

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: DPL 3W**

**Product name: IRONCLAD EVO**

**Chemical active substance(s):**

**Ferric phosphate, 36.25 g/kg technical hydrated (29 g/kg pure anhydrous)**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(new application)**

**Applicant: DOFF PORTLAND LIMITED**

**Date: 06/06/2022**

## Table of Contents

<b>1</b>	<b>Details of the application .....</b>	<b>4</b>
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
<b>2</b>	<b>Details of the authorisation decision .....</b>	<b>5</b>
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.....	7
2.5.1	Restrictions linked to the PPP.....	8
2.5.2	Specific restrictions linked to the intended uses .....	8
2.6	Intended uses (only NATIONAL GAP) .....	9
<b>3</b>	<b>Background of authorisation decision and risk management .....</b>	<b>11</b>
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
3.4.6	Combined exposure .....	14
3.5	Residues and consumer exposure (Part B, Section 7).....	14
3.6	Environmental fate and behaviour (Part B, Section 8) .....	17
3.7	Ecotoxicology (Part B, Section 9) .....	17
3.8	Relevance of metabolites (Part B, Section 10) .....	17
<b>4</b>	<b>Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009) .....</b>	<b>17</b>
<b>5</b>	<b>Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation.....</b>	<b>18</b>

IRONCLAD EVO (DPL 3W)  
Part A - National Assessment  
FRANCE

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5.1.1	Post-authorisation monitoring.....	18
5.1.2	Post-authorisation data requirements.....	18
<b>Appendix 1</b>	<b>Copy of the product authorisation .....</b>	<b>19</b>
<b>Appendix 2</b>	<b>Copy of the product label.....</b>	<b>24</b>

## PART A

# RISK MANAGEMENT

## 1 Details of the application

The company DOFF PORTLAND LIMITED has requested a marketing authorisation in France for the product IRONCLAD EVO (formulation code: PDL 3W), containing 36.25 g/kg technical hydrated (29 g/kg pure anhydrous) ferric phosphate<sup>1</sup> as a molluscicide 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 concerns the evaluation of DOFF PORTLAND LIMITED's application submitted on 04/05/2020 to market IRONCLAD EVO (DPL 3W) 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.

Ferric phosphate is a low risk active substance, nevertheless, **IRONCLAD EVO is not authorised as a low risk plant protection product as one of the co formulants is not considered as "low risk" substance.**

The present application (2020-1802) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009<sup>2</sup>, 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")<sup>3</sup>. 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 IRONCLAD EVO (DPL 3W) has been made using endpoints agreed in the EU peer review of ferric phosphate. It also includes assessment of data and information related to IRONCLAD EVO (DPL 3W) 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.

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<sup>1</sup> Commission Implementing Regulation (EU) 2015/1166 of 15 July 2015 renewing the approval of the active substance ferric phosphate 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 (Text with EEA relevance)

<sup>2</sup> 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

<sup>3</sup> 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](#)

IRONCLAD EVO (DPL 3W)  
Part A - National Assessment  
FRANCE

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011<sup>4</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of IRONCLAD EVO (DPL 3W).

## 1.2 Letters of Access

Not necessary: the applicant has provided equivalent studies to those essential for renewal of the active substance ferric phosphate via a data matching table (DMT).

## 1.3 Justification for submission of tests and studies

According to the applicant: « Studies submitted as part of the application for DPL3W were justified as they were identified as data gaps. ».

## 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of IRONCLAD EVO (DPL 3W), 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	DPL 3W
Product name in MS	IRONCLAD EVO
Authorisation number	2220268
Kind of use	Professional use
Low risk product (article 47)	No  The product IRONCLAD EVO (DPL 3W) is not compliant with Article 47 of Regulation (EC) no 1107/2009 due to the presence of a co-formulant identified as a substance of concern and currently evaluated under the REACH program.
Function	Molluscicide
Applicant	DOFF PORTLAND LIMITED
Active substance(s) (incl. content)	Ferric phosphate, 36.25 g/kg technical hydrated (29 g/kg pure anhydrous)
Formulation type	Ready to use bait (RB)
Packaging	Bags in polyethylene low density (5, 10, 15, 20, and 25 kg)

<sup>4</sup> 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

IRONCLAD EVO (DPL 3W)  
Part A - National Assessment  
FRANCE

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 IRONCLAD EVO (DPL 3W) 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:	Not classified
Hazard pictograms:	NONE
Signal word:	-
Hazard statement(s):	NONE
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	NONE

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

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

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

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

None.

## 2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017<sup>5</sup> 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.

Moreover, the French Order of 12 avril 2021<sup>6</sup> 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<sup>7</sup> is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

Finally, the French Order of 20 November 2021<sup>8</sup> on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive culture<sup>9</sup> when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific Spe 8 may include reference to this order.

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

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<sup>5</sup> 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>

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

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

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

<sup>9</sup> List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

### 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	
SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
Other specific restrictions	
Re-entry period	6 hours
Risk mitigation measures	NONE

### 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.

IRONCLAD EVO (DPL 3W)  
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 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: 06/06/2022

PPP (product name/code): IRONCLAD EVO / DPL 3W

Formulation type: RB Pellet <sup>(a, b)</sup>

Active substance 1: ferric Phosphate

Conc. of a.s. 1: 36.25 g/kg technical hydrated (29 g/kg pure anhydrous)<sup>(c)</sup>

Safener: -

Conc. of safener: -

Synergist: -

Conc. of synergist: -

Applicant: Doff Portland Limited

Professional use:

Zone(s): Southern Zone <sup>(d)</sup>

Non-professional use:

Verified by MS: Yes

Field of use: molluscicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)  RMS conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea- son	Min. interval be- tween applica- tions (days)	Kg prod/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
1	FR	All edible and non-edible crops	F	Slugs and snails All growth stages	overall broadcast or local- ised treatment	Pre-emergence, early post-emer- gence at onset of slug ac- tivity	4 4	7 days	7 kg 28 kg	<del>259</del> <b>253.75</b> (hyd.)/ 203 (anhy.) <del>1036</del> <b>1015</b> (hyd.)/ 812 (anhy.)	-	1 day	<b>Acceptable</b>

## IRONCLAD EVO (DPL 3W)

## Part A - National Assessment

## FRANCE

<b>Remarks table heading:</b>	(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 authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
<b>Remarks columns:</b>	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 <sup>3</sup> 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)**

IRONCLAD EVO (DPL 3W) is a Bait formulation (ready for use). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a uniform blue coloured granule approximately 2-5mm in length x 2mm wide, with a musty odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 250°C. In aqueous solution, it has a pH value of 5.21 (1% suspension) at 20.0 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. Its technical characteristics are acceptable for a formulation type formulation RB Ready to use Bait.

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

The shelf life study in commercial containers should be provided.

#### **3.2 Efficacy (Part B, Section 3)**

The efficacy of the product IRONCLAD EVO (DPL 3W) is considered acceptable for all the intended uses.

The phytotoxicity level of IRONCLAD EVO (DPL 3W) is considered negligible for all the intended uses.

The risk of negative impact on yield, quality, transformation processes, multiplication, succeeding crops, adjacent crops, are considered negligible for all the intended crops.

The risk of resistance apparition or development toward ferric phosphate does not require a monitoring for all the intended uses.

#### **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 substance ferric phosphate in the formulation are available and validated.

Analytical methods for the determination of relevant impurities (lead, cadmium and mercury) of ferric phosphate in the formulation are available and validated.

##### **3.3.2 Analytical methods for residues**

Ferric phosphate as active substance on Annex IV of EC Regulation no 396/2005 is exempt from MRL setting.

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

#### 3.4.1 Acute toxicity

The product IRONCLAD EVO (DPL 3W) has a low acute oral, inhalational and dermal toxicity. It is not irritating to the rabbit skin or eye and is not a skin sensitizer

Active substance (incl. content)	<b>Ferric phosphate</b> 29 g/kg
AOEL systemic	0.4 mg/kg bw/d (iron)
AAOEL	NONE
Inhalation absorption	100%
Vapour pressure	Non-volatile
Oral absorption	100 %
Dermal absorption	10%

#### 3.4.2 Operator exposure

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model<sup>18</sup>

Model data		Ferric phosphate	
Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	
<b>Application via vehicle mounted broadcast to bare soil</b>			
Application rate		4*0.077 kg iron/ha	
<b>Granule application</b> (PHED model; 75 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.0160	4.01
	Certified protective coverall (arms, body and legs covered) M/L and A	0.0002	0.7
	Certified protective coverall (arms, body and legs covered) M/L and A+ gloves	0.0016	0.39
<b>Application via vehicle mounted in-furrow to bare soil</b>			
Application rate		4*0.077 kg iron/ha	
<b>Granule application</b> (PHED model; 75 <sup>th</sup> percentile)	Potential exposure	0.0160	4.01

IRONCLAD EVO (DPL 3W)  
Part A - National Assessment  
FRANCE

Body weight: 60 kg	Certified protective coverall (arms, body and legs covered) M/L and A	0.0002	0.7
	Certified protective coverall (arms, body and legs covered) M/L and A+ gloves	0.0016	0.39
<b>Manual application of granules outdoors</b>			
		4*0.077 kg iron/ha	
Granule application (PHED model; 75 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	1.2506	312.65
	Certified protective coverall (arms, body and legs covered)	0.3756	94
	Certified protective coverall (arms, body and legs covered) M/L and A+ gloves	0.0131	3.28

According to the EFSA model calculations, it can be concluded that the risk for the operator using IRONCLAD EVO (DPL 3W) is **acceptable** taking into account the above mentioned personal protective equipment.

### 3.4.3 Worker exposure

Considering that the product is a granular bait formulation the worker exposure evaluation is not relevant.

### 3.4.4 Bystander exposure

IRONCLAD EVO (DPL 3W) is a granular bait formulation; no drift is expected. Therefore, bystander exposure estimation is considered not relevant.

### 3.4.5 Resident exposure

According to the intended uses (ready-to-use bait pellet applied on bare soil, in furrow), no spray drift, no fall out are expected. Therefore, the resident exposure assessment is not relevant.

IRONCLAD EVO (DPL 3W)  
Part A - National Assessment  
FRANCE

### 3.4.6 Combined exposure

Not relevant. The product contains only one active substance.

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

The respective intended uses on non edible commodities were not assessed.

In the framework of EU evaluation no residue definition has been proposed for ferric phosphate (EFSA, 2015). Furthermore ferric phosphate is included in Annex IV of Regulation (CE) No 396/2005 that regroups active substances for which no MRL are necessary.

Indeed ferric phosphate is naturally present in soils where its availability to plants is slow, linked to the fact that it is strongly adsorbed to soil constituents, and is poorly soluble in water. It disappears slowly, and degradation products (iron and phosphates) are natural nutritive compounds, necessary for plants to insure their growth.

Moreover, ferric phosphate is used as food additive, and, has been considered as a « generally considered as safe » substance in the United States of America.

Last, considering the formulation as «baits », product is not applied directly to consumable parts of plants and if eventually present on the crop surface it will be easily removed by normal food processing e.g. washing.

For all these reasons consumer is not exposed to a specific risk considering intended uses of DPL 3W and no risk mitigation measure is deemed necessary to insure consumer safety.

All intended uses are then considered acceptable. As ferric phosphate is included in annex IV of regulation 396/2005 and as DPL 3W is intended to be used as bait between the plants it is considered that it is not necessary to set a PHI.

#### Summary for IRONCLAD EVO (DPL 3W)

#### Information on IRONCLAD EVO (DPL 3W) (KCA 6.8)

Crop	PHI for DPL 3W proposed by applicant	PHI/ Withholding period* sufficiently supported for Ferric phosphate	PHI for DPL 3W proposed by zRMS	zRMS Comments (if different PHI proposed)
Oilseed rape BRSNN, linseed (LIUT), poppy, sunflower (HELAN), soya bean (GLXMA), mustard (3MUSC), borage (BOROF),	No PHI required	NR	No PHI required	/
Turnip (BRSRR), swede (BRSNN, BRSNA) celeriac (APUGR), radish (3RADC),				
Wheat (TRZAW/TRZAS), barley				

IRONCLAD EVO (DPL 3W)  
Part A - National Assessment  
FRANCE

Crop	PHI for DPL 3W proposed by applicant	PHI/ Withholding period* sufficiently supported for Ferric phosphate	PHI for DPL 3W proposed by zRMS	zRMS Comments (if different PHI proposed)
(HORVW/HORVS), oats (AVESW/AVESS) rye (SECCW/SECCS), triticale (TTLWI/TTLSO), durum wheat (TRZDW/TRZDS)				
Maize (ZEAMX), sweetcorn				
Sugar beet (BEAVA), fodder beet (BEAVC), red beet (BEAVD)				
Pea (PIBSX), vining pea, Field bean, (VICFX) broad bean, runner bean, dwarf green bean				
Potato				
Lettuce (3LETC), Baby leaf crops, chic- ory, witloof, endive, lamb's lettuce, land cress, purslane, red mustard, rocket, spin- ach beet				
Cauliflower (BRSOB), Broccoli/calabrese (BRSOK)				
Cabbage (BRSOL), Kale (BRSOA)				
Brussels sprout (BRSOF)				
Carrot (DAUCA)				
Celery (APUGD)				
Leek (ALLPO), bulb onions, garlic (ALLSA)				
Fennel, globe arti- choke, spring/salad onions				
Grassland				

IRONCLAD EVO (DPL 3W)  
Part A - National Assessment  
FRANCE

<b>Crop</b>	<b>PHI for DPL 3W proposed by applicant</b>	<b>PHI/ Withholding period* sufficiently supported for Ferric phosphate</b>	<b>PHI for DPL 3W proposed by zRMS</b>	<b>zRMS Comments (if different PHI proposed)</b>
Non edible crops	NR		NR	Not assessed (non edible commodity)

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 of the formulation has been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs for the active substance for the intended use patterns.

Due to the natural occurrence in the environment of ferric phosphate and its dissociation products (iron ions and phosphate ions), no specific study to address the fate and behavior of active substance in environment is needed.

The PEC of ferric phosphate in soil has been assessed according to FOCUS guidance documents, with standard FOCUS recommendations. The results for  $PEC_{SOIL}$  for ferric phosphate are used for the ecotoxicological risk assessment.

For the aquatic risk assessment the maximum solubility in water ( $1.86 \times 10^{-12}$  g/L) is used. Due to the nature of the active substance, no unacceptable risk of groundwater contamination by ferric phosphate 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 review for active substances and their 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, the risks for birds, mammals, aquatic organisms, bees and other non-target arthropods, earthworms and other soil macro-organisms, micro-organisms are acceptable for the intended uses without mitigation measures when the product DPL 3W (IRONCLAD EVO) is applied according to the intended GAP.

### **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 ferric phosphate is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

IRONCLAD EVO (DPL 3W)  
Part A - National Assessment  
FRANCE

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## **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**

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- Shelf life study after 2 years at ambient temperature in commercial container.

## Appendix 1 Copy of the product authorisation

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### 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 **IRONCLAD EVO***

*de la société DOFF PORTLAND LIMITED*

*enregistrée sous le n°2020-1802*

*Vu les conclusions de l'évaluation de l'Anses du 15 mars 2022,*

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.

Considérant que, bien que la substance active phosphate ferrique soit approuvée en tant que substance active à faible risque conformément à l'article 22 du règlement (CE) n°1107/2009, le produit IRONCLAD EVO contient un coformulant identifié comme substance préoccupante et ne répond pas à ce titre aux exigences de l'article 47 de ce règlement, le produit IRONCLAD EVO ne peut en conséquence être qualifié de produit à faible risque.

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.

IRONCLAD EVO (DPL 3W)  
Part A - National Assessment  
FRANCE

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Informations générales sur le produit	
Nom du produit	IRONCLAD EVO
Type de produit	Produit de référence
Titulaire	DOFF PORTLAND LIMITED block 3 Harcourt centre Harcourt road D02 A339 DUBLIN 2 Irlande
Formulation	Appât prêt à l'emploi (RB)
Contenant	29 g/kg - phosphate ferrique
Numéro d'intrant	412-2020.01
Numéro d'AMM	2220268
Fonction	Molluscicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 décembre 2031.

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

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

A Maisons-Alfort, le 06/06/2022

DocuSigned by:  
*Charlotte Grastilleur*  
AE281A955A42454...  
Directrice générale déléguée  
en charge du pôle produits réglementés  
Agence nationale de sécurité sanitaire de  
l'alimentation, de l'environnement et du travail (ANSES)

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## ANNEXE : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Sacs en polyéthylène basse densité	5 kg ; 10 kg ; 15 kg ; 20 kg ; 25 kg

Classification du produit
La classification retenue est la suivante : Sans classement.
Pour les phrases P se référer à la réglementation en vigueur.
<b>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.</b>

IRONCLAD EVO (DPL 3W)  
Part A - National Assessment  
FRANCE

DocuSign Envelope ID: 444DBF5F-34EA-4EE3-BD53-56D3471042D8



**Liste des usages autorisés**

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
<b>11012903</b> Traitements généraux*Trt Sol* Limaces et escargots	7 kg/ha	4/an	-	1	-	-	-	Non concerné
Intervalle minimum entre les applications : 7 jours.								

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## Conditions d'emploi du produit

### Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles.
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

### **Pour l'opérateur, porter**

Dans le cadre d'une application effectuée à l'aide d'un matériel d'épandage (ex : microgranulateur) :

#### • pendant le chargement du matériel d'épandage

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;

#### • pendant l'épandage

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique en cas d'intervention sur semoir, épandeur à engrais ou microgranulateur ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;

#### • pendant le nettoyage du matériel d'épandage

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

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

- 6 heures.

### Protection de l'environnement (milieux, faune et flore)

#### **Protection de l'eau**

- SP 1 : 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.

## 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.

### IRONCLAD EVO MOLLUSCICIDE

<p><b>IRONCLAD EVO - Molluscicide</b>  <b>Numéro d'AMM : XXXX</b>  <b>UFI : XXXXX</b></p>	
<p>Composition : Contient du phosphate ferrique anhydre – 29 g/kg (2.9 % p/p)          Formulation : Appât prêt à l'emploi (RB)</p>	
<p><b>RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL</b></p> <p>Lire les instructions ci-jointes avant l'emploi.</p> <p>RÉEMPLOI DE L'EMBALLAGE INTERDIT</p> <p><b>P501</b> Éliminer le contenu/récipient dans un centre de collecte pour déchets dangereux.  <b>EUH401</b> Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.</p> <p>Délai de rentrée : non applicable</p>	
<p style="text-align: center;"><b>EN CAS D'URGENCE</b></p> <p style="text-align: center;"><b>Composer le 15 ou le 112 ou contacter le centre anti-poison le plus proche</b></p>	
<p>Puis signalez vos symptômes au réseau <b>PhytAttitude</b>, n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).</p> <p>Fiche de données de sécurité disponible sur : <a href="http://www.doffagriculture.com">www.doffagriculture.com</a> ou sur demande auprès de votre revendeur.</p>	
<p><b>Premiers soins</b>          S'éloigner de la zone dangereuse.  <u>En cas de contact cutané</u> : rincer immédiatement et abondamment la peau sous l'eau du robinet. En cas d'irritation ou éruption cutanée, consulter un spécialiste.  <u>En cas de projection dans les yeux</u> : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Consulter un spécialiste.  <u>En cas d'inhalation</u> : en cas de trouble respiratoire, contacter sans délai les secours, le 15, le 112 ou un centre antipoison.  <u>En cas d'ingestion</u> : rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir sans avis médical. Contacter sans délai les secours, le 15, le 112 ou un centre antipoison. Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la Fiche de Données de Sécurité.  <u>En cas d'intoxication animale</u> : contacter votre vétérinaire.</p>	
<p><b>Fabrication</b> : Union européenne  <b>Date de fabrication et n° de lot</b> : voir emballage.</p>	<p><b>Détenteur de l'AMM</b> :          Doff Portland Limited          Block 3, Harcourt Centre          Harcourt Road          Dublin 2, D02 A339          Irlande          Tél: +44 115 963 2842          Web: <a href="http://www.doff.co.uk">www.doff.co.uk</a>          EMB : XXXXX</p>

IRONCLAD EVO (DPL 3W)  
Part A - National Assessment  
FRANCE

Volume net : **20 kg**

Code barre (code EAN)

appât molluscicide prêt à l'emploi utilisé pour lutter contre les limaces et escargots en

IRONCLAD EVO est un produit utilisable en agriculture biologique en application du Règlement (CE) no. 834/2007.

### DOSES ET USAGES AUTORISÉS

Culture/ Usage	Dose d'emploi	Nombre maximum d'applications
Traitements généraux*Traitement du sol*Limaces et escargots (Toutes cultures – plein champ)	7 kg/ha/application (maximum 28 kg/ha/an)	4

Aucune LMR (Limites maximales de résidus) n'est requise pour le phosphate ferrique : substance à faible risque incluse à l'Annexe IV du Règlement (CE) no. 396/2005.

### RECOMMANDATIONS D'EMPLOI

IRONCLAD EVO est utilisé pour attirer les limaces qui causent des dégâts aux plantes, sur toutes les cultures (plein champ).

IRONCLAD EVO doit être appliqué en fin de soirée ou tôt le matin, dans des conditions légèrement humides, lorsque les limaces sont les plus actives. Les pellets gonflent, absorbent l'eau des sols humides et deviennent plus attractifs pour les limaces. Après l'ingestion, aucune sécrétion de bave ne sera observée sur ou autour des cultures, les limaces se retirant sous terre pour mourir et généralement aucune limace morte ne seront observées à la surface du sol.

IRONCLAD EVO offre une protection dès le début de l'infestation, appliquer le produit à un stade ultérieur peut s'avérer inefficace. Pour certaines cultures, par exemple pour les céréales et le colza, si l'activité des limaces est présente avant la levée de la culture, il est conseillé de traiter la culture avant la levée et après la préparation du lit de germination.

L'application peut être répétée minimum 1 semaine plus tard s'il ne reste aucun granulé de l'application précédente à la surface du sol et si les conditions climatiques sont favorables aux limaces et aux escargots.

IRONCLAD EVO peut être appliqué à la main ou à l'aide d'un applicateur mécanique. Veillez à ce que les granulés ne restent pas dans le feuillage, les fleurs ou autres parties des plantes.

Se laver les mains après utilisation.

### PROTECTION DE L'OPÉRATEUR ET DU TRAVAILLEUR

*Dans le cadre d'une application par épandage (semer, épandeur à engrais ou **microgranulateur**)*

#### Pendant le chargement du matériel d'épandage

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester 65 %/coton 35 % (combinaison ou ensemble veste et pantalon) ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

#### Pendant l'épandage

- Gants certifiés EN 374-2 à usage unique en cas d'intervention sur le matériel d'épandage ;
- Combinaison de travail polyester/coton 65 %/35 % (combinaison ou ensemble veste et pantalon) ;

#### Pendant le nettoyage du matériel d'épandage

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester/coton 65 %/35 % (combinaison ou ensemble veste et pantalon) ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.

### CONDITIONS DE STOCKAGE

Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.

Conserver hors de portée des enfants.

Se laver soigneusement les mains après utilisation.

IRONCLAD EVO (DPL 3W)  
Part A - National Assessment  
FRANCE

Stocker le produit phytopharmaceutique dans un lieu de stockage adapté aux produits chimiques, dans son emballage d'origine bien fermé.

Il est interdit d'utiliser des emballages vides de produits phytopharmaceutiques à d'autres fins.

Tout produit non utilisé doit être remis à un organisme agréé pour la collecte des déchets dangereux.

Si vous avez des doutes concernant la manipulation des emballages, contactez un vendeur de produits phytopharmaceutiques.

### ÉLIMINATION DU PRODUIT ET DE L'EMBALLAGE

Réemploi de l'emballage interdit.

Apporter les emballages vidés et pliés à votre distributeur partenaire d'ADIVALOR ou à un autre service de collecte spécifique.

Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Interroger votre distributeur partenaire d'ADIVALOR ou faites appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux.

Rapporter les 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 déchets dangereux.

DOFF Portland Ltd est partenaire de la filière ADIVALOR.



### AVERTISSEMENT

Toute reproduction totale ou partielle de cette étiquette est interdite.

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte, sous la responsabilité de l'utilisateur, de tous les facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces, ...

Le fabricant garantit la qualité du produit vendu dans son emballage d'origine et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les autorités compétentes françaises. Pour des denrées issues de cultures protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.