REGISTRATION REPORT

Part A

Risk Management

Product code: DPL 3D FR

Product name: DPL 3D FR

Chemical active substance:

pure anhydrous Ferric phosphate 29.6 g/kg

(technical dihydrated Ferric phosphate 37 g/kg)

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: Doff Portland Limited

Date: 07/07/2022

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PART A

RISK MANAGEMENT

1 Details of the application

The company Doff Portland Limited has requested a marketing authorisation in France for the product DPL 3D FR (formulation code: DPL 3D FR), containing 29.6 g/kg pure anhydrous ferric phosphate[1] as a molluscicide for non-professional uses.

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

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

1.1 Application background

The present registration report concerns the evaluation of Doff Portland Limited's application submitted on 12/02/2021 to market DPL 3D FR 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, therefore DPL 3D FR shall be authorised as a low risk plant protection product where compliant with Article 47 of Regulation (EC) no 1107/2009.

The present application (2020-3772) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[2], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[3]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of DPL 3D FR has been made using endpoints agreed in the EU peer review of ferric phosphate. It also includes assessment of data and information related to DPL 3D FR 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[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

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1 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.

2 REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

3 SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

4 COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

This document also describes the specific conditions of use and labelling required for France for the registration of DPL 3D FR.

1.2 Letters of Access

Not necessary: the applicant is the owner of data which support the approval of the active substance.

1.3 Justification for submission of tests and studies

According to the applicant: "*Studies submitted as part of the application for DPL3 D FR 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 DPL 3 3 D FR, 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	DPL3 D FR
Product name in MS	DPL3 D FR
Authorisation number	975-2020.01
Kind of use	Non-professional use
Low risk product (article 47)	Yes
Function	Molluscicide
Applicant	Doff Portland Limited
Active substance(s) (incl. content)	Ferric phosphate, 29.6 g/kg
Formulation type	Pellet [RB]

Packaging	○ Cardboard type packaging made of coated natural kraft with perforation system (150g, 200g, 225g, 250g, 275g, 300g, 325g, 350g, 375g, 400g, 425g, 450g, 475g, 500g, 525g, 550g, 575g, 600g, 625g, 650g, 675g, 700g 725g, 750g, 775g, 800g, 825g, 850g, 875g, 900g, 925g, 950g, 975g, 1000g, 1025g, 1050g, 1075g, 1100g, 1125g, 1150g 1175g, 1200g, 1225g, 1250g, 1275g, 1300g, 1325, 1350g, 1375g, 1400g, 1425g, 1450g, 1475g, 1500g, 1525g, 1550g, 1575g, 1600g, 1625g, 1650g, 1675g, 1700g, 1725g, 1750g, 1775g, 1800g, 1825g, 1850g, 1875g, 1900g, 1925g, 1950g, 1975g, 2000g, 2025g, 2050g, 2075g, 2100g, 2125g, 2150g, 2175g, 2200g, 2225g, 2250g, 2275g, 2300g, 2325g, 2350g, 2375g, 2400g, 2425g, 2450g, 2475g, 2500g) ○ Bottle and can in HDPE[5] with an internal applicator insert (150g, 200g, 225g, 250g, 275g, 300g, 325g, 350g, 375g, 400g, 425g, 450g, 475g, 500g, 525g, 550g, 575g, 600g, 625g, 650g, 675g, 700g 725g, 750g, 775g, 800g, 825g, 850g, 875g, 900g, 925g, 950g, 975g, 1000g, 1025g, 1050g, 1075g, 1100g, 1125g, 1150g 1175g, 1200g, 1225g, 1250g, 1275g, 1300g, 1325, 1350g, 1375g, 1400g, 1425g, 1450g, 1475g, 1500g, 1525g, 1550g, 1575g, 1600g, 1625g, 1650g, 1675g, 1700g, 1725g, 1750g, 1775g, 1800g, 1825g, 1850g, 1875g, 1900g, 1925g, 1950g, 1975g, 2000g, 2025g, 2050g, 2075g, 2100g, 2125g, 2150g, 2175g, 2200g, 2225g, 2250g, 2275g, 2300g, 2325g, 2350g, 2375g, 2400g, 2425g, 2450g, 2475g, 2500g) ○ Polypropylene bucket only for mechanized application (1000g, 1025g, 1050g, 1075g, 1100g, 1125g, 1150g 1175g, 1200g, 1225g, 1250g, 1275g, 1300g, 1325, 1350g, 1375g, 1400g, 1425g, 1450g, 1475g, 1500g, 1525g, 1550g, 1575g, 1600g, 1625g, 1650g, 1675g, 1700g, 1725g, 1750g, 1775g, 1800g, 1825g, 1850g, 1875g, 1900g, 1925g, 1950g, 1975g, 2000g)
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 DPL 3D FRresulted 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:	-
Signal word:	-

[5] HDPE : high density polyethylene

Hazard statement(s):	-
Precautionary statement(s):	***For the P phrases, refer to the existing legislation***
Additional labelling phrases:	

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

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

	Do not discharge into the sink, gutter or any other water hole the non-used container leftovers and the sprayer washing water.
	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[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 12 April 2021[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.

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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 https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

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

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

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

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
Protection phrase	
Other specific restrictions	
Re-entry period	Not applicable.
Storage	-
SPa 1	
Risk mitigation measures	None.
Risk mitigation measures	-
Agricultural recommendations	- Contains a molluscicidal substance which may cause adverse effects on earthworms and other soil macro-organisms.

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.

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: 2022-07-07

PPP (product name/code):	DPL 3D FR	Formulation type:	RB [a, b]
Active substance 1:	Ferric phosphate	Conc. of a.s. 1:	29.6 g/kg [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	Doff Portland Limited	Professional use:	☐
Zone(s):	Southern Zone [d]	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. [e]	**Member state(s)**	**Crop and/ or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:**
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	g product/m² a) max. rate per appl. b) max. total rate per crop/season	g a.s./m² a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		e.g. g safener/synergist per ha [f] RMS CONCLUSION
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	All edible and non-edible crops	Fn Gn	Slugs & snails All growth stages	Shaker pack	NA	a) 1 b) 4	7 days	a) 0.7 b) 2.8	a) 20.72 b) 82.88	-	1	**Acceptable**

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)

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 0.5cm in length x 0.2cm 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 232ºC . In aqueous solution, it has a pH 4.59 value 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. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in packaging material HDPE, Polypropylene, LDPE, Cardboard. Its technical characteristics are acceptable for a formulation type formulation RB Pellet.

3.2 Efficacy (Part B, Section 3)

Given the submitted data:

The efficacy of the product DPL 3D FR is considered satisfactory for the intended use.

The phytotoxicity level of DPL 3D FR is considered negligible for the intended use.

The risk of negative impact on yield, quality, 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

Product yields no discernible residue it is found naturally throughout the environment.

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)

Endpoints used in risk assessment

Active substance(s) (incl. content)	**Ferric Phosphate** 30 g/kg
AOEL systemic	0.4 mg/kg bw/d
AAOEL systemic	-
Vapour pressure	Non volatile
Inhalation absorption	100 %
Oral absorption	100 %
Dermal absorption	10% (proposed conservative worst-case scenario)

3.4.1 Acute toxicity

DPL 3D FR containing 29.6 g/kg ferric phosphate has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.4.2 Operator exposure

Considering the proposed uses, the operator systemic exposure was estimated using the French study from UPJ 2009-2010[9] dedicated to non-agricultural areas and the EFSA model[10] / PHED model:

		Ferric Phosphate (Iron, Fe)	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AAOEL**
Indoor / outdoor, manual application of granules			
Application rate		4 x 0.078 kg (Fe)/ha	
Granule application (EFSA Calculator: PHED model; 75th percentile) • Application. • Area Treated: **1 ha** • Body weight: 60 kg	No PPE	1.267	316.71
Granule application (EFSA Calculator: PHED model; 75th percentile) • Application. • Area Treated:**0.05 ha** • Body weight: 60 kg	No PPE	0.0633	15.8

[9] Studies and models that can be used to estimate operator exposure during the use of plant protection products in non- agricultural areas. Report from expert group « produits phytosanitaires : substances et préparations chimiques » Working group "évaluation de l'exposition des utilisateurs de produits phytopharmaceutiques en zones non agricoles" - June 2011

[10] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

		Ferric Phosphate (Iron, Fe)	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AAOEL**
Outdoor, manual application of granules			
Application rate		4 x 0.078 kg (Fe)/ha	
Granule Application (model UPJ) • Application. • Body weight: 60 kg	No PPE	0.0363	9.06

The zRMS considers that compliance with the provisions of French regulation relating to the conditions of authorisation of plant protection products by non-professional users[11] is considered to be finalised only for the following packaging:

- HDPE bottle with an internal applicator insert (150 g and 200 g to 2500 g (increments of 25 g))
- HDPE can with an internal applicator insert (2000 g to 2500g)
- Polypropylene bucket only for mechanized application (1000 g to 2000 g)
- Cardboard type packaging made of coated natural kraft (water resistant) with perforation system and the resealable tab for application of pellets (150 g and 200 g to 2500 g (increments of 25 g))

3.4.3 Worker exposure

DPL 3D FR is intended to be used by amateurs during home garden application. In this case of the non-professional user, the worker is also the user. Therefore, the assessment of worker exposure is covered by the operator exposure.

There is no unacceptable risk anticipated for the worker reentering into treated crops.

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*."

[11] Arrêté du 6 avril 2020 relatif aux conditions d'autorisation d'un produit phytopharmaceutique pour la gamme d'usages « amateur » JORF n°0088 du 10 avril 2020

[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)

3.4.5 Resident exposure

In the context of use by non-professionals, it is considered that the assessment for bystanders is covered by that of the resident.

There is no suitable model to assess residential exposure for non-professional uses. As a worst case the EFSA model for resident (recreational exposure) has been used by zRMS. The estimated recreational exposure for resident is presented in the table below:

EFSA model – Recreational exposure Application rate: 4 x 0.078 kg Fe as./ha		
	Total absorbed dose (mg/kg bw/day)	**% of systemic AOEL**
Child	0.0022	0.54
Adult	0.0006	0.15

Furthermore, to address the potential for ingestion by infants of the pellets a reverse reference approach has been used to calculate the number of DPL 1D FR pellets that, if consumed by an infant would result in an exceedance of the ADI of 0.8 mg/kg bw/day for iron and of the AOEL of 0.4 mg/kg bw/day.

Infants are assumed to be 1 to 3 years old and have a body weight of 10 kg. DPL 1D FR is a non-dusty granular / pellet plant protection product containing 10 g/kg (1% w/w) Ferric Phosphate ($FePO_4$), corresponding to 3.7 g/kg (0.37% w/w) iron (Fe). The individual pellet weight is confirmed as 18 mg (please refer to section B9). Using these parameters the number of pellets which would need to be consumed to reach an intake equivalent to the reference dose is calculated as follows:

$$\text{Number of pellets} = \frac{\text{ADI (mg/kg bw/day) x body weight (kg bw)}}{\text{Concentration of a.s. in product (\%) x weight of a single pellet (mg)}}$$

$$\text{Number of pellets} = \frac{\text{AOEL (mg/kg bw/day) x body weight (kg bw)}}{\text{Concentration of a.s. in product (\%) x weight of a single pellet (mg)}}$$

Number of pellets that if consumed would exceed the ADI and the AOEL:

	Iron (ADI = 0.8 mg/kg bw/day)
Number of pellets	**40 pellets**
	Iron (AOEL = 0.4 mg/kg bw/day)
Number of pellets	**20 pellets**

The reverse reference approach shows that respectively 40 and 20 individual pellets are required to achieve an intake of iron which would be equivalent to the reference doses ADI and AOEL.

On the basis of this assessment the risk to resident (adults and children) is considered to be within acceptable levels. Consequently, there is no unacceptable risk to children (bystanders / residents).

3.4.6 Combined exposure

Not relevant. The product contains only one active substance.

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

Ferric phosphate is defined as an active substance for which no Maximum Residue Levels (MRLs) are required and listed in Annex IV to Regulation (EC) No 396/2005. As stated in the EFSA conclusion, for an essential element as ferric phosphate exposure is evaluated against background levels and ferric phosphate is considered to be low risk.

As far as consumer health protection is concerned, France agrees with the authorization of the intended use : lettuce, rapeseed, turnip, cereals, beets, pea and beans, potaton cauliflower, cabbage, brussels sprouts, strawberry, carrots, celery, leek, ornementals flower plants and non edible crops. According to available data, no specific mitigation measures should apply.

Summary for DPL 3D FR

Table : Information on DPL 3D FR (KCA 6.8)

Crop	PHI for DPL 3D FR proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for DPL 3D FR proposed by zRMS	zRMS Comments (if different PHI proposed)
		Ferric phosphate		
Lettuce	Not necessary	Yes	Not necessary	
Rapeseed	Not necessary	Yes	Not necessary	
Turnip	Not necessary	Yes	Not necessary	
Cereals	Not necessary	Yes	Not necessary	
Beets	Not necessary	Yes	Not necessary	
Pea, beans	Not necessary	Yes	Not necessary	
Potato	Not necessary	Yes	Not necessary	
Cauliflower	Not necessary	Yes	Not necessary	
Cabbage	Not necessary	Yes	Not necessary	
Brussels sprouts	Not necessary	Yes	Not necessary	
Strawberry	Not necessary	Yes	Not necessary	
Carrot	Not necessary	Yes	Not necessary	
Celery	Not necessary	Yes	Not necessary	
Leek	Not necessary	Yes	Not necessary	
Ornamentals, Flower plants			Not applicable	Not assessed (non edible commodity)

Crop	PHI for DPL 3D FR proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for DPL 3D FR proposed by zRMS	zRMS Comments (if different PHI proposed)
		Ferric phosphate		
Non edible crops			Not applicable	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).

Waiting periods before planting succeeding crops

Not relevant.

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.

Since the product DPL 3D FR is for non-professional uses, soil exposure is not considered requiring evaluation at FR national level.

For the aquatic risk assessment the maximum solubility in water (1.86×10^{-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.

Since the product DPL 3D FR is applied as bait (ready-to-use product) for amateur uses, exposure of soil and surface water compartments to active substance is considered negligible. Consequently, no risk assessment for non-target organisms is deemed necessary, except for bees where an exposure cannot be excluded. However, given that the ferric phosphate is a non-systemic compound, no risk assessment for bees is needed.

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.

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

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

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation DAMM

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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 règlementaire,

Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique ***DPL 3D FR***

de la société *DOFF PORTLAND LIMITED*

enregistrée sous le *n°2020-3772*

Vu les conclusions de l'évaluation de l'Anses du 31 mai 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.

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.

DPL 3D FR
AMM n°2220531

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Informations générales sur le produit	
Nom du produit	DPL 3D FR
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	29,6 g/kg - phosphate ferrique
Numéro d'intrant	975-2020.01
Numéro d'AMM	2220531
Fonction	Molluscicide
Gamme d'usage	Amateur / emploi autorisé dans les jardins
Mention particulière	Produit à faible risque au sens de l'article 47 du règlement (CE) n°1107/2009

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 07/07/2022

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**
Bouteilles en polyéthylène haute densité avec applicateur	De 150 g à 1,975 kg
Cartons kraft naturel enduit avec système de perforations	De 150 g à 2,5 kg
Bidons en en polyéthylène haute densité avec applicateur	De 2 kg à 2,5 kg
Seaux en polypropylène uniquement dans le cadre d'une application mécanisée.	De 1 kg à 2,5 kg

Les emballages de 150 g à 2,5 kg en polyéthylène téréphtalate doublé de polyéthylène basse densité et de 150 g à 2,5 kg en polypropylène sont refusés, car les données disponibles ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel dans le cadre des conditions d'utilisation.

Classification du produit
La classification retenue est la suivante : Sans classement.
Pour les phrases P se référer à la règlementation en vigueur. **Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.**

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
11012903 Traitements généraux* Trt Sol* Limaces et escargots	**0,7 g/m²**	**4/an**	-	1	-	-	-	Non concerné
	Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							

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Conditions d'emploi du produit

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

- 6 heures pour les usages en plein champ et 8 heures pour les applications en milieu fermé.

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

Protection de l'eau

- Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidon non utilisés.

Protection de la faune

- Dangereux pour les vers de terre et les autres macro-organismes du sol.

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.

Front Label 3%

Title:
Logo Portland Garden
DPL 3D FR

Headlines :

- **Plus** concentré = couvre au min. **4 fois plus** de surface
- On est préservé (photo cat & dog, hedgehog)
- Formulation résistante à la pluie jusqu'à 14 jours (picto Rainproof)
- A base de phosphate de fer, minéral naturellement présent dans le sol

Bottom :
Production biologique amateur.
Produit conforme au règlement (CE) de la production biologique.

350 g / 500 m² traités

Back Label

DESCRIPTION:
* DPL 3D FR est un appât sous forme de granulés prêt à l'emploi luttant contre les limaces et les escargots qui causent des dégâts au jardin.
* Les granulés gonflent, absorbent l'eau des sols humides et deviennent plus attrayants pour les limaces.
* Après avoir consommé les granulés, les limaces cessent immédiatement de s'alimenter et se retirent dans leurs abris pour mourir, ne laissant aucune trace de bave.
* Grâce à sa haute concentration, le produit couvre au minimum 4 fois plus de surface qu'un produit classique.
* Formulation résistante à la pluie jusqu'à 14 jours.
* A base de phosphate de fer, minéral naturellement présent dans le sol.
* Préserve les animaux domestiques et les hérissons.

MODE D'EMPLOI :
- DPL 3D FR doit être appliqué dès les premiers signes de dommages faits aux plantes ou aux cultures, de préférence en fin de soirée ou tôt le matin, dans des conditions légèrement humides, lorsque les limaces sont les plus actives.
- L'application peut être répétée au minimum 1 semaine plus tard s'il ne reste aucun granulé de l'application précédente à la surface du sol. Répéter l'opération au maximum 4 fois si nécessaire.
- Épandre régulièrement autour des plantes et non sur les feuilles et sans faire de petits tas.

(Picto Garden)

CONDITIONS D'EMPLOI

Usages	**Dose maximale d'emploi**	**Nombre maximum d'applications**
Traitements généraux*Trt Sol*Limaces et escargots	0,7 g/m²	4/an
Application dès le début de l'infestation. Intervalle minimum entre les applications : 7 jours.		

Délai de rentrée : Non pertinent.

PROTECTION DE L'ENVIRONNEMENT
Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidons non utilisés.

Side 1
DPL 3D FR

Nom homologué : DPL 3D FR
AMM N°xxxxx
Gamme : Amateur – EAJ Emploi autorisé dans les jardins
Usages autorisés : Traitement généraux * Trt du sol * Limaces et escargots
Détenteur de l'AMM : Doff Portland Limited, Block 3, Harcourt Centre, Harcourt Road, Dublin 2, D02 A339, Irlande
Tél: +44 115 963 2842, Web: www.doff.co.uk
Substance active : 29,6g/kg phosphate ferrique dihydraté (2,96 % p/p)
Formulation : Appât prêt à l'emploi (RB)
Type d'action : molluscicide (traitement du sol)
N° de lot / Date de fabrication : Voir sur l'emballage
Produit à faible risque au sens de l'article 47 du Règlement (CE) 1107/2009.

Side 2
PRECAUTIONS D'EMPLOI :
EUH401 Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.
P102 Tenir hors de portée des enfants.
P270 Ne pas manger, boire ou fumer en manipulant ce produit.
P501 Éliminer le contenu/récipient dans une déchèterie ou un organisme agréé.
SP1 Ne pas polluer l'eau avec le produit ou son emballage.

EN CAS D'URGENCE
Composer le 15 ou le 112 ou contacter le centre anti-poison le plus proche

CONDITIONS DE STOCKAGE ET D'ÉLIMINATION DU PRODUIT ET DES EMBALLAGES

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.
Stockez le produit phytopharmaceutique dans un lieu de stockage adapté aux produits chimiques, dans son emballage d'origine bien fermé.
Réemploi de l'emballage interdit. Ne pas jeter dans les poubelles ménagères, mais éliminer l'emballage avec ou sans produit en déchetterie ou par un organisme agréé.