 2024-11

PPP (product name/code) **FAETON JARDIN**
active substance **sulphur**
safener **none**
synergist **none**

Formulation type: **SC**
Conc. of as : **800 g/L**
Conc. of safener: **not applicable**
Conc. of synergist: **not applicable**

Applicant: **PHYTEUROP SA**
Zone(s): **southern zone for field**
Interzonal for GH

professional use
non professional use

Verified by MS:

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1.	FR	Grapevine (VITVI)	Fn	Powdery mildew: grapevine (oidium) <i>Erysiphe necator</i> (UNCINE)	Overall spraying directed on the plant	BBCH 10-79	a) 8 b) 8/season	7 days	a) 125 ml/100m ² b) 1000mL /100 m ²	a) 10 000 b) 80 000	5 à 10L/100m ²	F (BBCH 79)	Acceptable
2.	FR	Tomato (LYPES) Eggplant (SOLME)	Fn, Gn	Powdery mildew: tomato <i>Leveillula taurica</i> (LEVETA)	Overall spraying directed on the plant	1 st application at onset of disease	a) 6 b) 6/season	10 days	a) 20mL/ 100m ² b) 120 mL/10 m ²	a) 1 600 b) 9 600	5 à 10L/100m ²	1	Acceptable
3.	FR	Flowers Rose	Fn, Gn	Powdery mildew: rose <i>Sphaeroteca pannosa</i> (SPHRPA)	Overall spraying directed on the plant	1 st application at onset of disease	a) 6 b) 6/season	10 days	a) 33 mL/100 m ² b) 198 mL/100 m ²	a) 2 640 b) 13 200	5 à 10L/100m ²	Not applicable	Acceptable

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4	FR	Beetroot (BEAVD)	Fn	Powdery mildew : <i>Erysiphe betae</i> (ERYSBE)	Overall spraying directed on the plant	1 st application at onset of disease	a) 3 b) 3/season	10 days	a) 75 mL/100 m ² b) 225 mL/100 m ²	a) 6 000 b) 18 000	5 à 10L/100m ²	3	Acceptable
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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

- (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.

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.

- 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. F: The latest time of application must be maximum growth stage
 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)

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 yellowish viscous liquid, with characteristic odour. It is not explosive, has no oxidising properties. It has a self-ignition temperature greater than 400 °C. In aqueous solution, it has a pH value around 5.6. The accelerate stability data indicate a shelf life of at least 2 years at ambient temperature, the storage stability study for 2 years at ambient temperature confirmed the results. Its technical characteristics are acceptable for a Suspension Concentrate (SC). The intended concentration of use is 0,2 % to 2,5 % v/v for home garden. (Comprised in the range 0.225 to 3.3).

The formulation does not contain hydrocarbons or H304 formulants $\geq 10\%$.

The preparation is not the representative formulation of the DAR.

There are no toxicologically, ecotoxicologically or environmentally relevant impurities in the formulated product.

3.2 Efficacy (Part B, Section 3)

The level of effectiveness of the product FAETON JARDIN (1 40011 01) is considered acceptable for all the requested uses.

The level of phytotoxicity of the product FAETON JARDIN (1 40011 01) is considered acceptable for all the requested uses.

The risks of negative impact on succeeding crops or adjacent crops are considered negligible.

The resistance risk of resistance to sulphur used in amateur gardens should not be amplified with regard to its professional use.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of active substance 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

In accordance with Reg. (EC) No 459/2010, sulphur has not MRLs therefore no analytical methods for residues are required.

3.4 Mammalian toxicology (Part B, Section 6)

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Endpoints used in risk assessment

Agreed EU endpoints	
Active substance	Sulphur, 800 g/L
AOEL	Not applicable
AAOEL	Not applicable
Background intake value	26 mg/kg bw/day
Inhalation absorption	100%
Oral absorption	100%
Dermal absorption	Concentrate: 10% Spray dilution: 50%

3.4.1 Acute toxicity

FAETON JARDIN (1 40011 01) containing 800 g/L Sulphur shows a low toxicity in respect to acute oral, inhalation and dermal toxicity. FAETON JARDIN (1 40011 01) is neither corrosive nor irritant to the eye or to the skin and is not a skin sensitiser.

3.4.2 Operator exposure

Comments of zRMS	Estimation of operator exposure has been reassessed by zRMS and the results are presented in the table below :			
			SULPHUR	
	Model data	Level of PPE	Total absorbed dose	% of systemic AOEL
	EFSA model Non-professional operator Outdoor Critical use: grapes, manual-handheld application of SC Application rate: 8 x 10 kg a.s./ha / area treated: 4 ha/day			
	EFSA model Body weight: 60 kg	No PPE Potential exposure	1.66 mg/kg/day	6.40%
	EFSA model Non-professional operator Outdoor Critical use: grapes, manual knapsack application of SC Application rate: 8 x 10 kg a.s./ha / area treated: 1 ha/day			
EFSA model Body weight: 60 kg	No PPE Potential exposure	1.01 mg/kg/day	3.92%	

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<p>UPJ model (French garden exposure model) Non -professional operator Outdoor Critical use: grapevine Critical crop type: Hedgerows and other tall crops (>60cm) Prealable pressure sprayer Application rate: 12.5 mL product / 10m² Min. volume of slurry applied per surface: 0,05 L/m²</p>			
UPJ model Liquid application Body weight: 60 kg	No PPE Without gloves	39657 ug	2.54%
<p>No personal protective equipment is required for non-professional users. The outdoor exposure model can be extrapolated to the greenhouse model for the other recommended uses (beetroots, flowers, tomato and eggplant).</p> <p><u>Conclusion</u> Based on the EFSA model and the French UPJ garden model, the operator exposure for amateur use is below the background intake value (replacing the AOEL) of sulphur for all the intended uses.</p> <p><i>The proposed packaging has been described in detail. Compliance with the provisions of French regulation relating to the conditions of authorisation of plant protection products by non-professional users¹⁰ is considered to be finalised only for the following packaging:</i> HDPE Bottles with integrated dosing chamber (125 mL, 250 mL, 500 mL, 1L). HDPE Bottles with measuring cap (275 mL, 500 mL, 750 mL, 1 L)</p> <p>Other packaging proposed by the applicant are not accepted by zRMS for non-professional users: HDPE Bottle with a non-dosing cap and without dosing system (0.120 L, 0.275 L, 0.550 L, 1 L, 1.1 L)</p>			

3.4.3 Worker exposure

Comments of zRMS	zRMS considers that in the case of the non-professional user, the worker is also the operator of the product. Therefore, the assessment of worker exposure is covered by the operator exposure.
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3.4.4 Bystander exposure

Comments of zRMS	<p>Estimation of bystander exposure</p> <p>In the context of use by non-professionals, it is considered that the assessment for bystanders is covered by that of the resident.</p>
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¹⁰ Arrêté du 6 avril 2020 relatif aux conditions d'autorisation d'un produit phytopharmaceutique pour la gamme d'usages « amateur » JORF n°0088 du 10 avril 2020

3.4.5 Resident exposure

Comments of zRMS	Estimation of resident exposure	
	There is no suitable model to assess resident exposure for non-professional uses. As a worst case the EFSA model for resident (recreational exposure) has been used by zRMS. The estimated recreational exposure for resident is presented in the table below:	
	Sulphur	
	Model data	Total absorbed dose (mg a.s./kg bw/day)
	EFSA model- Recreational exposure	
	Critical use: golf course, turf or other sports lawns Application rate: 6 x 10 kg a.s./ha*	
1-3 year old child Body weight: 10 kg	5.25	20.20%
Adult	2.21	8.51%
* Covers all claimed uses		
Conclusion:		
This assessment covers also grapevine uses using EFSA 2014;12(10):3874 using 5m distance and results in 16.72% and 9.16% for all pathways (mean) respectively for children and adults. On the basis of this assessment, the risk to residents (adults and children) is considered to be within acceptable levels.		

3.4.6 Combined exposure

Not relevant.

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

Sulfur is listed in Annex IV of Regulation (EC) No. 396/2005, which lists active substances for which MRLs are not required.

The assessment of consumer exposure was therefore not considered relevant.

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

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009.

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The PEC of active substance in sediment 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.

According to the intended uses (home and garden uses), PEC_{sw} and PEC_{sediment} due to the drift only derived for the active substance are used for the ecotoxicological risk assessment.

PEC_{gw} values for sulfates do not exceed the drinking water limit of 250 mg/L set in the Regulation EU No 546/2011. Therefore, no unacceptable risk of groundwater contamination is expected for all intended uses.

3.7 Ecotoxicology (Part B, Section 9)

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

The risk to birds is considered acceptable for the intended uses. For aquatic organisms, the risk can be considered as acceptable, with mitigation measures.

For bees, an acceptable oral acute and chronic risks are concluded at Tier 1 for adult and larvae honeybees for all the intended use of FAETON JARDIN (1 40011 01) except the acute one for use one vineyard for which an acceptable risk is not demonstrated for exposure by contact.

No relevant refinement was provided to address the acute contact risk assessment for the product accordingly. Therefore, further refinement is needed to finalise the acute contact risk assessment for use on vineyard. **Without such data FR considers the acute contact risk assessment for honey-bees as not finalised for use on vineyard.**

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

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

The active substance sulphur is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

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5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation

Docusign Envelope ID: B46AD1C8-E7F0-496F-96AF-9D832AF8F2FF



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 et la demande associée du produit phytopharmaceutique FAETON JARDIN

de la société SIPCAM FRANCE
enregistrées sous les n° 2022-3036 et 2024-1387

Vu les conclusions de l'évaluation de l'Anses du 30 mai 2024,

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

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

Avertissement :

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

DocuSign Envelope ID: B46AD1C8-E7F0-496F-96AF-9D832AF8F2FF



Informations générales sur le produit		
Nom du produit	FAETON JARDIN	
Type de produit	Deuxième gamme	
Titulaire	SIPCAM FRANCE 14 rue Beffroy 92200 NEUILLY-SUR-SEINE France	
Formulation	Suspension concentrée (SC)	
Contenant	800 g/L - soufre	
Produit de référence	Nom commercial	ACTIOL
	N° AMM	8300063
Numéro d'intrant	929-2022.01	
Numéro d'AMM	2240385	
Fonction	Fongicide	
Gamme d'usage	Amateur / emploi autorisé dans les jardins	

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 15 avril 2026.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) n° 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le 07/11/2024

DocuSigned by:

Charlotte Grastilleur

AE201AR55AA2454

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 : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Bouteilles en polyéthylène haute densité avec chambre de dosage intégrée	125 mL ; 250 mL ; 500 mL ; 1 L
Bouteilles en polyéthylène haute densité avec bouchon doseur et système anti-débordement	275 mL ; 500 mL ; 750 mL ; 1 L

Les emballages équipés avec bouchon à vis non doseur et sans système de dosage 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
EUH208 : Contient de la 1,2 benzisothiazol-3(2H)-one et un mélange de 5-chloro-2-méthyl-2H-isothiazol-3-one et de 2-méthyl-2H-isothiazol-3-one. Peut produire une réaction allergique.
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 arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
16173204 Betterave potagère*Trt Part.Aer.*Oïdium(s)	0,75 mL/m²	3/an	-	3	5	-	-	Non pertinent
Intervalle minimum entre les applications : 10 jours.								
17303203 Rosier*Trt Part.Aer.*Oïdium(s)	0,33 mL/m²	6/an	-	Non applicable	5	-	-	Non pertinent
Également autorisé sous abri. Intervalle minimum entre les applications : 10 jours.								
16953206 Tomate - Aubergine*Trt Part.Aer.*Oïdium(s)	0,2 mL/m²	6/an	-	1	5	-	-	Non pertinent
Également autorisé sous abri. Intervalle minimum entre les applications : 10 jours.								
12703204 Vigne*Trt Part.Aer.*Oïdium(s)	1,25 mL/m²	8/an	entre les stades BBCH 10 et BBCH 79	F (BBCH 79)	5	-	-	Non pertinent
Intervalle minimum entre les applications : 7 jours.								

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Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15053202 Betterave industrielle et fourragère*Trt Part.Aer.*Maladies du feuillage	0,75 mL/m ²	3/an	14
	Motivation du refus : L'usage est refusé car transformé en l'usage 16173204 - Betterave potagère*Trt Part.Aer.*Oïdium mieux adapté à la revendication.		

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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.

Respect des limites maximales de résidus (LMR)

Le délai avant récolte est fixé à 1 ou 3 jours selon les cultures afin de limiter l'exposition potentielle des consommateurs.

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

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.

Draft étiquette	FAETON JARDIN
Date : 04/2022	Page 1

FAETON JARDIN

1

NOM HOMOLOGUÉ : FAETON JARDIN
N° D'AMM : xxxxxx
DETENTEUR DE L'AMM : PHYTEUROP-83 avenue de la Grande Armée-75016 PARIS
TYPE D'ACTION : Fongicide
FORMULATION : Suspension concentrée (SC)
COMPOSITION : 800 g/L (56,05 % p/p) soufre micronisé |

2

Culture / Cible	Dose	Nombre max. d'applications, Stades d'application, DAR, ZNT
Betterave industrielle et fourragère/ oïdium	75 mL/100m2	Se reporter au tableau des usages à l'intérieur du livret
Rosier / oïdium	33 mL/100m2	
Tomate-Aubergine / oïdium	20 mL/100m2	
Vigne / oïdium	125 mL/100m2	

3

FAETON® JARDIN

AMM n° xxxxxx

Contient : Soufre micronisé

EUH 208 : Contient de la 1,2 benzisothiazol-3(2H)-one. Peut produire une réaction allergique.

P101 En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette.

P102 Tenir hors de portée des enfants.

P103 Lire l'étiquette avant utilisation.

P270 Ne pas manger, boire ou fumer en manipulant ce produit

P501 Eliminer le contenu/récipient dans une déchetterie

Les chiffres 1 à 11 correspondent aux fichiers « squelette » (disposition des parties et des paragraphes).
Les bandeaux de titre sont à reporter sur l'étiquette.

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Draft étiquette	FAETON JARDIN
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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.]

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.

Délai de rentrée : Attendre le séchage complet de la zone avant d'y rentrer

4

EN CAS D'URGENCE

Composer le 15 ou le 112 ou contacter
le centre anti-poison le plus proche

Puis signalez vos symptômes au réseau
Phyt'attitude,
n° vert 0 800 887 887
(appel gratuit depuis un poste fixe).

5

ou

5 bis

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. En cas d'irritation ou éruption cutanée, consulter un spécialiste.
- **En cas de projection dans les yeux :** rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Consulter un spécialiste.
- **En cas d'inhalation :** en cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre anti-poison.
- **En cas d'ingestion :** rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir sans avis médical. Contacter sans délai les secours : le 15, le 112 ou un centre anti-poison.
- 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 :** contacter votre vétérinaire.

Fiche de données de sécurité disponible sur : www.quickfds.com

6

Les chiffres 1 à 11 correspondent aux fichiers « squelette » (disposition des parties et des paragraphes).
Les bandeaux de titre sont à reporter sur l'étiquette.

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Draft étiquette	FAETON JARDIN
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EMB : 49215 F

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N° de lot et date de fabrication : voir sur l'emballage



REEMPLOI DE L'EMBALLAGE INTERDIT.



DESCRIPTIF DU PRODUIT

FAETON® JARDIN est un fongicide préventif, curatif et éradiquant ; il est néanmoins conseillé de l'utiliser en traitement préventif sur oïdium. Par son mode d'action multi sites, il s'insère dans des programmes de traitement pour limiter le développement de souches résistantes aux molécules fongicides unisites. FAETON® JARDIN bénéficie de la formulation Xtraflow : une formulation liquide, plus pratique d'emploi (mise en œuvre et rinçage facilités), dans laquelle les particules de soufre ont une taille moyenne de 2,2µm.

Tableau des usages autorisés :

Usage ⁽¹⁾	Cultures ⁽¹⁾	Cible ⁽¹⁾	Dose max. d'emploi	Nbre max. d'appli.(2)	Délai avant récolte (DAR)	Stades d'application BBCH	Zone Non Traitée aquatique
Betterave Industrielle et fourragère ^{Tit} Part.Aer. ^{Tit} Maladies du feuillage	Betterave à sucre ou Industrielle (BEA/A), betterave fourragère (BEA/C)	Oïdium	75 mL/100m ²	3/an	14 jours	-	5 mètres
Rosier ^{Tit} Part.Aer. ^{Tit} Oïdium(s) ⁽³⁾	Toutes les espèces et cultivars du genre Rosa (rosier pour la fleur coupée, rosier de pépinière, incluant les porte-greffes.	Oïdium	33 mL/100m ²	6/an	-	-	5 mètres
Tomate-Aubergine ^{Tit} Part.Aer. ^{Tit} Oïdium(s) ⁽³⁾	Tomate (LYFES), Aubergine (SOLME)	Oïdium	20 mL/100m ²	6/an	5 jours	-	5 mètres
Vigne ^{Tit} Part.Aer. ^{Tit} Oïdium(s) ⁽⁴⁾	Vigne de table, vigne de cuve, vignes-mères, pépinières viticoles	Oïdium	125 mL/100m ²	8/an	5 jours	-	5 mètres

- (1) PHYTEUROP ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées dans le tableau ci-dessus et, à ce titre, décline toute responsabilité concernant son utilisation aux autres usages prévus par le catalogue des usages en vigueur.
- (2) Intervalle minimum entre les applications: 7-10 jours.
- (3) Également autorisé sous abri.
- (4) Eviter les traitements tardifs sur raisin de table afin de limiter le phénomène de marquage.

Les chiffres 1 à 11 correspondent aux fichiers « squelette » (disposition des parties et des paragraphes).
Les bandeaux de titre sont à reporter sur l'étiquette.

Draft étiquette	FAETON JARDIN
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RECOMMANDATIONS D'EMPLOI

- **Conditions d'application**
 Dans le cas de l'oïdium de la vigne, la dose de 40 mL/ 100m² peut être envisagée en début de cycle végétatif. Par la suite, à cette dose, il est nécessaire de l'associer avec un autre fongicide (autre famille chimique) afin d'obtenir une protection suffisante contre l'oïdium.
- **Précautions d'emploi** : Porter des gants et une tenue appropriée.
- **Préparation de la bouillie** : Avant utilisation, agiter correctement le bidon. Versez la quantité nécessaire de **FAETON@JARDIN** dans la cuve de l'appareil aux 2/3 remplie d'eau, sous agitation, et compléter le remplissage. Maintenir une bonne agitation. Après utilisation, il est impératif de bien nettoyer l'ensemble du matériel de pulvérisation.
 Sur vigne, **FAETON@JARDIN** est utilisable avec tous les types de pulvérisation : pulvérisateurs à jet porté, à jet projeté et pneumatique, y compris ceux à volume réduit. Vérifier le réglage du pulvérisateur pour prendre soin de protéger tous les organes visés.



MISE EN ŒUVRE RÉGLEMENTAIRE ET BONNES PRATIQUES

- **Stockage du produit** : Conserver le produit uniquement dans son emballage d'origine, dans un local à l'écart des aliments et boissons, y compris ceux pour animaux. Les locaux doivent être frais et ventilés. Conserver hors de la portée des enfants.
- **Protection de l'opérateur et du travailleur** : Porter des gants et une tenue appropriée.
 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.
- **Nettoyage du pulvérisateur et gestion des fonds de cuve** : À la fin de la période d'application du produit, l'appareil (cuve, rampe, circuit, buses...) doit être rincé intégralement 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 et de l'emballage** :
 - Réemploi de l'emballage interdit.
 - Après 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) et épandre les eaux de rinçage sur une parcelle préalablement traitée.
 - Éliminer le contenu/récipient dans une déchetterie

Les chiffres 1 à 11 correspondent aux fichiers « squelette » (disposition des parties et des paragraphes).
 Les bandeaux de titre sont à reporter sur l'étiquette.