

REGISTRATION REPORT

Part A

Risk Management

Product name: DETRUI-MOUSSE J

Active substance:

Iron Sulphate monohydrate, 152 g/kg

(Iron sulphate, 135 g/kg)

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: SBM Développement

Date: 2018-07-12

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PART A – Risk Management

The company SBM Développement has requested marketing authorisation in France for the product DETRUI-MOUSSE J, containing 135 g/kg iron sulphate for use as an herbicide and as fertilizer for non-professional use.

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 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 DETRUI-MOUSSE J where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of DETRUI-MOUSSE J 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 DETRUI-MOUSSE J.

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 of access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of SBM Développement's application to market DETRUI-MOUSSE J 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 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 substances iron sulphate, repellents by smell of animal or plant origin/tall oil crude and repellents by smell of animal or plant origin/tall oil pitch.

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 rev.5 1 June 2012 Rev6 09 October 2015).

1.3 Regulatory approach

The present application (2014-1370) 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, taking into account the worst-case uses (“risk envelope approach”)¹ – 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 French Order of 4th May 2017² provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight 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.

The current document (RR) based on Anses’s 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 to be 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

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 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/AGRGI632554A/jo/texte>

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>

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.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of DETRUI-MOUSSE J, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter of Access

The applicant has provided letter(s) of access.

2 The applicant has provided letter(s) of access. DETAILS OF THE AUTHORISATION

2.1 Product identity


Product name	DETRUI-MOUSSE J
Authorisation number	2180256
Function	Herbicide and fertilizer
Applicant	SBM Développement
Composition	152 g/kg iron sulphate monohydrate (135 g/kg iron sulphate)
Formulation type (code)	Granules (GR)
Packaging with a spreader	Polyethylene / polyethylene terephthalate bags: 3.5 kg, 4 kg, 7 kg, 8 kg, 10 kg, 14 kg Polyethylene bags in cardboard box: 3.2 kg, 3.5 kg, 4 kg Packaging over 14 kg are not authorised in France because they do not guarantee a minimal exposure of the non-professional user.
Packaging authorized for manual spreading	Polyethylene / polyethylene terephthalate bags with a clip and a holder: 3.5 kg, 4 kg, 8 kg Polyethylene bags in cardboard box with a spout cap: 3.5 kg, 4 kg Packaging over 14 kg are not authorised in France because they do not guarantee a minimal exposure of the non-professional user.

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, Hazard Category 1

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

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.
- To protect aquatic compartment from eutrophication, do not spread the granules close to a water source (wells, pond, stream, river ...).
- To protect non-target plants, precaution must be taken to avoid accidental application outside the treated area.

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 relevant
Other mitigation measures: Broadcast is strictly prohibited.
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:

PPP (product name/code): **DETRUI-MOUSS J**
Active substance: iron sulphate
Applicant: **SBM Développement**
Zone: southern ^(d)
Verified by MS: yes
Field of use: Herbicide and fertilizer

GAP rev. 1, date: 2018-07-12
Formulation type: **GR** ^(a, b)
Conc. of as: **152 g /kg (monohydrate)**
Professional use: ☐
Non professional use: ☒

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)
					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	kg as/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	Turf	F	Moss	manual spreading or with spreader	From February to June or From October to December	a) 2 b) 2	40 days	a) 400 kg/ha (40 g/m ²) b) 800 kg/ha (80 g/m ²)	a) 60.8 kg/ha b) 121.6 kg/ha	-	-	Acceptable

Remarks
table heading: (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(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	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use/situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	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

DETRUI-MOUSSE J is a granules 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 brown granules, with a characteristic odour. It is not explosive, has no oxidising properties and is not flammable. It has a self-ignition temperature of 312 °C. In aqueous solution (1 % in CIPAC D water), it has a pH value of 4.79 at 21.3 °C. There is no effect of high temperature on the stability of the formulation, since 14 days at 54 °C, neither the active substances' content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in PE/PET bag or PE bag. Its technical characteristics are acceptable for a granules 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 is available and validated. This method is not specific to iron sulphate (divalent iron). An analytical method for the determination of oxidation rate of iron from the active substance contained in the product is required in post-authorization.

As the relevant impurities (arsenic, cadmium, chromium, lead, and mercury) are by-products of the manufacturing process of iron sulphate and as such cannot be formed by storage of the formulation, an analytical method for the determination of these relevant impurities in the formulation is not necessary.

Analytical methods for the determination of iron sulphate residues in plants and foodstuffs of animal origin are not necessary.

Analytical methods for the determination of iron sulphate residues in soil and air are not required.

As a data gap has been identified in the EFSA conclusions, a validated analytical method for the determination of iron in drinking water with a limit of quantitation (LOQ) covering the acceptable level of iron in EU drinking water (from Council Directive No 98/83/EC) of 0.2 mg/L is required.

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

3.1.3 Mammalian Toxicology

The endpoints used in risk assessment are shown below.

Active substance: iron			
ADI	0.8 mg kg body weight/day		EU (2009)
ARfD	not applicable		
AOEL	0.38 mg/kg body weight/day		
Dermal absorption	Based on default values according to guidance on dermal absorption (EFSA 2012):		
		Concentrate (used in formulation) 55 g/kg	Spray dilution (used in formulation) x g/L
	Dermal absorption endpoints	10 %	

Active substance: sulphate			
ADI	12.5 mg kg body weight/day		EU (2009)
ARfD	not applicable		
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) 94 g/kg	Spray dilution (used in formulation) x g/L
	Dermal absorption endpoints	10 %	

3.1.3.1 Acute Toxicity

DETRUI-MOUSSE J has a low acute oral, inhalation and dermal toxicity, is not irritating to the rabbit skin but is an irritant for rabbit eye. It is not a skin sensitiser.

3.1.3.2 Operator Exposure

Critical use patterns (worst cases) are summarized in the table below.

Crop	F/G ¹⁰	Equipment	Application rate (g a.s./10m ²)	Spray dilution (L/ha)	Model
turf	F	Manual spreading	400 g/10 m ² (iron: 22 g/10m ² sulphate: 37.8 g/10m ²)	Not applicable	French garden studies (UPJ, 2005)

Considering 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 (0.38 mg/kg bw/d)	% AOEL sulphate (1.3 mg/kg bw/d)
Turf	Manual spreading	no PPE	8.7 %	17 %

According to the model calculations, it may be concluded that the risk for the operator using DETRUI-MOUSSE J is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

3.1.3.3 Bystander Exposure

DETRUI-MOUSSE J is a granular bait formulation; no drift is expected. Therefore, bystander exposure estimation is considered not relevant.

Moreover, in the context of use by non-professionals, it is considered that the assessment for bystanders is covered by that for the operator.

3.1.3.4 Worker Exposure

DETRUI-MOUSSE J is a granular bait formulation; no work is expected to be practiced after application.

Moreover, DETRUI-MOUSSE J is intended to be used by amateurs during home garden application. In this case of the non-professional user, the worker is also the user of the product. Therefore, worker exposure estimation is considered not relevant.

3.1.4 Residues and Consumer Exposure

¹⁰ Open field or glasshouse

Not relevant. The use of DETRUI-MOUSSE J is restricted to amenity turf as a moss killer. Consequently no consideration of residues levels in food stuffs either for animal or human consumption is required.

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 and its metabolites 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 use of the preparation DETRUI-MOUSSE J, PEC_{soil} values are not needed for the ecotoxicological risk assessment. Only spray drift could be considered relevant to estimate PEC_{sw} values. However, considering the granular formulation of this product, no PEC_{sw} calculation was required in this specific case.

PEC_{gw} values for iron sulphate and its metabolites have been assessed according to FOCUS guidance documents, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided. PEC_{gw} values for iron sulphate and its metabolites do not occur at levels exceeding those mentioned in regulation (EC) No 1107/2009 and guidance document SANCO 221/2000 on the relevance of metabolites in groundwater. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT₅₀ calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

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 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 the risk assessment for birds, mammals and aquatic organisms was 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 may be considered acceptable.

For aquatic organisms, only spray drift is considered relevant to estimate PEC_{sw} for uses in gardens. As DETRUI-MOUSSE J is a granular formulation, no PEC_{sw} calculation was required in this specific case. However, DETRUI-MOUSSE J is used to control mosses and as a fertiliser. A risk of eutrophication of aquatic ecosystems due to phosphorous cannot be excluded. In view of their national requirements, Member States may recommend to take precaution in order to avoid spreading of granules close to water source (see Section 2.2.3).

3.1.7 Efficacy

Considering the data submitted:

- The efficacy level of DETRUI-MOUSSE J is considered satisfactory for all the claimed uses.
- The selectivity level of DETRUI-MOUSSE J is considered acceptable for all the claimed uses.
- The risks of negative impact on quality, succeeding crops, adjacent crops are considered acceptable.
- The risk of resistance development or appearance to iron sulphate does not require monitoring for all the claimed uses.

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:

- Attrition resistance of the preparation after storage at room temperature for about 2 years.
- A validated analytical method for the determination of iron oxidation rate in the product.

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 du produit mixte **DETRUI-MOUSSE J***

*de la société **SBM DEVELOPPEMENT***

*enregistrée sous le **n°2014-1370***

Vu les conclusions de l'évaluation de l'Anses du 4 mai 2018,

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	DETRUI-MOUSSE J
Type de produit	Produit de référence
Titulaire	SBM DEVELOPPEMENT 160, route de la Valentine CS70052 13374 MARSEILLE Cedex 11 FRANCE
Formulation	Granulé (GR)
Contenant	152 g/kg - sulfate de fer (II), monohydrate (équivalent à 135 g/kg de sulfate de fer) Eléments fertilisants NPK déclarés conformes à une norme d'application obligatoire
Numéro d'intrant	9650-2014.01
Numéro d'AMM	2180256
Fonction	Engrais (NPK), Herbicide (produit mixte)
Gamme d'usages	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.

A Maisons-Alfort, le 12 JUIL. 2018

Le Directeur Général

Roger GENET

DETRUI-MOUSSE J
AMM n°2180256

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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 :	
Pour application avec un épandeur	Contenance
Sacs en polyéthylène basse densité (inclus dans une boîte en carton)	3,2 kg ; 3,5 kg ; 4 kg
Sacs en polyéthylène téréphtalate / polyéthylène basse densité	3,5 kg ; 4 kg ; 7 kg ; 8 kg ; 10 kg ; 14 kg
Pour épandage manuel	Contenance
Sacs en polyéthylène basse densité munis d'un bec verseur (inclus dans une boîte en carton)	3,5 kg ; 4 kg
Sacs en polyéthylène téréphtalate / polyéthylène basse densité munis d'une fermeture et d'une poignée	3,5 kg ; 4 kg ; 8 kg

Les emballages de plus de 15 kg sont refusés car ils ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnels.

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	Epoque d'application	Délai avant récolte (jours)	Zone Non Traitee aquatique (mètres)	Zone Non Traitee arthropodes non cibles (mètres)	Zone Non Traitee plantes non cibles (mètres)	Mention abeilles
18505902 Gazons de graniniées* Trit. Aér. Moussets	400 g/10 m²	2/an	février à juin ou octobre à décembre	Non applicable	-	-	-	-
Intervalle minimum entre les applications : 40 jours.								

DETRUI-MOUSSE J
AMM n°2180256



Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

- L'épandage à la volée est interdit.

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 les fonds de bidon non utilisés et les eaux de lavage de l'épandeur

Protection de la faune

- Afin de limiter le risque d'eutrophisation, éviter d'appliquer le produit à proximité d'un point d'eau (puits, bassin, mare, ruisseau, rivière, fossé...).

Protection de la flore

- Eviter 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)	Récurrence (mois)
Fournir des données d'attrition des granulés après un stockage de 2 ans à température ambiante.	24	-
Fournir une méthode d'analyse pour la détermination du taux d'oxydation du fer de la substance active dans le produit.	24	-

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- DETRUI-MOUSSE J est un produit mixte : engrais NPK conforme à une norme d'application obligatoire (à rappeler) et herbicide.

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



SOLABIOL • Date : 04/07/14 • Ref : SOGAZMOU80 - XXXXXX-14A - Dim : 194x114x278 mm - Couleurs : CMJN

Evaluator: FRANCE
Date : 2018-07-12

Appendix 3 – Letter of Access