# REGISTRATION REPORT

# Part A

# Risk Management

## Product code: DSPF023

## Product name: GADAROCK

**Chemical active substances:**

**potassium phosphonates, 629 g/L**
**fluazinam, 60 g/L**

## Southern Zone

## Zonal Rapporteur Member State: France

## NATIONAL ASSESSMENT FRANCE

## (New application)

## Applicant: DE SANGOSSE

## Date: 07/04/2021

# Table of Contents

# PART A

# RISK MANAGEMENT

## 1 Details of the application

The company DE SANGOSSE has requested a marketing authorisation in France for the product GADAROCK (product code: DSPF023), containing 629 g/L potassium phosphonates[1] and 60 g/L fluazinam[2], as a fungicide for professional uses.

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

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

### 1.1 Application background

The present registration report (RR) concerns the evaluation of DE SANGOSSE's application submitted in April 2017 to market GADAROCK (DSPF023) 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 (2017-1196) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[3], 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")[4]. 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 GADAROCK (DSPF023) has been made using endpoints agreed in the EU peer reviews of potassium phosphonates and fluazinam. It also includes assessment of data and information related to GADAROCK (DSPF023) 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 546/2011[5], 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 240/2011.

2 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.

3 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

4 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

5 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

This document also describes the specific conditions of use and labelling required for France for the registration of GADAROCK (DSPF023).

### 1.2 Letters of Access

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

### 1.3 Justification for submission of tests and studies

According to the applicant: "*This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013*".

### 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of GADAROCK (DSPF023), 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 | DSPF023. |
| Product name in MS | GADAROCK. |
| Authorisation number | N/A : no marketing authorisation granted |
| Kind of use | Professional use. |
| Low risk product (article 47) | No. |
| Function | Fungicide. |
| Applicant | DE SANGOSSE. |
| Active substance(s) (incl. content) | Potassium phosphonates, 629 g/L (equivalent to 420 g/L phosphonic acid), Fluazinam, 60 g/L. |
| Formulation type | Suspension concentrate [SC]. |
| Packaging | N/A : no marketing authorisation granted |
| Coformulants of concern for national authorisations | - |
| Restrictions related to identity | - |
| Mandatory tank mixtures | None. |
| Recommended tank mixtures | None. |

## 2.2 Conclusion

The evaluation of the application for GADAROCK (DSPF023) resulted in the decision **to refuse** the authorisation.

## 2.3 Substances of concern for national monitoring

Refer to 5.1.1.

## 2.4 Classification and labelling

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

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

| | |
|---|---|
| Hazard class(es), categories: | Skin sensitisation, category 1B.<br>Eye irritation, category 2.<br>Reproductive toxicity, category 2.<br>Hazardous to the aquatic environment - Chronic Hazard, category 1. |
| Hazard pictograms: |  |
| Signal word: | Danger. |
| Hazard statement(s): | H317: May cause an allergic skin reaction.<br>H319: Causes serious eye irritation.<br>H361d: Suspected of damaging the unborn child.<br>H410: Very toxic to aquatic life with long-lasting effects. |
| Precautionary statement(s): | ***For the P phrases, refer to the existing legislation*** |
| Additional labelling phrases: | Contains 1,2-benzisothiazol-3(2H)-one. |
| | |

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

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

N/A : no marketing authorisation granted

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

None.

## 2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4 May 2017[6] 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 26 March 2014[7] 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 extrapolation[8] 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:

The applicant is required to comply with the current applicable standard for clothing type PPE (NF ISO EN 27065/A1)[9].
N/A : no marketing authorisation granted.

### 2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

---

6 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/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

7 http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

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

9 NF EN ISO 27065/A1 (October 2019) Protective clothing – Performance requirements for protective clothing worn by operators applying pesticides and for re-entry workers.

## 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 26 March 2014 (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" or "not finalised", 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: 2021-04

| | | | |
|---|---|---|---|
| PPP (product name/code): | GADAROCK / DSPF023 | Formulation type: | SC [a, b] |
| Active substance 1: | Potassium phosphonates | Conc. of a.s. 1: | 629 g/L [c] |
| Active substance 2: | fluazinam | Conc. of a.s. 2: | 60 g/L [c] |
| Applicant: | DE SANGOSSE | Professional use: | ☒ |
| Zone(s): | Southern Zone [d] | Non-professional use: | ☐ |
| Verified by MS: | Yes | | |
| Field of use: | Fungicide | | |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Use-No.** [e] | **Member state(s)** | **Crop and/or situation (crop 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** Method/Kind | Timing/Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. interval between applications (days) | **Application rate** 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 | **PHI** (days) | **Remarks:** e.g. g safener/synergist per ha [f] |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | |
| 1 | South-ern Zone (FR) | Potato | F | Late blight (*Phytophthora infestans*) | Foliar application, using a sprayer | From BBCH stage 10 (leaf development) | a) 3<br>b) 3 | 7 days | a) 2<br>b) 6 | a) 1258 g/ha potassium phosphonates (equiv. 840 g/ha phosphonic acid<br>120 g/ha fluazinam<br>b) 3774 g/ha potassium phosphonates (equiv. 2520 g/ha phosphonic acid)<br>360 g/ha fluazinam | 100 / 500 | 7 | **Not acceptable** (herbivorous mammals, non-target aquatic organisms, PPE*) |

*As some standards may have undergone changes, it is the responsibility of the applicant to update the reference.

**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 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
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
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)

GADAROCK (DSPF023) is a brown water-based suspension concentrate formulation, containing 629 g/L potassium phosphonates and 60 g/L fluazinam. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The product is not flammable, is not explosive and has no oxidising properties. It has a self-ignition temperature of 335 °C. In aqueous solution (1 %), it has a pH value of 4.6 at ambient temperature. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0° C, 14 days at 54 °C and two years at ambient temperature in glass bottles and HDPE bottles (the latter being the commercial packaging), neither the active substances' content nor the technical properties were changed.

The technical characteristics are acceptable for a SC formulation.

The formulation is not classified for the physico-chemical aspect.

## 3.2 Efficacy (Part B, Section 3)

Considering the data provided:

- GADAROCK(DSPF023)'s efficacy level is considered satisfactory for the intended use.
- GADAROCK(DSPF023)'s phytotoxicity level is considered negligible for the intended use.
- The risks of negative impact on yield, quality, propagation, succeeding and adjacent crops are considered negligible.
- The risk of resistance developing or appearing to fluazinam and potassium phosphonates does not require monitoring for the requested use.

## 3.3 Methods of analysis (Part B, Section 5)

### 3.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substances in the formulation are available and validated.

### 3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Reports (DARs) and in this dossier and validated for the determination of residues of potassium phosphonates and fluazinam in plants (high-water-content crops), foodstuffs of animal origin, soil, water (surface and drinking) and air.

An analytical method is available in the DAR and validated for the determination of residues of fluazinam in tissues and body fluids.

## 3.4 Mammalian toxicology (Part B, Section 6)

**Endpoints used in risk assessment**

| Active substance: **potassium phosphonates** | | | |
|---|---|---|---|
| ADI | 2.25 mg/kg bw/d | | EU (2013) |
| ARfD | Not applicable | | |
| AOEL | 5 mg/kg bw/d | | |
| AAOEL | - | | |
| Dermal absorption | No study was performed on the formulation or on a similar formulation. Consequently default values according to guidance on dermal absorption (Efsa 2012) were used. | | |
| | | Concentrate (used in formulation) 629 g/L | Spray dilution (used in formulation) 2.5 g/L -13 g/L |
| | **Dermal absorption endpoints %** | **25** | **75** |
| Oral absorption | More than 60 % based on urine excretion (bridging data from sodium phosphonate). | | |

***EFSA Journal 2012;10(12):2963 :***
*Log Pow (potassium phosphonates): no data*
*MM monopotassium phosphonate: 120.1 g/mol*
*MM dipotassium phosphonate: 158.2 g/mol*
*Vapour pressure (potassium phosphonates): not relevant (aqueous TK solution)*

| Active substance: **fluazinam** | | | |
|---|---|---|---|
| ADI | 0.01 mg/kg bw/d | | EU (2008) |
| ARfD | 0.07 mg/kg bw | | |
| AOEL | 0.004 mg/kg bw/d | | |
| AAOEL | - | | |
| Dermal absorption | Based on an *in vitro/vivo* rat/human study performed on the formulation (using a triple pack approach; *pro rata* correction) according to guidance on dermal absorption (Efsa 2012): | | |
| | | Concentrate (used in formulation) 60 g/L | Spray dilution (used in formulation) 0.24-1.2 g/L |
| | **Dermal absorption endpoints %** | **0.66** | **0.24 g/L: 5.9<br>1.2 g/L: 12** |
| Oral absorption | 35 % absorbed based on excretion rates in bile and urine. | | |

***EFSA Scientific Report (2008) 137, 1-82:***
*Log Pow (fluazinam): 4.03 at 25°C (pH 5.5-7.0)*
*MM fluazinam: 465.1 g/mol*
*Vapour pressure (fluazinam): 7.5 x $10^{-3}$ Pa at 20 °C (DRAR 2019: 1.72 x $10^{-5}$ Pa at 20 °C)*

### 3.4.1 Acute toxicity

No study was performed with GADAROCK (DSPF023) for acute oral toxicity, acute percutaneous toxicity, acute inhalational toxicity or skin irritation. Characterisation of the corresponding toxicological properties has been performed by calculation. On this basis, GADAROCK (DSPF023), containing 629 g/L potassium phosphonates and 60 g/L fluazinam, is of low toxicity in by the acute oral, inhalational and dermal routes, and is not irritating to the rabbit skin.

Studies have been performed with GADAROCK (DSPF023) for eye irritation (Richeux F, 2016) and skin sensitisation (Richeux. F, 2016), and demonstrated both properties.

| **Type of test, species, model system (Guideline)** | **Result** | **Classification (acc. to the criteria in Reg. 1272/2008)** | **Reference** |
|---|---|---|---|
| $LD_{50}$ oral | - | None | *Calculation according to EU criteria (Regulation 1272/2008)* |
| $LD_{50}$ dermal | - | None | |
| $LC_{50}$ inhalation | - | None | |
| Skin irritation | - | None | |
| Eye irritation, rabbit (OECD 405) | Irritant | Irritating to eyes, cat 2 H319 | Richeux, 2016 |
| Skin sensitisation, guinea pig (OECD 406, M&K) | Sensitising | Skin sens. Cat 1**B** H317 | Richeux, 2016 |

The preparation GADAROCK (DSPF023) has also been classified as Repr. 2, H361d, since it contains more than 3 % of the active substance fluazinam, which bears this classification.

### 3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

| Crop type | F/G[10] | Equipment *Application method* | Maximum application rate g a.s./ha | Minimum volume water (L/ha) |
|---|---|---|---|---|
| Potato *(root and tuber vegetables)* | F | Vehicle-mounted *Downward spraying* | 1258g potassium phosphonates<br>120 g fluazinam | 100-500 L/ha** |

*** For fluazinam, assessments were performed based on the following two conditions: a spray volume of 100 L/ha modelled with a dermal absorption of 5.9 %, and a spray volume of 500 L/ha modelled with a dermal absorption of 12 %.*

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model[11]:

| Crop | Equipment | PPE and/or working coverall | % AOEL potassium phosphonates | % AOEL fluazinam |
|---|---|---|---|---|
| Potato | Vehicle-mounted *Downward spraying* | Working coverall and gloves during mixing/loading and application | 0.6 | 8.8-13 ** |

*** For fluazinam, assessments were performed based on the following two conditions: a spray volume of 100 L/ha modelled with a dermal absorption of 5.9 %, and a spray volume of 500 L/ha modelled with a dermal absorption of 12 %.*

[10] Open field or glasshouse
[11] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

According to the model calculations, it may be concluded that the risk for the operator using GADAROCK (DSPF023) is acceptable with a working coverall and gloves during mixing/loading and application.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

### 3.4.3 Worker exposure

Workers may have to enter treated areas after treatment for crop inspection/irrigation, searching, reaching and picking activities. Therefore, estimation of worker exposure was calculated according to the AOEM. Exposure is estimated to be a maximum of 6.8 % of the AOEL of potassium phosphonates and 130 % of the AOEL of fluazinam with working clothing.

It may thus be concluded that there is an unacceptable risk anticipated for the worker.

However, the applicant refined the worker exposure calculations by using a refined dislodgeable foliar residue (DFR) value (the same as that used in the context of the fluazinam EU assessment).

However, the value of DFR defined in the DAR is a value corresponding to the residues found immediately after the first application (i.e., 1.6 µg/cm²/kg a.s. applied/ha) and was used as an input in the EUROPOEM model, with an application dose value concomitantly proportioned by the intended number of applications. On this basis, a more realistic value for this dossier relative to the model used (AOEM) and the intended GAPs (three applications) has been considered (i.e., foliar residues immediately after the third application) and leads to a DFR value after normalisation to 1000 g a.s./ha, of 2.9 µg/cm²/kg a.s. applied/ha.

**Considering this updated value of DFR (and reducing the number of applications to one into the AOEM, being understood that no theoretical estimation is needed through the multiple applications since an experimental final cumulative value is used), the worker exposure calculated according to AOEM was estimated to be a maximum of 49 % of the AOEL of fluazinam with working clothing.**

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

### 3.4.4 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e., no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[12].

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*."

### 3.4.5 Resident exposure

Residential exposure was assessed according to the EFSA model.

[12] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

**POTASSIUM PHOSPHONATES**: An acceptable risk was determined for residents (adult and child) when no drift reduction technology or no mitigation measures are taken to reduce the resident exposure.

**FLUAZINAM**: An acceptable risk was determined for residents (adult and child) when drift reduction technology and mitigation measures such as a buffer zone from 5 metres are taken to reduce the resident exposure, and when a DFR value (immediately after the third application) of 2.9 µg/cm²/kg a.s. applied/ha is considered (whereas the $DFR_0$ value of 1.6 µg/cm²/kg a.s. applied/ha was requested by the applicant):

***With no drift reduction technology or no mitigation measures and with DFR default value***

| Model (AOEM) - All pathways (mean)<br><br>*Buffer zone: 3 m*<br>*With no drift-reduction technology* | % AOEL potassium phosphonates | % AOEL fluazinam |
|---|---|---|
| Resident (children) | 9.9 | 217 |
| Resident (adults) | 4.5 | 91 |

***With experimental DFR value***

| Model (AOEM) - All pathways (mean)<br><br>*Buffer zone: 3 m*<br>*Considering a 100 L/ha spray volume and the respective dermal absorption of 5.9 % for fluazinam* | % AOEL fluazinam |
|---|---|
| Resident (children) | 79 |
| Resident (adults) | 25 |

| Model (AOEM) - All pathways (mean)<br><br>*Buffer zone: 3 m*<br><br>*Considering a 500 L/ha spray volume and the respective dermal absorption of 12 % for fluazinam* | % AOEL fluazinam |
|---|---|
| Resident (children) | 89 |
| Resident (adults) | 36 |

### 3.4.6 Combined exposure

Currently no EU-harmonised guidance is available on the risk assessment of combined exposure to multiple active substances. Most assessment approaches employed up to now make use of the Hazard Index (HI) concept. It is therefore suggested to use this as a first-tier assessment.

A cumulative assessment for operators, bystanders/residents and workers was performed. At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.

Hazard quotients (HQs) for each active substance and the HI (sum of hazard quotients) are:

| Population groups and PPE | | Active substance | Estimated exposure / AOEL (HQ) |
|---|---|---|---|
| Operators | Working coverall and gloves during mixing/loading and application | potassium phosphonates | 0.6 |
| | | fluazinam | 13 |
| | **Cumulative risk operators (HI)** | | **0.14** |
| Bystanders/ Residents *(3 m buffer zone)* | Children - All pathways (mean) | potassium phosphonates | 9.9 |
| | | fluazinam | 89 |
| | **Cumulative risk bystanders/residents (child) (HI)** | | **0.99** |
| | Adults - All pathways (mean) | potassium phosphonates | **4.5** |
| | | fluazinam | **36** |
| | **Cumulative risk bystanders/residents (adult) (HI)** | | **0.41** |
| Worker | Working coverall and gloves | potassium phosphonates | 6.8 |
| | | fluazinam | 49 |
| | **Cumulative risk workers (HI)** | | **0.56** |

The Hazard Index is < 1. Thus combined exposure to all active substances in GADAROCK (DSPF023) is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

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

### 3.5.1 Residues

**Overall conclusion**

The data available are considered sufficient for risk assessment.

For the active substance fluazinam, no exceedance of the current MRL of 0.02 mg/kg as laid down in Reg. (EU) 396/2005 is expected. No exceedance of the MRL for phosphonic acid (expressed as fosetyl) set out in in SANTE/11822/2019 (Draft Commission Regulation) is expected for potatoes pending the publication of this Regulation at EU level.

The chronic and short-term intakes of fluazinam and potassium phosphonates residues are unlikely to present a public health concern.

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

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

**Data gaps:** None.

**Summary of the evaluation**

**Table 3.5-1: Summary for potassium phosphonates**

| Use-No.* | Crop | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample storage covered by stability data? | MRL compliance (SANTE/11822/2019 pending publication as an EU Regulation) | Chronic risk for consumers identified? | Acute risk for consumers identified? |
|---|---|---|---|---|---|---|---|---|
| 1 | Potato | Yes | Yes | Yes | Yes | Yes*** | - | - |

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
*** The residue levels of fosetyl found in potato tubers (HR of 53.33 mg/kg) are in compliance with the proposed MRL of 200 mg/kg (SANTE/11822/2019).

The effects of processing on the nature of potassium phosphonates residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

**Table 3.5-2: Summary for fluazinam**

| 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

As residues of fluazinam do not exceed the trigger values defined in Reg. (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin are therefore not necessary.

**Table 3.5-3: Information on DSPF023 (KCA 6.8)**

| Crop | PHI for DSPF023 requested by applicant | PHI/withholding period* sufficiently supported for | | PHI for DSPF023 proposed by zRMS | zRMS Comments (if different PHI proposed) |
|---|---|---|---|---|---|
| | | potassium phosphonates | fluazinam | | |
| Potato | 7 days | Yes | Yes | 7 days | - |

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).

**Waiting periods before planting succeeding crops**

None.

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

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active substances and their metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC values of active substances and their metabolites in soil and groundwater, and the PEC of phosphonic acid equivalents and its metabolites in surface water 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.

PECsoil values derived for the active substances and their metabolites and PECsw values derived for phosphonic acid equivalents and its metabolites are used for the ecotoxicological risk assessment. For the active substance potassium phosphonates, the maximum PECsw values were higher than 35 µg of phosphorous equivalent/L (OECD, 1982[13]). **Thus there is a potential risk of eutrophication for surface water.**

The refined FOCUS STEP 4 PECsw,sed values for fluazinam were not validated since they were not calculated using input parameters derived according to the EU recommendations and to the current FOCUS guidance documents; in particular, the Kfoc and crop interception values. Indeed, the estimation of redeposition was not considered conservative enough, given the intended uses and inappropriate crop interception values used in the calculations.

[13] OECD, 1982. Eutrophication of Waters. Monitoring, Assessment and Control. OECD, Paris. 154 pp.

PECgw values for the active substances and its metabolites do not occur at levels exceeding those mentioned in Regulation (EC) no 1107/2009, and in regulation Directive 98/83/EC[14]. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and $DT_{50}$ calculation, no significant contamination of the air compartment is expected for the intended uses.

### 3.7 Ecotoxicology (Part B, Section 9)

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

**Based on the guidance documents, unacceptable dietary risks were identified for mammals exposed to fluazinam. For aquatic organisms, no valid Step 4 PECsw and Step 3 PECsed values were available for fluazinam, therefore the risk to aquatic organisms could not be further addressed**.

Otherwise, the risks for birds, bees and other non-target arthropods, earthworms, other soil macro- and micro-organisms and terrestrial plants are acceptable for the intended use.

### 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 substances potassium phosphonates and fluazinam are not approved as candidates 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

N/A : no marketing authorisation granted

[14] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

### 5.1.2 Post-authorisation data requirements

N/A : no marketing authorisation granted

# Appendix 1 Copy of the product authorisation

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses

## 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 règlementaire,*

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique* ***GADAROCK***

| | |
|---|---|
| *de la société* | *DE SANGOSSE* |
| *enregistrée sous le* | *n°2017-1196* |

*Vu les conclusions de l'évaluation de l'Anses du 8 décembre 2020,*

*Considérant qu'un risque d'effet inacceptable pour les mammifères herbivores et les organismes non-cibles aquatiques, lié à l'utilisation du produit, ne peut être exclu,*

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

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

*GADAROCK*
*AMM n°-*

*Page 1 sur 3*

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses

| Informations générales sur le produit | |
|---|---|
| **Nom du produit** | GADAROCK |
| **Type de produit** | Produit de référence |
| **Titulaire** | DE SANGOSSE<br>Bonnel CS 10005<br>47480 Pont du Casse<br>France |
| **Formulation** | Suspension concentrée (SC) |
| Contenant | 629 g/L - phosphonates de potassium<br>60 g/L - fluaziname |
| **Numéro d'intrant** | 367-2017.01 |
| **Numéro d'AMM** | - |
| **Fonction** | Fongicide |
| **Gamme d'usage** | Professionnel |

A Maisons-Alfort, le 07 AVR. 2021

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

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses

## ANNEXE I : Conditions de mise sur le marché demandées

**Liste des usages refusés**

| Usages | Dose d'emploi | Nombre maximum d'applications | Délai avant récolte (jours) |
|---|---|---|---|
| **15653201**<br>Pomme de terre*Trt Part.Aer.*Mildiou(s) | 2 L/ha | 3/an | 7 |
| | **Motivation du refus :**<br>L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les mammifères herbivores et les organismes non-cibles aquatiques. | | |

# 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.

**GADAROCK**

Fongicide pour le traitement du mildiou de la pomme de terre

Formulation liquide : Suspension concentrée (SC)
Produit réservé aux professionnels

Substances actives : 629 g/L de phosphonates de potassium (44.6%) + 60 g/L de fluazinam (4.2%)
Autorisation de mise sur le marché n°xxxxxx délivrée le xx/xx/xx

Mis sur le marché et distribué par :
DE SANGOSSE S.A.S
BONNEL CS 10005
47480 PONT DU CASSE
France
Tel : +33(0)5 53 69 36 30
Fax : +33(0)5 53 66 30 65
www.desangosse.fr

Volume :
Numéro de lot :
Date de fabrication de la préparation :

**ATTENTION**

**H317 Peut provoquer une allergie cutanée**
**H319 Provoque une sévère irritation des yeux**
**H332 Nocif par inhalation**
**H361d Susceptible de nuire au fœtus**
**H412 Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme**

P261 Éviter de respirer les brouillards/vapeurs
P273 Eviter le rejet dans l'environnement
P280 Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage
P302+P352 EN CAS DE CONTACT AVEC LA PEAU : laver abondamment à l'eau et au savon
P305+P351+P338 EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime emporte et si elles peuvent être facilement enlevées. Continuer à rincer
P312 Appeler un centre anti poison ou un médecin en cas de malaise
P501 Eliminer le contenu/le récipient conformément aux réglementations locales/nationales

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

SP1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter 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

Délai de rentrée dans les cultures (DRE) : 48 heures

**PRODUIT POUR LES PROFESSIONNELS : UTILISEZ LES PRODUITS PHYTOPHARMACEUTIQUES AVEC PRECAUTION. AVANT TOUTE UTILISATION, LISEZ L'ETIQUETTE ET LES INFORMATIONS CONCERNANT LE PRODUIT.**

**Premiers Secours**

En cas d'inhalation : retirer la personne de la zone contaminée. Donner de l'air frais. Consulter un médecin en cas de malaise.
En cas de contact avec les yeux : Rincer immédiatement avec de l'eau pendant 15 minutes. Oter les lentilles de contact si la victime en porte. Consulter un médecin si l'irritation persiste ou si des symptômes apparaissent.
En cas de contact avec la peau : Laver immédiatement avec de l'eau et du savon. Retirer les vêtements contaminés. Consulter un médecin si l'irritation persiste ou si des symptômes apparaissent.
En cas d'ingestion : Ne pas faire vomir. Consulter un médecin si des symptômes apparaissent.

En cas d'urgence, appeler le 15 ou le 112 ou contacter le centre anti poison le plus proche. Puis signaler vos symptômes au réseau Phyt'attitude, n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Fiche de données de sécurité disponible en consultant le site : www.desangosse.fr ou www.quickfds.com ou en appelant DE SANGOSSE au 05 53 69 36 30

**Mode d'action et résistances**

GADAROCK est un fongicide alliant l'action de contact préventive du fluazinam à l'effet systémique des phosphonates de potassium contre le mildiou de la pomme de terre (*Phytophthora infestans*).
Le phosphonate de potassium agit d'une part directement sur le mildiou en déstabilisant les voies métaboliques impliquant le phosphate, et d'autre part de façon indirecte en stimulant les défenses naturelles de la pomme de terre, agissant comme éliciteur. Le phosphonate de potassium appartient à une nouvelle famille chimique dans la lutte contre le mildiou de la pomme de terre. Rattaché au groupe FRAC 33, il est considéré comme à faible risque en termes d'apparition de résistances.
Le fluazinam a une action directe sur les *Oomycètes*, et plus particulièrement sur *Phytophthora infestans*, en affectant le processus respiratoire et la production d'énergie cellulaire du pathogène par découplage de la phosphorylation oxydative. Il appartient au groupe FRAC C5, et est considéré comme à très faible risque en termes d'apparition de résistances.

**Usages**

| Usages autorisés | Stades d'application | Dose/ ha | Nombre maximum d'applications par an | Intervalle d'application | DAR |
|---|---|---|---|---|---|
| Pomme de terre*Trt Part.Aer.* Mildiou (*Phytophthora infestans*) | A partir de BBCH 10 | 2 L/ha | 3 | 7 jours | 7j |

**Recommandations d'emploi**

Appliquer GADAROCK en préventif de tout évènement contaminant, à partir du développement des premières feuilles (stade BBCH 10).
Il est recommandé d'adapter le volume d'eau au stade de développement de la culture et de soigner l'application afin que le produit recouvre bien l'ensemble de la végétation.
GADAROCK est à l'abri du lessivage 2 heures après application. Si une pluie lessivante survient dans cet intervalle, renouveler l'application

3 applications à 2 L/ha maximum peuvent être réalisées. Pour limiter le risque d'apparition de souches résistantes de *Phytophthora infestans*, il est conseillé d'utiliser GADAROCK dans des programmes saisonniers de traitement combinant d'autres fongicides de différentes familles chimiques et ayant différents modes d'actions.

La systémie descendante de GADAROCK permet la protection directe des tubercules contre le mildiou.

Les limites Maximales de Résidus : se reporter aux LMR du fosétyl-Al et du fluazinam définies au niveau de l'Union Européenne : http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database

Se laver soigneusement les mains après toute utilisation/manipulation.
Ne pas manger, ne pas boire, ne pas téléphoner et ne pas fumer lors de l'utilisation de ce produit.

**Mélanges**
Consulter DE SANGOSSE pour toute association avec d'autres produits phytopharmaceutiques. Avant toute association avec d'autres fongicides, faire un test de sélectivité et de compatibilité.
Ne pas mélanger GADAROCK avec des engrais foliaires contenant de l'azote ou ses dérivés.
Les mélanges doivent être mis en œuvre conformément à la législation en vigueur et aux recommandations des guides de bonnes pratiques agricoles.

**Préparation de la bouillie**
Après avoir rempli à moitié d'eau la cuve du pulvérisateur, verser GADAROCK, puis terminer le remplissage en maintenant une agitation suffisante de la bouillie. Utiliser cette bouillie dans la journée.

**La pulvérisation**
Prendre conseil auprès de notre service technique si nécessaire. Éviter d'atteindre le point de ruissellement, ajuster pression et vitesse d'avancement afin d'obtenir une couverture (en gouttelettes) suffisante de la végétation.

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

**Autres informations**
Nos préconisations sont issues d'essais réalisés sur plusieurs années. Cependant, plusieurs facteurs tels que les conditions climatologiques, techniques de traitement, mélanges non préconisés peuvent présenter des conséquences sur l'efficacité ou la sélectivité du traitement.

**Recommandations de stockage**
Stocker le produit dans l'emballage d'origine. Stocker le produit dans un local réservé à cet usage, frais, sec et bien ventilé et fermant à clé.
Conserver hors de la portée des enfants et des animaux domestiques. Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.

**Instructions pour l'élimination**
Lors de l'utilisation du produit, bien vider et rincer le bidon (rinçage manuel à 3 reprises en agitant pendant 30s le bidon rempli au 1/3 ou rinçage mécanique pendant 30s minimum), en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Apporter les emballages ouverts, rincés et égouttés à votre distributeur partenaire d'ADIVALOR ou à une autre collecte organisée. Réemploi de l'emballage interdit.
Pour l'élimination des produits non utilisables, rapporter le produit dans son emballage d'origine à votre distributeur partenaire d'ADIVALOR ou faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.
Rapporter les équipements de protection individuelle (EPI) usagés dans un sac translucide, à votre distributeur partenaire ECO EPI ou faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux. De Sangosse est partenaire de la filière ADIVALOR.

**Equipements de protection individuelle**
**Pour protéger l'opérateur porter :**
• Pendant le mélange/chargement :
- Gants en nitrile certifiés EN 374-3,

- Combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant,
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée,
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143) ou A2P3 (EN 14387),
- Lunettes de sécurité conforme à la réglementation et selon la norme EN 166.

• Pendant l'application
Si application avec tracteur avec cabine :
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m² avec traitement déperlant,
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

*Si application avec tracteur sans cabine (application basse) :*
- Gants en nitrile certifiés EN 374-2 à usage unique pendant l'application et dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation,
- Combinaison de travail en coton 35% polyester 65%, avec un grammage d'au moins 230 g/m² (avec traitement déperlant),
- Lunettes de sécurité conforme à la réglementation et selon la norme EN 166.

• Pendant le nettoyage du matériel de pulvérisation :
- Gants en nitrile certifiés EN 374-3,
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant,
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée,
- Lunettes de sécurité conforme à la réglementation et selon la norme EN 166.

**Pour protéger le travailleur s'il doit intervenir sur une parcelle traitée :**
Porter des gants en nitrile certifiés EN 374-3 et une combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant.

**Important**
Respectez 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. 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, la pression parasitaire... Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture. Compte-tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées protégées ou issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur. DE SANGOSSE ne saurait être tenu en aucun cas responsable des conséquences inhérentes à toute copie de cette étiquette, totale ou partielle et la diffusion ou à l'utilisation non autorisée de cette dernière.