

REGISTRATION REPORT

Part A

Risk Management

Product code: UKS 150C

Product name: SCOTTS ANTIMOUSSE

Active substance:

Iron sulphate monohydrate, 182 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: Evergreen Garden Care France SAS

Date: 2019-08-01

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PART A – Risk Management

The company Evergreen Garden Care France SAS has requested marketing authorisation in France for the product SCOTTS ANTIMOUSSE (product code: UKS 150C), containing 182 g/kg iron sulphate monohydrate and mineral elements (NPK) for use as an herbicide for moss control and a fertiliser, for home garden users.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate on 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 European (EU) peer review. It also includes assessment of data and information relating to SCOTTS ANTIMOUSSE (UKS 150C) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of SCOTTS ANTIMOUSSE (UKS 150C) have been made using endpoints agreed in the EU peer review of iron sulphate.

This document describes the specific conditions of use and labelling required for France for the registration of SCOTTS ANTIMOUSSE (UKS 150C).

Appendix 1 of this document provides a copy of the French Decision.

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

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

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of Evergreen Garden Care France SAS's application to market SCOTTS ANTIMOUSSE (UKS 150C) in France as an herbicide (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.

1.2 Active substance approval

Iron sulphate

Commission Implementing Regulation (EU) No 637/2012 of 13 July 2012 amending implementing Regulation (EC) No 540/2011 as regards the conditions of approval of the active substance iron sulphate.

Specific provisions of Regulation (EU) No 637/2012 were as follows :

PART A

Only uses as herbicide may be authorised.

PART B

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the amended review report on iron sulphate (SANCO/2616/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

- the risk for operator;
- the risk to children/residents playing on treated turf;
- the risk to surface waters and to aquatic organisms.

Conditions of use shall include, where appropriate, risk mitigation measures and the application of adequate

personal protective equipment. The notifier shall submit to the Member States, the Commission and the Authority, confirmatory information as regards the equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicity dossiers.

The Member States concerned shall ensure that the notifier submits to the Commission such information by 1 May 2013.

An EFSA conclusion is available (EFSA Journal 2012;10(1):2521).

A Review Report is available (SANCO/2616/08 rev. 1, 27 October 2008).

1.3 Regulatory approach

The present application (2014-0198 and 2017-1504) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)¹ in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses (“risk envelope approach”)² – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The current document (Registration Report, RR), based on Anses’assessment of the application submitted for this product, is in compliance with Regulation (EC) no 1107/2009³, implementing regulations, and French regulations.

The data taken into account are those deemed valid either at European Union level or at 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 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁵ 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 extrapolation⁶ 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.

¹ French Food Safety Agency, Afssa, before 1 July 2010

² 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

³ REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

⁴ 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

⁵ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of SCOTTS ANTIMOUSSE (UKS 150C), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter of Access

A copy of the letter of access is included in Part A, Appendix 3.


2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	SCOTTS ANTIMOUSSE (UKS 150C)
Authorisation number	2190066
Function	Herbicide and fertiliser
Applicant	Evergreen Garden Care France SAS
Composition	182 g/kg iron sulphate monohydrate
Formulation type (code)	Granules (GR)
Accepted packaging with a spreader	<p>HDPE or LDPE or PET/LDPE bags with a handle and a zip: 1.8 kg – 2 kg – 2.8 kg – 3 kg – 3.5 kg – 4 kg – 4.3 kg – 4.5 kg – 5 kg – 5.3 kg – 5.5 kg – 6 kg – 6.3 kg – 6.5 kg – 7 kg – 8.8 kg – 10 kg – 10.5 kg – 11 kg – 12 kg – 12.3 kg – 13 kg – 13.8 kg – 14 kg – 15 kg – 15.8 kg – 16.3 kg – 17.5 kg – 18 kg – 20 kg – 25 kg</p> <p>LDPE bags (included in a cardboard box): 1.8 kg – 2 kg – 2.8 kg – 3 kg – 3.5 kg – 4 kg – 4.3 kg – 4.5 kg – 5 kg – 5.3 kg – 5.5 kg – 6 kg – 6.3 kg – 6.5 kg – 7 kg – 7.5 kg</p> <p>Cardboard cases coated with LDPE (inside): 1.8 kg – 2 kg – 2.8 kg – 3 kg – 3.5 kg – 4 kg – 4.3 kg – 4.5 kg – 5 kg – 5.3 kg – 5.5 kg – 6 kg – 6.3 kg – 6.5 kg – 7 kg – 7.5 kg</p> <p>PP buckets: 1.8 kg – 2 kg – 2.8 kg – 3 kg – 3.5 kg – 4 kg – 4.3 kg – 4.5 kg – 5 kg – 5.3 kg – 5.5 kg – 6 kg – 6.3 kg – 6.5 kg – 7 kg – 7.5 kg</p>
Accepted packaging for “manual” spreading	HDPE bottles with a spout cap: 1.8 kg – 2 kg – 2.8 kg – 3 kg – 3.5 kg – 4 kg – 4.3 kg – 4.5 kg – 5 kg – 5.3 kg – 5.5 kg – 6 kg – 6.3 kg – 6.5 kg – 7 kg – 7.5 kg

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No 1272/2008

Physical hazards	-
Health hazards	Serious eye damage category 1
Environmental hazards	-
Hazard pictograms	
Signal word	Warning
Hazard statements	H318 Causes serious eye damage

Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	-

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

2.2.2 Other phrases in compliance with Regulation (EU) No 547/2011

The authorisation of the preparation is linked for non-professional uses only to the following conditions:

- Do not discharge into the sink, gutter or any other water hole the non-used container leftovers and the sprayer washing water.
- Avoid spreading the pellets near non-target plants.
- Do not spread the product manually.

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment ⁷ : refer to the Decision in Appendix 1 for the details
Re-entry period ⁸ : Not Applicable
Pre-harvest interval ⁹ : Not Applicable
Other mitigation measures: -
The label must reflect the conditions of authorisation.

⁷ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

⁸ The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

⁹ According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

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”, 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: 2019-08-01

PPP (product name/code): SCOTTS ANTIMOUSSE (UKS 150C)
active substance: iron sulphate monohydrate
Applicant: Evergreen Garden Care France SAS
Zone: Southern
Verified by MS: yes

Formulation type: < GCPF code>
Conc. of as: 182 g/kg
professional use: ☐
non-professional use: ☒

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Turf	South	UKS 150C	F	Moss	GR	Iron sulphate 16.3% (18.3% as monohydr ate)	Manual spread (home garden uses)	When mosses are growing (spring and autumn)	Max 2	3 months (90 days)	NA	NA	57.05 Iron sulphate anhydrou s (pure)	NA	Acceptab le

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
 - (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
 - (f) All abbreviations used must be explained
 - (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at 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
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

SCOTTS ANTIMOUSSE (UKS 150C) is a granule formulation (GR). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a light brown coloured (similar to Munsell book of colour reference 10YR7/4) with brick red and occasionally blue coloured granules interspersed in the formulation, with no perceptible odour. It is not explosive, has no oxidising properties and is not flammable. It has a self-ignition temperature above 400°C. In aqueous solution (1 %), it has a pH value of 3.3 at 20°C. The stability data indicate a shelf life of at least two years at ambient temperature when stored in cardboard box and LDPE sack. As the formulation is a granule, HDPE, PE/PE and polypropylene packaging can be considered as acceptable. Its technical characteristics are acceptable for a granule formulation.

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

3.1.2 Methods of analysis

Analytical method for the determination of the active substance in the formulation is available and validated.

The confirmation of the acceptability of the analytical method for the determination of the relevant impurities of iron sulphate (arsenic, cadmium, chromium, lead and mercury) in the technical active substance to the preparation is required.

Considering the intended uses (home garden), analytical methods for the determination of residues of iron sulphate in plants and foodstuffs of animal origin are not necessary.

Considering that there is no residue definition, analytical methods for the determination of residues in soil and air are not necessary.

A validated analytical method for the determination of iron in drinking water with a LOQ covering the EU acceptable level of 0.2 mg/L, as laid down in Council Directive 98/83/EC, is required.

3.1.3 Mammalian Toxicology

Endpoints used for risk assessment purposes:

Active substance: iron sulphate		
ADI	0.8 mg/kg body weight/day (iron)	EU (2009)
ARfD	Not applicable	
AOEL	0.38 mg/kg body weight/day (iron)	
Dermal absorption	Based on default values according to guidance on dermal absorption (EFSA 2012):	
		Concentrate (used in formulation) 182 g/kg iron sulphate monohydrate (pure) 163 g/kg iron sulphate anhydrous (pure) or 60 g/kg iron (pure)
	Dermal absorption endpoints %	10
Active substance: sulphate		
ADI	12.5 mg/kg body weight/day (as a food additive)	EFSA (2012)
ARfD	Not applicable	EFSA (2012)
AOEL	1.3 mg/kg body weight/day	

Dermal absorption	Based on default values according to guidance on dermal absorption (EFSA 2012):	
		Concentrate (used in formulation) 103 g/kg or 487.7 g/kg (total)
	Dermal absorption endpoints %	10

3.1.3.1 Acute Toxicity

SCOTTS ANTI-MOUSSE has a low acute oral, inhalation and dermal toxicity. The product is not irritating to the rabbit skin but causes serious eye damage (by calculation) and is not a skin sensitizer.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G ¹⁰	Equipment	Application rate g product/m ²	Spray dilution (L/ha)	Model
Lawns	F	Spreader/hand application	35 g/m ² (350 kg/ha) 6.37 g/m ² iron sulphate monohydrate or 5.7 g/m ² iron sulphate anhydrous 2.1 g/m ² iron (pure) 17.1 g/m ² total sulphate*	NA	UPJ

* Total sulphate = sulphate from iron sulphate monohydrate and from ammonium sulphate

Considering the proposed uses, operator systemic exposure was estimated using the French study 2005 dedicated to amateur use:

Crop	Equipment	PPE and/or working coverall	% AOEL iron	% AOEL sulphate	% AOEL sulphate (total)
Lawns	Spreader/hand application	No PPE	19	9.6	45

According to the model calculations, it may be concluded that the risk for the operator using SCOTTS ANTIMOUSSE (UKS 150C) is acceptable with no personal protective equipment (PPE).

3.1.3.3 Bystander Exposure

In the context of use by non-professionals, it is considered that the assessment for bystanders is covered by that for the operator. Moreover, as the formulation is a granular bait formulation, no drift is expected. Therefore, bystander exposure estimation is considered not relevant.

3.1.3.4 Resident exposure

A specific assessment according to the intended uses was performed in order to take into account the accidental poisoning of infant after ingestion.

A single pellet has a weight of 0.176 mg (and a diameter of 0.5 to 1 mm), corresponding to a dose of 0.001 mg of iron, and 0.086 mg of total sulfate. Infants are assumed to be 1 to 3 years old and have a body weight of 10kg.

The reverse reference approach shows that 3598 pellets (intake of iron) and 151 pellets (total sulfate) are required to reach the respective AOEL of iron and sulfate.

Therefore, it is concluded that there is no unacceptable risk to the resident exposed to SCOTTS ANTIMOUSSE (UKS 150C).

3.1.3.5 Worker Exposure

¹⁰ Open field or glasshouse

SCOTTS ANTIMOUSSE (UKS 150C) is intended to be used by non-professionals during home garden application. In this case, the worker is also the user of the product. It will be necessary to ensure complete drying of the treated area or of treated plants before handling them.

3.1.4 Residues and Consumer Exposure

Not relevant.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active substance 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.

Considering the intended uses (home and garden) and the formulation of the product (granules), exposure calculations to soil and surface water are not considered relevant.

PEC_{gw} values of iron and sulphate were estimated using a conservative approach as proposed during the EU review. PEC_{gw} values of sulphate do not exceed the EU drinking water limit of 250 mg/L defined in Directive (EU) 98/83/CE. PEC_{gw} values of iron exceed the EU drinking water limit of 0.2 mg/L defined for iron. However it is reminded that it is clearly indicated in the EFSA conclusions that these calculations are overestimates, based on worst-case assumptions.

Compared to the natural contents of iron and sulphate in soil, the additional amounts resulting from the representative use of SCOTTS ANTIMOUSSE (UKS 150C) are negligible. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

No significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the product SCOTTS ANTIMOUSSE (UKS 150C) was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU peer review for the active substance and its metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Given the home and garden uses, only risk assessment for birds, mammals and aquatic organisms has been performed.

For the other organisms (bees, non-target arthropods, soil organisms and non-target plants), safety sentences are considered depending on the hazard of the formulation.

For birds and mammals, the risk can be considered acceptable according to EFSA guidance (2009).

For aquatic organisms, the main route of exposure in such area is expected by spray drift. However, as SCOTTS ANTIMOUSSE (UKS 150C) is a granular formulation, no PEC_{sw} calculation was required in this specific case.

For non-target plants, as iron sulphate is approved for use as herbicide, **precautions must be taken to avoid spreading of pellets outside the treated area.**

3.1.7 Efficacy

Considering the data submitted:

- The efficacy level of SCOTTS ANTIMOUSSE (UKS 150C) is considered as satisfactory for the claimed uses.
- The selectivity level of SCOTTS ANTIMOUSSE (UKS 150C) is considered as satisfactory for the claimed uses.
- The risks of negative impact on yield, quality, succeeding crops and adjacent crops are considered as negligible.
- The risk of resistance development or appearance to iron sulphate is considered as very low and does not require a monitoring for the claimed use.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation **can be granted** as proposed in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

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

- A confirmation of the acceptability of the analytical method for the determination of the relevant impurities of iron sulphate (arsenic, cadmium, chromium, lead and mercury) in the technical active substance to the preparation is required.
- A validated analytical method for the determination of iron in drinking water with a LOQ covering the EU acceptable level of 0.2 mg/L as laid down in Council Directive 98/83/EC.

3.4.3 Label amendments

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision



Décision relative à une demande d'autorisation de mise sur le marché d'un produit mixte

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et réglementaire,

Vu le code rural et de la pêche maritime, notamment le chapitre V du titre V du livre II des parties législative et réglementaire,

*Vu la demande d'autorisation de mise sur le marché, et la demande de modification d'information déclarée du produit mixte **SCOTTS ANTIMOUSSE***

de la société EVERGREEN GARDEN CARE FRANCE SAS

enregistrées sous les n°2014-0198 et 2017-1504

Vu les conclusions de l'évaluation de l'Anses du 12 février 2019,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** 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.



Informations générales sur le produit	
Nom du produit	SCOTTS ANTIMOUSSE
Type de produit	Produit de référence
Titulaire	Evergreen Garden Care France SAS 21, chemin de la Sauvegarde 69130 ECULLY France
Formulation	Granulé (GR)
Contenant	182 g/kg - sulfate de fer (II), monohydrate (équivalent à 163 g/kg de sulfate de fer) Eléments fertilisants NPK déclarés conformes à une norme d'application obligatoire
Numéro d'intrant	9619-2014.01
Numéro d'AMM	2190066
Fonction	Herbicide, engrais
Gamme d'usage	Amateur / emploi autorisé dans les jardins

L'échéance de validité de la présente décision est fixée à trois 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 août 2021.

A défaut pour le titulaire de demander le 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, l'autorisation de mise sur le marché est échue de plein droit. Le dépôt d'une demande de renouvellement prolonge de plein droit la durée de validité de l'autorisation de mise sur le marché 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.

Attention : à compter du 1^{er} janvier 2019, la mise sur marché, la délivrance, l'utilisation et la détention des produits de la gamme d'usages « amateur » sont exclusivement réservées aux utilisateurs professionnels, en application de l'article L. 253-7-III du Code rural et de la pêche maritime, à l'exception des produits de la gamme amateurs inscrits sur la liste des produits de biocontrôle, des produits utilisables en agriculture biologique ou des produits à faible risque. Cette interdiction ne s'applique pas aux traitements et mesures nécessaires à la destruction et à la prévention de la propagation des organismes nuisibles mentionnés à l'article L. 251-3, en application de l'article L. 251-8 du même Code.

A Maisons-Alfort le,

01 AOÛT 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)



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 :	
Pour application avec un épandeur	Contenance
Etuis en carton avec enduit intérieur en polyéthylène basse densité	1,8 kg ; 2 kg ; 2,8 kg ; 3 kg ; 3,5 kg ; 4 kg ; 4,3 kg ; 4,5 kg ; 5 kg ; 5,3 kg ; 5,5 kg ; 6 kg ; 6,3 kg ; 6,5 kg ; 7 kg ; 7,5 kg
Sacs en polyéthylène basse densité munis d'une poignée et d'une fermeture à glissière	1,8 kg ; 2 kg ; 2,8 kg ; 3 kg ; 3,5 kg ; 4 kg ; 4,3 kg ; 4,5 kg ; 5 kg ; 5,3 kg ; 5,5 kg ; 6 kg ; 6,3 kg ; 6,5 kg ; 7 kg ; 8,8 kg ; 10 kg ; 10,5 kg ; 11 kg ; 12 kg ; 12,3 kg ; 13 kg ; 13,8 kg ; 14 kg ; 15 kg ; 15,8 kg ; 16,3 kg ; 17,5 kg ; 18 kg ; 20 kg ; 25 kg
Sacs en polyéthylène basse densité dans un étui en carton	1,8 kg ; 2 kg ; 2,8 kg ; 3 kg ; 3,5 kg ; 4 kg ; 4,3 kg ; 4,5 kg ; 5 kg ; 5,3 kg ; 5,5 kg ; 6 kg ; 6,3 kg ; 6,5 kg ; 7 kg ; 7,5 kg
Sacs en polyéthylène haute densité munis d'une poignée et d'une fermeture à glissière	1,8 kg ; 2 kg ; 2,8 kg ; 3 kg ; 3,5 kg ; 4 kg ; 4,3 kg ; 4,5 kg ; 5 kg ; 5,3 kg ; 5,5 kg ; 6 kg ; 6,3 kg ; 6,5 kg ; 7 kg ; 8,8 kg ; 10 kg ; 10,5 kg ; 11 kg ; 12 kg ; 12,3 kg ; 13 kg ; 13,8 kg ; 14 kg ; 15 kg ; 15,8 kg ; 16,3 kg ; 17,5 kg ; 18 kg ; 20 kg ; 25 kg
Sacs en polyéthylène téréphtalate / polyéthylène basse densité munis d'une poignée et d'une fermeture à glissière	1,8 kg ; 2 kg ; 2,8 kg ; 3 kg ; 3,5 kg ; 4 kg ; 4,3 kg ; 4,5 kg ; 5 kg ; 5,3 kg ; 5,5 kg ; 6 kg ; 6,3 kg ; 6,5 kg ; 7 kg ; 8,8 kg ; 10 kg ; 10,5 kg ; 11 kg ; 12 kg ; 12,3 kg ; 13 kg ; 13,8 kg ; 14 kg ; 15 kg ; 15,8 kg ; 16,3 kg ; 17,5 kg ; 18 kg ; 20 kg ; 25 kg
Seaux en polypropylène	1,8 kg ; 2 kg ; 2,8 kg ; 3 kg ; 3,5 kg ; 4 kg ; 4,3 kg ; 4,5 kg ; 5 kg ; 5,3 kg ; 5,5 kg ; 6 kg ; 6,3 kg ; 6,5 kg ; 7 kg ; 7,5 kg
Pour un épandage manuel	Contenance
Bouteilles en polyéthylène haute densité avec bec verseur	1,8 kg ; 2 kg ; 2,8 kg ; 3 kg ; 3,5 kg ; 4 kg ; 4,3 kg ; 4,5 kg ; 5 kg ; 5,3 kg ; 5,5 kg ; 6 kg ; 6,3 kg ; 6,5 kg ; 7 kg ; 7,5 kg

Teneurs garanties retenues en éléments fertilisants
Indiquer sur l'étiquette les teneurs (en % MB) des éléments fertilisants revendiqués : N (et ses différentes formes), P ₂ O ₅ (et ses différentes formes), et K ₂ O soluble dans l'eau, conformément à la norme d'application obligatoire qui encadre le produit.
Il est de la responsabilité du détenteur de s'assurer de la conformité à la norme à laquelle il se réfère.



Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Lésions oculaires graves et irritation oculaire - Catégorie 1	H318 : Provoque des lésions oculaires graves
Pour les phrases P se référer à la réglementation 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.	



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
18505902 Gazons de graminées*Trt Part.Aer.*Mousses	35 g/m²	2/an	Application durant la période végétative	Non applicable	-	-	-	-

Intervalle minimum entre les applications : 90 jours.

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Ne pas épandre les granulés à la main.
- Appliquer le produit avec un épandeur, sauf si l'emballage dispose d'un bec verseur.

Délai de rentrée :

- Non applicable.

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 le produit non utilisé et les eaux de lavage de l'épandeur.

Protection de la flore

- Éviter d'épandre les granulés vers les plantes voisines.

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)	Réurrence (mois)
Fournir une méthode d'analyse validée pour la détermination de la substance active dans l'eau.	24	-
Démontrer l'applicabilité de la méthode de détermination des impuretés pertinentes dans la substance technique à l'analyse des impuretés dans le produit.	24	-

Appendix 2 – Copy of the draft product label as proposed by the applicant





Appendix 3 – Letter of Access

Available on request.