REGISTRATION REPORT

Part A

Risk Management

Product code: F3965

Product name(s): IRONMAX PRO

Chemical active substance(s):

24.2 g pure active/kg ferric phosphate anhydrous

(25.6 g technical/kg)

Low risk active substance

Southern Zone (Field uses)

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(Autorisation renewal according to Art. 43)

Applicant: De Sangosse SAS

Date: 2019/06/11

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PART A
RISK MANAGEMENT

1 Details of the application

The company De Sangosse SAS has requested marketing authorisation in France for the product IRONMAX PRO (product Code F3965), containing 24.2 g pure active/kg ferric phosphate anhydrous for use as a molluscicide for professional uses.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to IRONMAX PRO (F3965) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of IRONMAX PRO (F3965) have been made using endpoints agreed in the EU peer review of ferric phosphate.

This document describes the specific conditions of use and labelling required for France for the registration of IRONMAX PRO.

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

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

Appendix 3 of this document is a copy of the letter(s) of Access.

Appendix 4 of this document is the list of data considered for national authorisation

1.1 Application background

The present registration report concerns the evaluation of De Sangosse SAS's application to market IRONMAX PRO (F3965) in France as a molluscicide (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 renewal of authorisation after approval of the active substance of this product in France and in other MSs of the Southern zone.

Ferric phosphate is a low risk active substance; therefore IRONMAX PRO (F3965) shall be authorized as a low risk plant protection product if compliant with article 47.

The present application (2016-1276) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone for field uses, taking into account the worst-case uses ("risk envelope approach")[1] – the highest application rates over the Southern zone for field uses. When risk mitigation measures were necessary, they are adapted to the situation in France.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[2], implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at

[1] 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

[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

zonal/national level. 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 conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[3], and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

1.2 Letters of Access

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

1.3 Justification for submission of tests and studies

Not required for applications submitted in accordance with Article 43.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of IRONMAX PRO (F3965), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

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2 Details of the authorisation decision

2.1 Product identity

Product code	F3965
Product name in MS	IRONMAX PRO
Authorisation number	2160226
Low risk (article 47)	Yes
Function	Molluscicide
Applicant	De Sangosse SAS
Active substance(s) (incl. content)	24.2 g pure active/kg ferric phosphate anhydrous (25.6 g technical/kg)
Formulation type	Ready to use bait (RB)
Packaging	Bags in paper: 5 kg, 10 kg, 15 kg and 20 kg Bags in polypropylene (Big bags): 400 kg Professional user
Coformulants of concern for national authorisations	-
Restrictions related to identity	Maximum content of relevant impurities is established by EU Endpoints (EFSA, 2014; ferric phosphate)
Mandatory tank mixtures	None

[3] 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

Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for IRONMAX PRO (F3965) resulted in the decision to grant the authorization.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	-
Hazard pictograms:	-
Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	***For the P phrases, refer to the extant legislation***
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

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 4th May 2017 [4] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally 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, drift buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 26 March 2014[5] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" 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 "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] 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	
	-

[4] 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 https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

[5] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

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

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)

GAP rev. 1, date: 2019-06-11

PPP (product name/code):	IRONMAX PRO (F3965)	Formulation type:	RB (ready to use bait) [a, b]
Active substance 1:	Ferric phosphate anhydrous	Conc. of as 1:	24.2 g/kg [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	De Sangosse SAS	Professional use:	☒
Zone(s):	southern[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:** e.g. g safener/synergist per ha [f] **RMS CONCLUSION**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	All situations, crop and non-crop	F,	Slugs and snails	Spreading Broadcast	At any time	a) 1 b) 4	Not specified	a) 7 kg/ha b) 28 kg/ha	a) 169.4 g as/ha b) 677.6 g as/ha	n/a	3 days pfor edible crops	Acceptable (Indoor uses also registered according to UK assessment)

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)

IRONMAX PRO (F3965) is a ready to use bait formulation (RB). 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 homogeneous green granules, without odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 140°C. In aqueous solution (1%), it has a pH value of 4.8 at ambient temperature. 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 paper commercial packaging (extrapolable to PP packaging). Its technical characteristics are acceptable for a RB formulation.

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

3.2 Efficacy (Part B, Section 3)

Considering the first registration of IRONMAX PRO (F3965) data and the new data submitted:

- The level of efficacy of IRONMAX PRO (F3965) is considered as satisfactory for all the claimed uses.
- The level of phytotoxicity of IRONMAX PRO (F3965) is considered as negligible for all the claimed uses.
- The risks of negative impact on yield, quality, transformation processes, propagation, succeeding crops and adjacent crops are considered as negligible.
- The risk of resistance development or appearance to phosphate ferric is considered as very low.

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 and the relevant impurities (lead, cadmium, mercury) in the formulation are available and validated. Nevertheless, **a specific analytical method for the determination of Fe^{3+} in the formulation is required in post-registration.**

3.3.2 Analytical methods for residues

No residues have to be monitored in crops and foodstuff of animal origin, as well as in soil, water and air. As a consequence, no analytical methods are proposed.

The active substance is neither toxic nor very toxic hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active Substance: **ferric phosphate**		
ADI	0.8 mg kg bw/d	EU/ (January 2016)
ARfD	Not required	
AOEL	0.4 mg/kg bw/d	
Dermal absorption	No relevant dermal absorption of FePO4 is expected (extremely low solubility in water and lipids). The oral absorption is an active energy dependent process which will not take place in the skin. A dermal absorption value of 10% is proposed as worst-case scenario. (EFSA 2015).	
Oral absorption	50% oral bioavailability	

3.4.1 Acute toxicity

IRONMAX PRO (F3965) containing 24.2 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 sensitizer.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G[7]	Equipment *Application method*	Maximum application rate kg as /ha	Minimum volume water (L/ha)
Bare soil, and around all edible and non-edible crops Strawberries, Cabbages, Lettuces, Ornamental plants	F	Broadcast application of granules Vehicle mounted Manual (hand-held equipment)	0.169 kg s.a/ha	n.a.

Considering proposed uses, operator systemic exposure was estimated using EFSA model[8]:

Crop	Equipment	PPE and/or working coverall	% AOEL Ferric phosphate

[7] Open field or glasshouse
[9] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev.10-final, 25 February 2003.

Bare soil, and around all edible and non-edible crops	Vehicle mounted	Working coverall and gloves during mixing/loading and application	0.9 %
Strawberries, Cabbages, Lettuces, Ornamental plants	Manual application		7.2 %

According to the model calculations, it can be concluded that the risk for the operator using IRONMAX PRO (F3965) is acceptable with a working coverall and gloves during mixing/loading and application.

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

3.4.3 Worker exposure

Broadcast application and manual application of granules is intended for IRONMAX PRO; no work is expected to be practiced after application. Therefore, worker exposure estimation is considered not relevant.

3.4.4 Bystander and resident exposure

IRONMAX PRO (F3965) is a granular bait formulation; no drift is expected. Therefore, bystander and residential exposure estimation is considered not relevant.

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

Overall conclusion

The data available are considered sufficient for risk assessment. Ferric phosphate is included in Annex IV of Regulation (CE) No 396/2005 that groups 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, according the formulation as « granular 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 F3965 / IRONMAX PRO (F3965) and no risk mitigation measure is deemed necessary to insure consumer safety.

All intended uses are then considered acceptable, and a PHI is not necessary for the intended uses on all edible crops under evaluation.

Data gaps

- None

The preparation F3965 / IRONMAX PRO (F3965) is composed of ferric phosphate.

Summary for ferric phosphate

Use-No.	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
16	All situations, crop and non-crop	Not required	Not required	N/A	Not required	N/A	No	No

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

Ferric phosphate is included in Annex IV of Regulation (CE) No 396/2005 that regroups active substances for which no MRL are necessary no specific studies are required. Therefore, no additional data are required to support the intended use of F3965 / IRONMAX PRO.

Summary for F3965 / IRONMAX PRO (F3965)

Information on F3965 / IRONMAX PRO (F3965) (KCA 6.8)

Crop	PHI for F3965 / Ironmax Pro proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for F3965 / Ironmax Pro proposed by zRMS	zRMS Comments (if different PHI proposed)
		Ferric phosphate		
All situations, crop and non-crop	/	NR	not necessary	a 3 days PHI is proposed for edible crops in compliance with FR order

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. Ferric phosphate is considered as a low-risk active substance. 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.

The formulate product being applied as granules, only the exposure routes, drainage and runoff, are considered in the PEC_{SW} calculations. The maximum concentration of the active substance in water will

correspond to the water solubility of ferric phosphate (1.86 x 10^{-12} mg/L). In addition, no unacceptable risk of eutrophication due to the application of ferric phosphate is expected according to the intended uses.

According to the guidance document SANCO 221/2000[9] , iron ions and phosphate ions are considered as compounds of no-concern. Given the very low water solubility and the low soil mobility of ferric phosphate, no unacceptable risk of groundwater contamination is expected for the intended uses. No PEC_{GW} were required according to EU conclusions (EFSA, 2015).

As ferric phosphate is a non-volatile salt, no significant contamination of the air compartment is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for active substance and preparation 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 terrestrial vertebrates, aquatic organisms, bees and other non-target arthropods, earthworms and other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses.

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 of 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

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:

- An analytical method for the specific determination of Fe^{3+} in the formulation.

[9] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev.10-final, 25 February 2003.

Appendix 1 Copy of the product authorisation

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Décision relative à une demande de renouvellement de l'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 de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active phosphate ferrique, du produit phytopharmaceutique ***IRONMAX PRO***

de la société	*DE SANGOSSE*
enregistrée sous les	*n°2016-1276 et 2017-1608*

Vu les conclusions de l'évaluation de l'Anses du 17 mai 2019,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **est renouvelée** en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

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.

IRONMAX PRO
AMM n°2160226

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Informations générales sur le produit	
Noms du produit	IRONMAX PRO MUSICA IRONMAX MG
Type de produit	Produit de référence
Titulaire	DE SANGOSSE Bonnel CS 10005 47480 Pont du Casse France
Formulation	Appât (prêt à l'emploi) (RB)
Contenant	24,2 g/kg - phosphate ferrique anhydre
Numéro d'intrant	386-2015.01
Numéro d'AMM	2160226
Fonction	Molluscicide
Gamme d'usage	Professionnel
Mention particulière	Produit à faible risque au sens de l'article 47 du règlement (CE) 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,

11 JUIN 2019

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

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ANNEXE I : 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 papier	5 kg ; 10 kg ; 15 kg ; 20 kg
Sacs en polypropylène (Big bag)	400 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 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
11012903 Traitements généraux* Trt Sol*Limaces et escargots	**7 kg/ha**	**4/an**	-	3	-	-	-	-
	Également autorisé sous abri. Uniquement sur cultures alimentaires.							
11012903 Traitements généraux* Trt Sol*Limaces et escargots	**7 kg/ha**	**4/an**	-	Non applicable	-	-	-	-
	Également autorisé sous abri. Uniquement sur cultures non alimentaires.							

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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 par épandage

• pendant le chargement du matériel d'épandage

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester/coton 65 %/35 % (combinaison ou ensemble veste+ 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 semoir, épandeur à engrais ou microgranulateur ;
- Combinaison de travail polyester/coton 65 %/35 % (combinaison ou ensemble veste+ pantalon) ;

• pendant le nettoyage du matériel d'épandage

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

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

- Non pertinent pour ce type d'application

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.

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

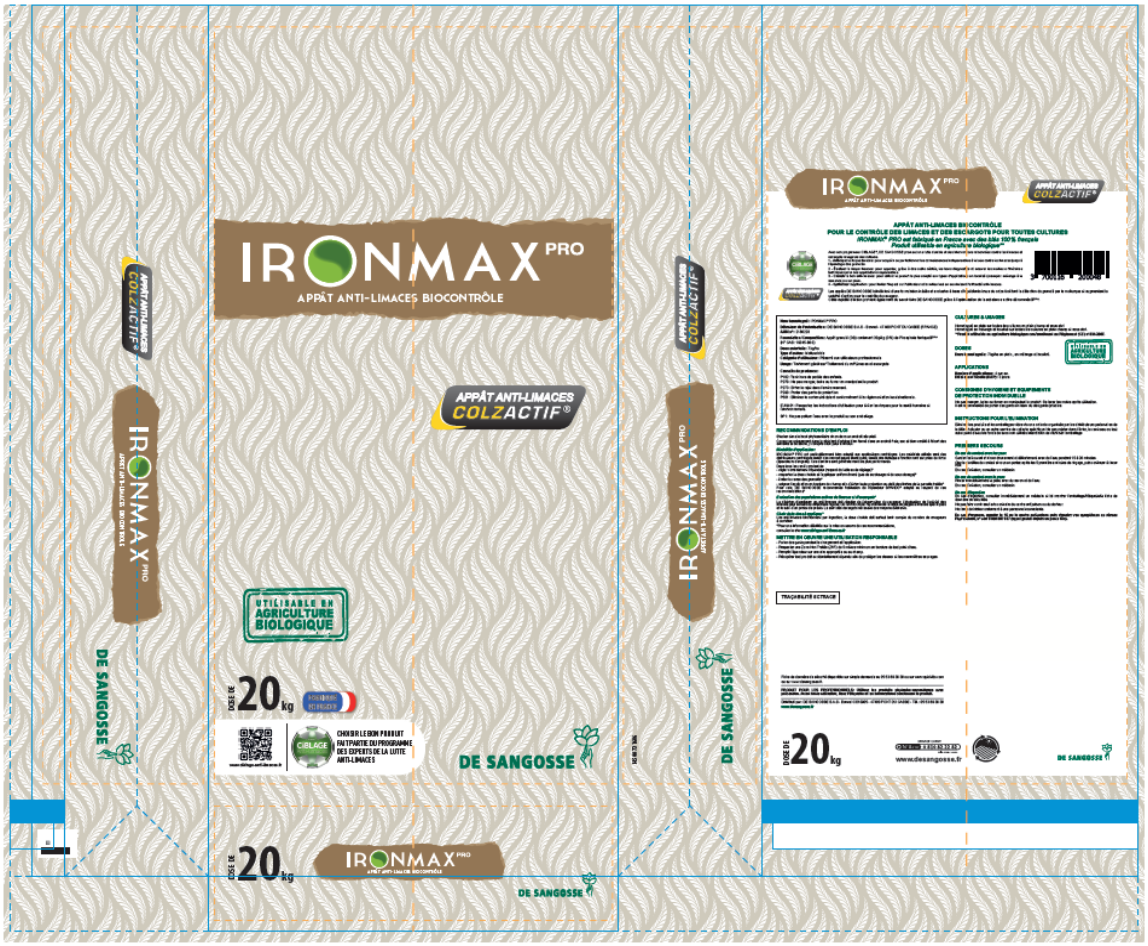
Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir une méthode de détermination spécifique du Fe^{3+} dans le produit.	24	-

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.

SAC 20 kg
PBB F300
370+130x800

IRONMAX PRO
FRANCE
HS087316-06



Appendix 3 Letter of Access

Not applicable