

REGISTRATION REPORT

Part A

Risk Management

Product code: DSPF016

Product name: JARDIZEN PYGMALION

Chemical active substance(s):

Potassium Phosphonates, 755 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Non Professional uses

Applicant: DE SANGOSSE

Date: 12 June 2015

Table of Contents

1	Details of the application	4
1.1	Application background	4
1.2	Letters of Access	5
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims	5
2	Details of the authorisation decision	5
2.1	Product identity	5
2.2	Conclusion	6
2.3	Substances of concern for national monitoring	6
2.4	Classification and labelling	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011	6
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	6
2.5	Risk management	6
2.5.1	Restrictions linked to the PPP	7
2.5.2	Specific restrictions linked to the intended uses	8
2.6	Intended uses (only NATIONAL GAP)	9
3	Background of authorisation decision and risk management	11
3.1	Physical and chemical properties (Part B, Section 2)	11
3.2	Efficacy (Part B, Section 3)	11
3.3	Methods of analysis (Part B, Section 5)	11
3.3.1	Analytical method for the formulation	11
3.3.2	Analytical methods for residues	11
3.4	Mammalian toxicology (Part B, Section 6)	12
3.4.1	Acute toxicity	12
3.4.2	Operator exposure	12
3.4.3	Worker exposure	13
3.4.4	Bystander exposure	13
3.4.5	Resident exposure	13
3.5	Residues and consumer exposure (Part B, Section 7)	13
3.5.1	Residues	13
3.6	Environmental fate and behaviour (Part B, Section 8)	14
3.7	Ecotoxicology (Part B, Section 9)	14
3.8	Relevance of metabolites (Part B, Section 10)	15
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	15

5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation.....	15
5.1.1	Post-authorisation monitoring.....	15
5.1.2	Post-authorisation data requirements	15
Appendix 1	Copy of the product authorisation	16
Appendix 2	Copy of the product label	21

PART A

RISK MANAGEMENT

1 Details of the application

The company DE SANGOSSE has requested a marketing authorisation in France for the product JARDIZEN PYGMALION (product code: DSPF016), containing 755 g/L potassium phosphonates¹ 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 DE SANGOSSE's application submitted on 20/01/2023 to market JARDIZEN PYGMALION (DSPF016) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation/ of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2023-1065) 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 of the Southern zone, 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 JARDIZEN PYGMALION (DSPF016) has been made using endpoints agreed in the EU peer review of potassium phosphonates. It also includes assessment of data and information related to JARDIZEN PYGMALION (DSPF016) 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.

¹ COMMISSION IMPLEMENTING REGULATION (EU) No 369/2013 of 22 April 2013 approving the active substance potassium phosphonates, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

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](#)

DSPF016 / JARDIZEN PYGMALION
Part A - National Assessment
FRANCE

This document also describes the specific conditions of use and labelling required for France for the registration of JARDIZEN PYGMALION (DSPF016).

1.2 Letters of Access

The applicant has provided letters of access for active substance and PPP data. These letters of access are available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: “Several new studies have been performed with JARDIZEN PYGMALION (DSPF016) in order to complete the data package on JARDIZEN PYGMALION (DSPF016), due to the not EU approved uses in wheat and potato.”

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of JARDIZEN PYGMALION (DSPF016), 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	DSPF016
Product name in MS	JARDIZEN PYGMALION
Authorisation number	2250202
Kind of use	Non-professional use
Low risk product (article 47)	No
Function	Fungicide
Applicant	DE SANGOSSE
Active substance(s) (incl. content)	755 g/L Potassium Phosphonates
Formulation type	Formulation type SL (soluble concentrate)
Packaging	0.25, 0.5, 1L HDPE-f with an integrated dosing system
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None

DSPF016 / JARDIZEN PYGMALION
Part A - National Assessment
FRANCE

Recommended tank mixtures	None
---------------------------	------

2.2 Conclusion

The evaluation of the application for JARDIZEN PYGMALION (DSPF016) 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:	-

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

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

	For other restrictions refer to 2.5

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:

- 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.

Finally, 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.

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

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
-	
Environmental protection	
	Do not discharge into the sink, gutter or any other water hole the non-used container leftovers and the sprayer washing water.

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/eli/arrete/2017/5/4/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

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

DSPF016 / JARDIZEN PYGMALION
 Part A - National Assessment
 FRANCE

	To protect aquatic organisms do not apply at least 5 meters away from any surface water bodies (well, pond, stream, river...).
Other specific restrictions	
Re-entry period	Wait until the treated zone or plants have dried.
Storage	/
SPa 1	/
Risk mitigation measures	Several fungicidal active substances (fosetyl-Al, potassium phosphonates and disodium phosphonate) may lead to the presence of phosphonic acid in harvested products. The cumulated uses of these active sub-stances on the same crop might lead to an exceedance of the MRL set jointly for these 3 active substances.
Risk mitigation measures	/
Agricultural recommendations	/

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.

DSPF016 / JARDIZEN PYGMALION

Part A - National Assessment

FRANCE

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

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

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: June 2025

PPP (product name/code): JARDIZEN PYGMALION / DSPF016

Formulation type: SL ^(a, b)

Active substance 1: Potassium phosphonates

Conc. of a.s. 1: 755 g/L ^(c)

Applicant: DE SANGOSSE

Professional use:

Zone(s): Southern Zone ^(d)

Non-professional use: X

Verified by MS: Yes

Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop 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 (day s)	Remarks: e.g. g safener/synergis per ha (f) RMS CONCLUSION
					Method/Ki nd	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 a.s./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	Potato	Fn	Late blight (Phytophthora infestans)	Foliar application using a sprayer	From BBCH stage 10 (leaf development)	a) 3 b) 3	7	a) 4 L/ha b) 12 L/ha	a) 3020 g as/ha potassium phosphonates (equivalent to 2016 g as/ha of phosphonic acid) b) 9060 g as/ha potassium phosphonates (equivalent to 6048 g as/ha of phosphonic acid)	100/500	7	Acceptable

DSPF016 / JARDIZEN PYGMALION

Part A - National Assessment

FRANCE

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application 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)

The product JARDIZEN PYGMALION (DSPF016) is a blue aqueous, odourless water soluble concentrate, containing 755 g/L of potassium phosphonates. This formulation does not present explosive and oxidising or reducing properties. It is not autoflammable and not flammable. Its density is 1450kg/m³ at 20°C. The pH of a 1% solution at 25°C is 6.03. Its viscosity is 5.81cSt at 20°C and 3.36cSt at 40°C.

There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed.

The surface tension is 72.7 mN/m, which indicates that the preparation is not a surface tension product.

The content of active substance is unchanged by 2-years storage at ambient temperature in HDPE containers demonstrating an acceptable 2 years shelf life for the product.

Under recommended use, no particular problems should be expected due to technical characteristics or physico-chemical properties.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The effectiveness level of JARDIZEN PYGMALION (DSPF016) is considered as acceptable for the claimed use.
- The phytotoxicity level of JARDIZEN PYGMALION (DSPF016) is considered as negligible for the claimed use.
- The risks of negative impact on yield, quality, propagation, succeeding crops and adjacent crops are considered as negligible.
- The risk of resistance development or appearance to Potassium phosphonates is considered as low and does not require a monitoring for the claimed use.

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 the active substance potassium phosphonates does not contain relevant impurity, no analytical method is required.

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of potassium phosphonates in plants (potato), food of animal origin, soil, water (surface and drinking).

3.4 Mammalian toxicology (Part B, Section 6)

Active substance	Potassium phosphonates
AOEL systemic	5 mg/kg bw/day
AAOEL	-
Oral absorption	100%
Vapour pressure	100%
Reference	EFSA 2012; 10 (12):2963
Dermal absorption	Concentrate: 0.24% Dilution (1:400): 2.6%

3.4.1 Acute toxicity

Comments of zRMS	JARDIZEN PYGMALION has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to skin or eye and is not a skin sensitiser.
------------------	---

3.4.2 Operator exposure

Comments of zRMS	Estimation of operator exposure was conducted using the EFSA model and the French UPJ model as detailed in the table below:			
			Potassium phosphonates	
	Model data	Level of PPE	Total absorbed dose	% of systemic AOEL
	EFSA model 2022 Outdoor Critical use: potatoes (low vegetables), manual knapsack Application rate: 3*3.02 kg a.s./ha			
	EFSA model Body weight: 60 kg	Potential exposure	0.08 mg/kg/day	1.6%
	UPJ model (French garden exposure model) Outdoor Critical use: potatoes Pre-pressure sprayer, vegetable crop (<60 cm) Application rate: 4 mL product / 10m²			
	UPJ model Liquid application Body weight: 60 kg	No PPE Without gloves	2002 ug	0.67%
	No personal protective equipment is required for non-professional users.			
<u>Conclusion</u> Based on the EFSA 2022 model and the French UPJ garden model, the operator exposure for amateur use is below the AOEL of potassium phosphonates for the intended use.				

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 that of the operator.
------------------	--

3.4.4 Bystander exposure

Comments of zRMS	zRMS considers that in the case of the non-professional user, the assessment for bystanders is covered by that of the operator.
------------------	---

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 scenario, the EFSA model for resident (recreational scenario) has been used by zRMS. The estimated exposure for resident is presented in the table below:																	
	<table><tr><th colspan="3">Potassium phosphonate</th></tr><tr><th>Model data</th><th>Total absorbed dose (mg a.s./kg bw/day)</th><th>% of systemic AOEL</th></tr><tr><td colspan="3">EFSA model 2022 Critical use: Amenity grassland Application rate: 4 kg a.s./ha</td></tr><tr><td>Resident Child Body weight: 10 kg</td><td>0.1</td><td>3,3%</td></tr><tr><td>Adult</td><td>0.02</td><td>0,5%</td></tr></table>			Potassium phosphonate			Model data	Total absorbed dose (mg a.s./kg bw/day)	% of systemic AOEL	EFSA model 2022 Critical use: Amenity grassland Application rate: 4 kg a.s./ha			Resident Child Body weight: 10 kg	0.1	3,3%	Adult	0.02	0,5%
	Potassium phosphonate																	
	Model data	Total absorbed dose (mg a.s./kg bw/day)	% of systemic AOEL															
	EFSA model 2022 Critical use: Amenity grassland Application rate: 4 kg a.s./ha																	
	Resident Child Body weight: 10 kg	0.1	3,3%															
	Adult	0.02	0,5%															
	* Covers all claimed uses																	
	<u>Conclusion:</u>																	
According to the EFSA model 2022, the resident (child and adult) exposure is below the AOEL of potassium phosphonates.																		

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

3.5.1 Residues

The data available are considered sufficient for risk assessment. No exceedance of the current MRL for phosphonic acid (expressed as fosetyl) as laid down in Reg. (EU) 396/2005 is expected for potatoes

The chronic intakes of phosphonic acid residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, ANSES, France agrees with the authorization of the intended use(s).

DSPF016 / JARDIZEN PYGMALION
Part A - National Assessment
FRANCE

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

Summary for potassium phosphonates

Use- No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Potato	Yes	Yes	Yes	Yes	Yes	No	No

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

Information on JARDIZEN PYGMALION (KCA 6.8)

Crop	PHI for JARDIZEN PYGMALION proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for JARDIZEN PYGMALION proposed by zRMS	zRMS Comments (if different PHI proposed)
		potassium phosphonates		
Potato	7 days	Yes	/	/

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

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

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

For home and gardens uses, the PEC of the active substance and its products of dissociation in surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions.

PEC_{sw} derived for phosphonic acid are used for the ecotoxicological risk assessment.

PEC_{gw} for phosphonic acid do not occur at levels exceeding those mentioned in regulation EU No 546/2011. Therefore, no unacceptable risk of groundwater contamination is expected for the intended home and gardens 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

DSPF016 / JARDIZEN PYGMALION
Part A - National Assessment
FRANCE

considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Given the intended use of JARDIZEN PYGMALION (DSPF016) with spray application for amateur uses, exposure of mammals, non-target arthropods other than bees, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants is considered negligible. For other organisms for which an exposure could not be excluded, the risk was considered acceptable.

Regarding bees, the estimated exposure levels related to the use of the JARDIZEN PYGMALION (DSPF016) product are higher than the reference chronic toxicity values for adult bees and larvae. A tunnel study conducted with the JARDIZEN PYGMALION (DSPF016) product demonstrates no unacceptable effect on the brood. However, the results of this study cannot be used to evaluate the effects of the product JARDIZEN PYGMALION (DSPF016) on adult bees (lack of appropriate toxic reference). As a result, the risk assessment could not be finalized for these organizations.

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 potassium phosphonates is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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

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

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation

Docusign Envelope ID: BA798DD2-BB23-4E02-8A49-83EDCCD22E5F



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 JARDIZEN PYGMALION

de la société DE SANGOSSE S.A.S.

enregistrée sous le n° 2023-1065

Vu les conclusions de l'évaluation de l'Anses du 14 mars 2025,

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.

DSPF016 / JARDIZEN PYGMALION
Part A - National Assessment
FRANCE

DocuSign Envelope ID: BA798DD2-BB23-4E02-8A49-83EDCCD22E5F



Informations générales sur le produit		
Nom du produit	JARDIZEN PYGMALION	
Type de produit	Deuxième gamme	
Titulaire	DE SANGOSSE S.A.S. Bonnell CS 10005 47480 PONT-DU-CASSE France	
Formulation	Concentré soluble (SL)	
Contenant	755 g/L - phosphonates de potassium	
Produit de référence	Nom commercial	PYGMALION
	N° AMM	2210128
Numéro d'intrant	242-2023.01	
Numéro d'AMM	2250202	
Fonction	Fongicide	
Gamme d'usage	Amateur / emploi autorisé dans les jardins	

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 janvier 2027.

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 12/06/2025

DocuSigned by:

 AJ2E1A915A427E14
 Directrice générale déléguée
 en charge du pôle produits réglementés
 Agence nationale de sécurité sanitaire de
 l'alimentation, de l'environnement et du travail (ANSES)

JARDIZEN PYGMALION
AMM n° 2250202

Page 2 sur 5

DSPF016 / JARDIZEN PYGMALION
Part A - National Assessment
FRANCE

DocuSign Envelope ID: BA798DD2-BB23-4E02-8A49-83EDCCD22E5F



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 fluoré munies d'un système de dosage intégré	250 mL ; 500 mL ; 1 L

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.

DSPF016 / JARDIZEN PYGMALION
Part A - National Assessment
FRANCE

DocuSign Envelope ID: BA798DD2-8B23-4E02-8A49-83EDCCD22E5F



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)
15653201 Pomme de terre*Trt Part. Aer.*Mildiou(s)	4 mL/10 m²	3/an	à partir du stade BBCH 10	7	5	-	-	Non pertinent
Intervalle minimum entre les applications : 7 jours.								

DSPF016 / JARDIZEN PYGMALION
Part A - National Assessment
FRANCE

Docusign Envelope ID: BA798DD2-BB23-4E02-8A49-83EDCCD22E5F



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)

- Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.
- Plusieurs substances actives fongicides (fosétyl d'aluminium, phosphonates de potassium et phosphonate de disodium) peuvent engendrer la présence d'acide phosphonique dans les produits récoltés. L'utilisation cumulée sur la même culture de ces substances actives est susceptible de conduire à un dépassement des LMR fixées conjointement pour ces 3 substances actives.

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...).

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.

DSPF016 / JARDIZEN PYGMALION
Part A - National Assessment
FRANCE

DRAFT ETIQUETTE JARDIZEN® PYGMALION®

RECTO

- ACTION : PROTEGER
- NOM HOMOLOGUE : JARDIZEN® PYGMALION®
- FONCTION : ANTI MILDIOU
 - Concentré
 - Doseur intégré - pratique
- Volume Net : 200 ml
- ACTION SYSTEMIQUE – PROTECTION DE TOUTES LES PARTIES DE LA PLANTE
- PREVENTIF ET CURATIF
- SPECIFIQUE MILDIOU
- A BASE DE SUBSTANCE NATURELLE D'ORIGINE MINERALE

VERSO

Feuillet 1 :

JARDIZEN® PYGMALION®

N° AMM : xxxxxxxx délivrée le xxxxxxxx

Fongicide pour le traitement contre le mildiou de la pomme de terre

Composition : 755 g/L (51.7%) de phosphonates de potassium (504 g/L d'équivalent d'acide phosphonique)

Formulation : concentré soluble (SL)

Type de produit : fongicide

Détenteur de l'autorisation : DE SANGOSSE S.A.S Bonnel CS10005 – 47480 PONT DU CASSE – France – Tél 05 53 69 36 30 – www.desangosse.fr

Emploi autorisé dans les jardins

EUH401 **Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.**

P102 Tenir hors de portée des enfants.

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

P501 Éliminer le contenu/récipient conformément à la réglementation locale.

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.

Délai de rentrée dans la zone traitée : attendre le séchage complet de la zone traitée.

Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidon/le produit non utilisé(s) et les eaux de lavage du pulvérisateur.

Pour protéger les organismes aquatiques, ne pas appliquer à moins de 5 mètres d'un point d'eau (puits, bassin, mare, ruisseau, rivière, fossé...).

Délai avant récolte : 7 jours

REEMPLOI DE L'EMBALLAGE INTERDIT

Code emballer : xxxxxxxx

N° de lot/date de fab : voir sur l'emballage

Draft Etiquette JARDIZEN® PYGMALION® 200ML



DSPF016 / JARDIZEN PYGMALION
Part A - National Assessment
FRANCE

Réf. Produit :
Gencod/ Code barre :

Distribué par : LIPHATECH SAS – Bonnel – CS10005 – 47 480 PONT DU CASSE – Tél. : 05 53 69 35 70.
JARDIZEN® PYGMALION®.
JARDIZEN® marque déposée par LIPHATECH S.A.S et PYGMALION® marque déposée par DE SANGOSSE S.A.S

INSTRUCTIONS D'EMPLOI, DOSAGE : voir à l'intérieur

JARDIZEN® PYGMALION® est un fongicide systémique à base de phosphonates de potassium, substance active naturelle d'origine minérale. Ce fongicide pénètre via le système foliaire et se répartit dans l'ensemble de la plante. Il agit efficacement contre le mildiou de la pomme de terre. JARDIZEN® PYGMALION® peut-être appliqué en curatif et en préventif dès le développement des premières feuilles.

PRECONISATIONS D'EMPLOI

Usages et doses autorisées pour un traitement des parties aériennes

Cultures	Cibles	Dose maximale d'emploi pour traiter 10m ²	Nombre maximum d'applications
		Stades d'application	Intervalle minimum entre les applications
Pomme de terre	Mildiou(s) (<i>Phytophthora infestans</i>)	> 4 ml / 0.5l d'eau > Dès développement des 1 ^{ère} feuilles	> 3 / an > 7 jours

RECOMMANDATIONS D'UTILISATION

- Intervenez dès l'apparition des premiers symptômes.
- Respecter la dose et le volume de bouillie préconisé. Il est nécessaire d'utiliser un volume d'eau suffisant adapté au stade de développement de la culture et de soigner l'application afin que le produit recouvre bien l'ensemble de la végétation.
- Une fois pulvérisé, le produit doit rester à l'abri du lessivage 2 heures après son application. Si par cas une pluie lessivante survient dans cet intervalle, renouveler la protection.
- Ne pas traiter en cas de pluie imminente et éviter les heures de plein soleil
- Se laver les mains après toute manipulation/utilisation.
- Ne pas manger, ne pas boire, téléphoner ou fumer lors de l'utilisation du produit.

PREPARATION DU TRAITEMENT

Préparation de la bouillie

- Nettoyer soigneusement le pulvérisateur avant d'utiliser JARDIZEN® PYGMALION®. Remplir le pulvérisateur aux ¾ avec de l'eau propre, puis ajouter la quantité nécessaire de JARDIZEN® PYGMALION® et compléter au volume d'eau désiré. Ne pas trop agiter afin d'éviter la formation de mousse.
- Utilisez la solution de pulvérisation immédiatement après la préparation. Videz complètement la cuve du pulvérisateur et ne gardez aucune solution inutilisée.

STOCKAGE

Conserver le produit uniquement dans son emballage d'origine, à l'écart des aliments et boissons y compris ceux pour les animaux. Conserver hors de la portée des enfants. Les locaux doivent être secs et ventilés. Protéger contre les rayons du soleil. Éviter le stockage du produit à des températures inférieures à 0° C.

Draft Etiquette JARDIZEN® PYGMALION® 200ML

PRECAUTIONS D'EMPLOI

Elimination du produit et de l'emballage.

REEMPLOI DE L'EMBALLAGE INTERDIT.

Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidon ou le produit non utilisés et les eaux de lavage du pulvérisateur. Ne pas jeter dans les poubelles ménagères, mais éliminer l'emballage avec ou sans produit en déchèterie.

PREMIERS SECOURS :

En cas d'urgence composer le 15 ou le 112 ou contacter le centre anti-poison le plus proche

PREMIERS SOINS :

Conseils généraux : s'éloigner de la zone dangereuse.

En cas d'inhalation : Placer la personne à l'air frais. Consulter un médecin si les symptômes persistent ou se développent.

En cas de contact avec les yeux : Rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. Si l'irritation persiste, consulter un médecin

En cas de contact avec la peau : Rincer immédiatement la zone éclaboussée avec du savon et de l'eau pendant au minimum 5 minutes. Consulter un médecin si des symptômes se développent.

Enlever les vêtements imprégnés et laver soigneusement les parties exposées à l'eau.

En cas d'ingestion: Consulter un médecin en lui montrant l'étiquette.

NE PAS faire vomir. Rincer la bouche si la personne est consciente. Consulter un médecin si des symptômes se développent.

Ne rien faire absorber par la bouche.

En cas d'intoxication animale : contactez votre vétérinaire

AVERTISSEMENT

Toute reproduction totale ou partielle de cette étiquette est interdite.

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. Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine et stockés selon les conditions préconisées, ainsi que leur conformité à l'autorisation de mise sur le marché en vigueur.