

REGISTRATION REPORT

Part A

Risk Management

Product name:

ENGRAIS GAZON ANTIMOUSSE PREMIUM

Active substance:

iron sulphate heptahydrated, 288 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: AGRONUTRITION

Date: 2018-11-21

Table of Contents

| | | |
|----------|---|-----------|
| 1 | DETAILS OF THE APPLICATION..... | 3 |
| 1.1 | APPLICATION BACKGROUND..... | 3 |
| 1.2 | ACTIVE SUBSTANCE APPROVAL..... | 3 |
| 1.3 | REGULATORY APPROACH | 4 |
| 1.4 | DATA PROTECTION CLAIMS | 5 |
| 1.5 | LETTERS OF ACCESS..... | 5 |
| 2 | DETAILS OF THE AUTHORISATION | 5 |
| 2.1 | PRODUCT IDENTITY | 5 |
| 2.2 | CLASSIFICATION AND LABELLING..... | 5 |
| 2.2.1 | <i>Classification and labelling in accordance with Regulation (EC) No1272/2008</i> | <i>5</i> |
| 2.2.2 | <i>Other phrases in compliance with Regulation (EU) No 547/2011</i> | <i>6</i> |
| 2.2.3 | <i>Other phrases linked to the preparation</i> | <i>6</i> |
| 2.3 | PRODUCT USES..... | 7 |
| 3 | RISK MANAGEMENT..... | 9 |
| 3.1 | REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES..... | 9 |
| 3.1.1 | <i>Physical and chemical properties</i> | <i>9</i> |
| 3.1.2 | <i>Methods of analysis</i> | <i>9</i> |
| 3.1.3 | <i>Mammalian Toxicology</i> | <i>9</i> |
| 3.1.4 | <i>Residues and Consumer Exposure</i> | <i>11</i> |
| 3.1.5 | <i>Environmental fate and behaviour</i> | <i>11</i> |
| 3.1.6 | <i>Ecotoxicology.....</i> | <i>11</i> |
| 3.1.7 | <i>Efficacy</i> | <i>12</i> |
| 3.2 | CONCLUSIONS ARISING FROM FRENCH ASSESSMENT | 12 |
| 3.3 | SUBSTANCES OF CONCERN FOR NATIONAL MONITORING | 12 |
| 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 | 12 |
| 3.4.1 | <i>Post-authorisation monitoring</i> | <i>12</i> |
| 3.4.2 | <i>Post-authorisation data requirements</i> | <i>12</i> |
| 3.4.3 | <i>Label amendments</i> | <i>12</i> |
| | APPENDIX 1 – COPY OF THE FRENCH DECISION | 13 |
| | APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT | 18 |
| | APPENDIX 3 – LETTERS OF ACCESS | 19 |

PART A – Risk Management

The company AGRONUTRITION has requested marketing authorisation in France for the product ENGRAIS GAZON ANTIMOUSSE PREMIUM, containing 288 g/kg iron sulphate heptahydrated for use as an herbicide for moss control and a fertiliser.

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 ENGRAIS GAZON ANTIMOUSSE PREMIUM where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of ENGRAIS GAZON ANTIMOUSSE PREMIUM 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 ENGRAIS GAZON ANTIMOUSSE PREMIUM.

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 letters of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of AGRONUTRITION's application to market ENGRAIS GAZON ANTIMOUSSE PREMIUM in France as an herbicide for moss control and a fertiliser (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 (2013-1333 and 2017-2252) 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

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/AGRG1632554A/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/AGRG1407093A/jo>

“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.

1.4 Data protection claims

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

1.5 Letters of Access

The applicant has provided letter(s) of access.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity


| | |
|--------------------------------|---|
| Product name | ENGRAIS GAZON ANTIMOUSSE PREMIUM |
| Authorisation number | 2180283 |
| Function | Herbicide and fertiliser |
| Applicant | AGRONUTRITION |
| Composition | 288 g/kg iron sulphate heptahydrated + normalised fertilizer |
| Formulation type (code) | Granules (GR) |
| Accepted packaging | Carton case (seeder box) : 4 kg Polyethylene terephthalate bag (with zipper, grip handle and side handle) : 6 kg, 7 kg, 12 kg, 20 kg |

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No1272/2008

| | |
|------------------------------|----------------------------|
| Physical hazards | - |
| Health hazards | Eye irritation, Category 2 |
| Environmental hazards | - |

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

| | | |
|--|---|-------------------------------|
| Hazard pictograms |  | |
| Signal word | Warning | |
| Hazard statements | H319 | Causes serious eye irritation |
| 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 ...).
- For non-target plants, precaution must be taken to avoid accidental application outside the treated area.
- Only for a use with a spreader.

2.2.3 Other phrases linked to the preparation

| |
|--|
| Re-entry period ⁷ : not applicable (ready-for-use granules) |
| Pre-harvest interval ⁸ : not relevant |
| The label may include the following recommendations. |

⁷ 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]

⁸ 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” or “not finalised”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev.1, date: 2018-11-21

| | | | |
|---------------------------|---|-----------------------------|--|
| PPP (product name) | ENGRAIS GAZON ANTIMOUSSE PREMIUM | Formulation type: | GR |
| active substance 1 | iron sulphate heptahydrated | Conc. of as 1: | 288 g/kg (pure Iron sulphate heptahydrated) |
| Applicant: | AGRONUTRITION | professional use | <input type="checkbox"/> |
| Zone: | southern | non-professional use | <input checked="" type="checkbox"/> |
| Verified by MS: | yes | | |
| Field of use: | herbicide | | |

| 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) | Conclusion |
|--------------------------------------|--------|-----------------|--------------------------|--|-------------|--|--|-------------------------------|-------------------|--|--|------------|---|------------------------------|--|
| | | | | | Type | Conc. of as | method kind | growth stage & season | number min max | interval between applications (min) | kg product/ha | water L/ha | kg as/ha | | |
| | | | | | (d-f) | (i) | (f-h) | (j) | (k) | | min max | min max | min max | | |
| Turf | France | - | F | Moss | GR | Technical Iron sulphate (heptahy- drate): 32% | Manual spread (home garden uses) | From March to September | 1 | n.a. | 400 kg/ha (40 g/m ²) . | n.a. | Iron sulphate (heptahy- drated pure): 11.52 g/m ² | n.a. | Acceptable (except on young turfs) |

-
- 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

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

ENGRAIS GAZON ANTIMOUSSE PREMIUM is a granule formulation (GR). The physical and chemical properties determined with the product SELECT GREEN were extrapolated to ENGRAIS GAZON ANTIMOUSSE PREMIUM.

The appearance of the product is a brown solid without odour. It is not explosive, has no oxidising properties and is not auto-flammable. It has a self-ignition temperature of 339.7 °C.

The storage stability was performed with the formulation SELECT GREEN which has similar physical and chemical properties. However **shelf-life storage should be determined with the formulation ENGRAIS GAZON ANTIMOUSSE PREMIUM in commercial PET/PE bag and provided in post authorization**. Its technical properties indicate that no particular problem is expected when used as recommended by the manufacturer.

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

3.1.2 Methods of analysis

Analytical method for the determination of active substance (iron) is available and validated.

As relevant impurities (arsenic, cadmium, chromium, lead and mercury) cannot be formed by storage of the formulation, **an analytical method for the determination of relevant impurities in the formulation is not necessary**.

As required in EFSA conclusions, a validated analytical method for determination of iron sulphate residues in drinking water with an LOQ covering the acceptable level of iron in EU drinking water (from Directive 98/83/EC) is 0.2 mg/L is required.

Analytical method for the determination of residues of iron sulphate in foodstuffs of animal origin is not necessary.

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.

3.1.3 Mammalian Toxicology

The endpoints used in risk assessment are shown below:

| Active substance: iron | | | |
|-------------------------------|---|---|---|
| ADI | 0.8 mg/kg bw/d | | EU (2009) |
| ARfD | Not applicable | | |
| AOEL | 0.38 mg/kg bw/d | | |
| Dermal absorption | Based on default values according to guidance on dermal absorption (EFSA 2012): | | |
| | | Concentrate (used in formulation) 64 g/kg | Spray dilution (used in formulation) |
| | Dermal absorption endpoints | 10 % | / |

| Active substance: ion sulphate | | |
|---------------------------------------|-----------------|-----------|
| ADI | 12.5 mg/kg bw/d | EU (2009) |

| | | | |
|-------------------|---|--|---|
| ARfD | Not applicable | | |
| AOEL | 1.3 mg/kg bw/d | | |
| Dermal absorption | Based on default values according to guidance on dermal absorption (EFSA 2012): | | |
| | | Concentrate (used in formulation) 171 g/kg | Spray dilution (used in formulation) |
| | Dermal absorption endpoints | 10 % | / |

3.1.3.1 Acute Toxicity

ENGRAIS GAZON ANTIMOUSSE PREMIUM has a low acute oral, inhalation and dermal toxicity. It is not irritating to the rabbit skin, but to the rabbit eye and is not a skin sensitiser.

3.1.3.2 Operator Exposure

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

| Crop | F/G ⁹ | Equipment | Application rate kg product/ha | Model |
|------|------------------|--------------------|---|-----------|
| Turf | F | Manual application | 40 g/m ² = 400 kg/ha (25600 g iron/ha and 68400 g ion sulphate/ha) | UPJ Model |

Considering the proposed use, operator systemic exposure was estimated using the French study from UPJ 2009-2010¹⁰ dedicated to amateur use:

| Crop | Equipment | PPE and/or working coverall | % AOEL iron | % AOEL ion sulphate |
|------|--------------------|-----------------------------|----------------|------------------------|
| Turf | Manual application | None | 5.95 % | 15.89 % |

According to the model calculations, it may be concluded that the risk for the operator using ENGRAIS GAZON ANTIMOUSSE PREMIUM is acceptable with no PPE or working coverall.

The proposed packaging has been described in sufficient detail, and it is not compliant with the use by non-professional.

3.1.3.3 Bystander Exposure

For use by non-professionals, it is considered that the assessment for bystanders is covered by that for the operator.

Furthermore ENGRAIS GAZON ANTIMOUSSE PREMIUM is a granular bait formulation; no drift is expected.

3.1.3.4 Worker Exposure

ENGRAIS GAZON ANTIMOUSSE PREMIUM is intended to be used by non-professional users during home garden application. In this case, the worker is also the user of the product.

⁹ Open field or glasshouse

¹⁰ Studies and models that can be used to estimate operator exposure during the use of plant protection products in non- agricultural areas. Report from expert group « produits phytosanitaires : substances et préparations chimiques » Working group "évaluation de l'exposition des utilisateurs de produits phytopharmaceutiques en zones non agricoles" - June 2011

ENGRAIS GAZON ANTIMOUSSE PREMIUM is a granular bait formulation; no work is expected to be practiced after application.

Furthermore ENGRAIS GAZON ANTIMOUSSE PREMIUM is used as herbicidal treatment on several crops where there is no need to re-enter the treated area after application.

Therefore, worker exposure estimation is considered not relevant.

3.1.3.5 Resident Exposure

ENGRAIS GAZON ANTIMOUSSE PREMIUM is a granular bait formulation applied on turf.

Children may have access to treated areas soon after products have been applied and their exposure was considered as a worst case. An exposure assessment should therefore be provided to assess the exposure of children through playing in the treated areas. This exposure could be via the oral route through object-to-mouth activities is considered as accidental. Therefore the exposure should be compared to an acute reference value as an ARfD.

No ARfD have been set for iron or iron sulphate.

Consequently, no estimation of resident exposure is feasible.

3.1.4 Residues and Consumer Exposure

Not relevant. The use of ENGRAIS GAZON ANTIMOUSSE PREMIUM is restricted to turf for controlling broadleaf weeds and mosses. Consequently no consideration of residues levels in foodstuffs 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 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 (granular application), exposure calculations to soil and surface water are not considered relevant.

The PECs of iron and sulphate in groundwater have been assessed using a conservative approach as proposed during the EU review. PEC_{gw} values for sulphate do not occur at levels exceeding the EU drinking water limit of 250 mg/L defined for sulphate in Directive 98/83/CE. PEC_{gw} values for iron exceed the EU drinking water limit of 0.2 mg/L defined for iron.

However PEC_{gw} values for both iron and sulphate in soil, resulting from the representative use of ENGRAIS GAZON ANTIMOUSSE PREMIUM are below natural background. 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 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 use, a risk assessment is performed only for birds, mammals and aquatic organisms.

For birds and mammals, the risk may be considered acceptable.

For aquatic organisms, only spray drift is considered relevant to estimate PEC_{sw} values for uses in gardens. As ENGRAIS GAZON ANTIMOUSSE PREMIUM is a granular formulation, no PEC_{sw} calculation is required in this specific case.

However, ENGRAIS GAZON ANTIMOUSSE PREMIUM is used to control mosses and as a fertiliser. A risk of eutrophication of aquatic ecosystems due to phosphorous cannot be excluded.

For non-target plants, precaution must be taken to avoid accidental application outside the treated area.

3.1.7 Efficacy

Considering the data submitted:

- The efficacy of ENGRAIS GAZON ANTIMOUSSE PREMIUM is considered satisfactory in the claimed conditions,
- The selectivity of ENGRAIS GAZON ANTIMOUSSE PREMIUM is considered satisfactory in the claimed conditions,
- The risk of negative impact on turf quality and adjacent plants is considered negligible,
- The risk of resistance appearance regarding iron sulphate is considered low.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted. A copy of the decision issued can be found 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 following data would have been required to update the dossier:

- A validated analytical method for the determination of iron sulphate (oxidation rate II) in the product.
- A shelf-life storage study 2 years at room temperature performed with the formulation ENGRAIS GAZON ANTIMOUSSE PREMIUM in commercial packaging.

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 **ENGRAIS GAZON ANTIMOUSSE PREMIUM***

de la société **AGRONUTRITION**

enregistrée sous le **n°2013-1333 et 2017-2252**

Vu les conclusions de l'évaluation de l'Anses du 23 mai 2018,

Vu les éléments complémentaires transmis par la direction en charge de l'évaluation des produits réglementés de l'Anses le 27 septembre 2018 et le 13 novembre 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 | ENGRAIS GAZON ANTIMOUSSE PREMIUM |
| Type de produit | Produit de référence |
| Titulaire | AGRONUTRITION PARC ACTIVESTRE 3 Avenue de l'Orchidée 31390 CARBONNE France |
| Formulation | Granulé (GR) |
| Contenant | 288 g/kg - sulfate de fer heptahydrate (équivalent à 156 g/kg de sulfate de fer) Eléments fertilisants déclarés conformes à une norme d'application obligatoire |
| Numéro d'intrant | 9890-2013.01 |
| Numéro d'AMM | 2180283 |
| Fonction | Herbicide, engrais (produit mixte) |
| 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.

A Maisons-Alfort, le 21 NOV. 2018

Françoise WEBER
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 : | |
| Emballage | Contenance |
| Etui en carton refermable (type boîte semoir) | 4 kg |
| Sac en polyéthylène téréphtalate (avec fermeture zip, muni d'une poignée de préhension et d'une poignée latérale dans le soufflet) | 6 kg ; 7 kg ; 12 kg ; 20 kg |

| Teneurs garanties retenues en éléments fertilisants |
|--|
| 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 2 | H319 : Provoque une sévère irritation des yeux |
| 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 | | | | | | | | | |
|---|------------------------|-------------------------------|----------------------|-----------------------------|-------------------------------------|--|--|------------------|---|
| Usages | Dose maximale d'emploi | Nombre maximum d'applications | Epoque d'application | 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 | 40 g/m ² | 1/an | de mars à septembre | Non applicable | - | - | - | - | - |

ENGRAIS GAZON ANTIMOUSSE PREMIUM
AMM n°2180283

Page 4 sur 5



Conditions d'emploi du produit

Stockage et manipulation du produit :

- Application uniquement à l'aide d'un épandeur.

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.

- 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) | Réurrence (mois) |
|--|--------------|------------------|
| Fournir les résultats de l'étude en cours de réalisation, concernant la stabilité au stockage pendant 2 ans, à température ambiante. | 24 | - |
| Fournir une méthode d'analyse pour la détermination spécifique du fer divalent dans le produit. | 24 | - |

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

Avril 2017

PROJET D'ETIQUETTE ENGRAIS GAZON ANTI MOUSSE PREMIUM
AMM N°

| | | |
|--|---|---|
| <p>Nom homologué : ENGRAIS GAZON ANTI MOUSSE PREMIUM AMM N° : xxxxxx Détenteur de l'AMM : AGRONUTRITION</p> <p>Composition : 32% de sulfate de fer heptahydraté 4.30 D'azote (N) total dont : <0.57 % ammoniacal <0.1 % uréique <0.1 % nitrique 4.0% organique 2.4% d'anhydride phosphorique (P₂O₅) soluble dans l'eau 6.4% d'oxyde de potassium (K₂O) soluble dans l'eau 6.8% d'oxyde de calcium total (CaO) 15.6% d'anhydride sulfurique (SO₃) 1.9% d'oxyde de magnésium (MgO) 6.50% de Fer (Fe)</p> <p>Formulation : granulés</p> <p>Type d'action du produit : engrais gazon, destruction des mousses des gazons de graminées.</p> <p>Usage : gazons de graminées –mousses.</p> <p>Dose homologuée : 400 Kg/ha ou 40g/m²</p> <p>Eliminer les produits non utilisables dans une déchetterie et les emballages vides et rincés dans la poubelle ménagère.</p> <p>Masse nette : kg</p> <p>N° de lot : (voir sur l'emballage) Date de fabrication : (voir sur l'emballage) N° en cas d'urgence : appeler le 112 ou le centre antipoison Accès FDS sur le serveur : http://www.quickfds.fr</p> | <div data-bbox="598 465 687 555" data-label="Image"> </div> <p>ATTENTION</p> <p>H319 : Provoque une sévère irritation des yeux.</p> <ul style="list-style-type: none"> • P102 : Tenir hors de portée des enfants. • P264 : Se laver les mains soigneusement après manipulation. • P270 : Ne pas manger, boire ou fumer en manipulant ce produit. • P280 : Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage. • P305+P351+P338 : EN CAS DE CONTACT AVEC LES YEUX: Rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. • P501 : Éliminer le contenu /récipient conformément à la réglementation en vigueur. • SP1 : Ne pas polluer l'eau avec le produit ou son emballage. <p>EUH401 : Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.</p> | <p>PRECAUTIONS D'EMPLOI :</p> <ul style="list-style-type: none"> • Ce produit tache les surfaces dures poreuses telles que les dallages, murs, etc... • Ne pas utiliser à proximité des fleurs, des arbustes, des arbres fruitiers, des légumes. Sur l'emplacement des plantes à bulbes, attendre le dessèchement des feuilles avant application. • Tenir les animaux domestiques à l'écart des lieux traités durant les 2 ou 3 jours qui suivent l'épandage. • Ne pas traiter sur sol gelé. • Ne pas appliquer à une température supérieure à 25°C ou inférieure à 15°C. • Ne pas arroser le gazon dans les 24h suivant l'application (l'eau laverait le désherbant sur les feuilles et réduirait l'efficacité du produit). • Ne pas appliquer s'il y a un risque de pluie dans les prochaines 24h. • Ne pas utiliser sur les jeunes gazons (attendre la 4^{ème} tonte). • Attendre un mois après application si vous envisagez de semer ou de poser des plaques de gazons. • Ne pas utiliser les déchets des 2 à 3 premières tontes pour la formation de compost. • Ne pas utiliser à proximité d'un point d'eau. • Se laver les mains après utilisation. • Stocker dans un endroit frais et sec à l'abri de l'humidité. • Ne pas respirer les poussières. • Ne pas réutiliser l'emballage vide. <p>RECOMMANDATIONS D'EMPLOI :</p> <ul style="list-style-type: none"> • Traiter la pelouse 3 jours après une tonte • Appliquer le produit sur une pelouse légèrement humide (arroser avant l'application en cas de temps sec). |
| <p>AGRONUTRITION Rue Albert EINSTEIN – ZI des Cauquillous 81500 LAVAUR Tél. 05.63.83.12.00 Distribué par :</p> | | |

Appendix 3 – Letters of Access

Provided upon request.