REGISTRATION REPORT

Part A

Risk Management

Product code: DPL 3D Pro

Product name: DPL 3D Pro

Chemical active substance:

pure anhydrous Ferric phosphate 29.6 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: Doff Portland Limited

Date: 30/06/ 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 PRO, containing 29.6 g/kg pure anhydrous ferric phosphate[1] 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 08/02/2021 to market DPL 3D PRO 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 PRO shall be authorised as a low risk plant protection product where compliant with Article 47 of Regulation (EC) no 1107/2009.

The present application (2020-3823) 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 PRO 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 PRO 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 PRO.

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 Pro were justified as they were identified as data gaps."*

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 3.

2 Details of the authorisation decision

2.1 Product identity

Product code	DPL 3D PRO
Product name in MS	DPL 3D PRO
Authorisation number	2220532
Kind of use	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	Bags in LDPE[5] (5 kg, 10 kg, 15 kg, 20 kg)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

[5] LDPE : low density polyethylene

2.2 Conclusion DAMM

The evaluation of the application for DPL 3D PRO 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. (low risk product according to Art. 47 of Regulation (EC) No 1107/2009))
Hazard pictograms:	-
Signal word:	-
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

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[6] provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;

[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

- 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.

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	
	-
Other specific restrictions	
Re-entry period	Not applicable.
Storage	-
SPa 1	-

[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

Risk mitigation measures	-
Risk mitigation measures	-
Agricultural recommendations	-

2.5.2 Specific restrictions linked to the intended uses

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

None.

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: 2022-06-30

PPP (product name/code):	DPL 3D PRO	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)	kg 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		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	F/G	Slugs & snails	Soil, over-all broadcast or local-ised treatment	NA	a) 1 b) 4	7	a) 7 b) 28	a) 207.2 b) 828.8	-	1	**Acceptable**

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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)	kg 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		e.g. g safener/synergist per ha [f] RMS conclusion

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 LDPE plastic. 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 PRO is considered satisfactory for all the intended uses.

The phytotoxicity level of DPL 3D PRO is considered negligible for all the intended uses.

The risk of negative impact on yield, quality, multiplication, transformation processes, 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)

Active substance(s) (incl. content)	**Ferric Phosphate** 30 g/kg

AOEL systemic	0.4 mg/kg bw/d (Iron, Fe)
AAOEL systemic	-
Vapour pressure	Non volatile
Inhalation absorption	100 %
Oral absorption	50%
Dermal absorption	10% (proposed conservative worst-case scenario) *Note* – Dermal absorption is expected to be negligible as it is unlikely that ferric phosphate would be dermally absorbed. The product is a solid, non-dusty granule and would generally not adhere to skin. Ferric phosphate is also not soluble in water or in lipids and would therefore not penetrate the skin. It can also be noted that there is self-reguilation of iron levels in the body, meaning that an increased iron level caused by dermal absorption would lead to decrease oral iron absorption. These points are also reflected in the Renewal Assessment Report (RAR) for Ferric Phosphate where dermal absorption for a similar solid granule formulation was also stated to be unlikely on this basis. The EFSA Conclusion (EFSA Journal 2015; 13(1):3973) also states in the List of End Points (LoEPs) that 'no relevant dermal absorption of $FePO_4$ is expected (extremely low solubility in water and lipids)' and that 'the oral absorption is an active energy dependent process which will not take place in the skin'. The EFSA conclusion LoEPs proposes that a dermal absorption value of 10% is used as a worst-case scenario. This approach has therefore also proposed to be used for conducting the human exposure estimations. A dermal absorption value of 10% has therefore been used.

3.4.1 Acute toxicity

DPL 3D PRO containing 30 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 proposed uses, operator systemic exposure was estimated using the EFSA model[9]:

		Ferric Phosphate (Iron, Fe)	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AAOEL**
Outdoor, vehicle-mounted, granule, broadcast application			
Application rate		4 x 0.078 kg Fe/ha	
Granule application (EFSA Calculator: PHED model; 75th percentile) • Mixing and loading, and application. • Area Treated: 50 ha Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A + chemical resistant gloves	0.00158	0.39
Outdoor, vehicle-mounted, granule, in-furrow application			

[9] 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**
Application rate		4 x 0.078 kg Fe/ha	
Granule application (EFSA Calculator: PHED model; 75th percentile) • Mixing and loading, and application. • Area Treated: 50 ha Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A + chemical resistant gloves	0.00158	0.39
Outdoor, manual application of granules *Indoor manual application of granules*			
Application rate		4 x 0.078 kg Fe/ha	
Granule application (EFSA Calculator: PHED model) Application. Area Treated: 1 ha Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A + chemical resistant gloves	0.0133	3.32

According to the model calculations, it can be concluded that the risk for the operator using DPL 3D PRO is acceptable with a working coverall and gloves during mixing/loading and application.

3.4.3 Worker exposure

Considering that the product is a in ready-to-use bait product, the worker exposure assessment is not relevant.

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[10].

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*."

[10] 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

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.

The resident exposure in glasshouse is not relevant.

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

Summary for DPL 3D PRO

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

Crop	PHI for DPL 3D PRO proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for DPL 3D PRO proposed by zRMS	zRMS Comments (if different PHI proposed)
		Ferric phosphate		
Edible and non edible crops			Not applicable	

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.

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 (1.86×10^{-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 end-points 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 on field and greenhouse without mitigation measures when the product DPL 3D PRO 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.

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

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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 PRO***

de la société	*DOFF PORTLAND LIMITED*
enregistrée sous le	*n°2020-3823*

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.

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Informations générales sur le produit	
Nom du produit	DPL 3D PRO
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	998-2020.01
Numéro d'AMM	2220532
Fonction	Molluscicide
Gamme d'usage	Professionnel
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 30/06/2022

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

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	**7 kg/ha**	**4/an**	-	1	-	-	-	Non concerné
	Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							

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AGENCE NATIONALE DE SÉCURITÉ SANITAIRE de l'alimentation, de l'environnement et du travail

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 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

- 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.

DPL 3D Pro

MOLLUSCICIDE

DPL 3D Pro - Molluscicide
Numéro d'AMM : xxxxx
UFI : xxxx
Composition : Contient du phosphate ferrique dihydraté – 29,6 g/kg (2,96 % p/p)
Formulation : Appât prêt à l'emploi (RB)

RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

Lire les instructions ci-jointes avant l'emploi.

Sans classement. Produit à faible risque au sens de l'article 47 du règlement (CE) 1107/2009.
P102 Tenir hors de portée des enfants.
P270 Ne pas manger, boire ou fumer en manipulant ce produit.
P280 Porter des gants de protection.
P501 Eliminer le contenu/récipient dans un centre de collecte pour déchets dangereux.
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. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

Délai de rentrée : non pertinent.

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

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

Premiers soins
S'éloigner de la zone dangereuse.
En cas de contact cutané : rincer immédiatement et abondamment la peau sous l'eau du robinet. En cas d'irritation ou éruption cutanée, consulter un spécialiste.
En cas de projection dans les yeux : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Consulter un spécialiste.
En cas d'inhalation : en cas de trouble respiratoire, contacter sans délai les secours, le 15, le 112 ou un centre antipoison.
En cas d'ingestion : rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir sans avis médical. Contacter sans délai les secours, le 15, le 112 ou un centre 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.
En cas d'intoxication animale : contacter votre vétérinaire.

Fabrication : Union européenne
Date de fabrication et n° de lot: voir emballage.

Titulaire 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
EMB : xxxx

Volume net : **20 kg**

DPL 3D PRO est un appât molluscicide prêt à l'emploi utilisé pour lutter contre les limaces, y compris *Deroceras*.

Stockez 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.

- 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 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.