

## **REGISTRATION REPORT**

### **Part A**

### **Risk Management**

**Product name: FABRIMOUS+2**

**Active substances:**

**Iron sulphate (heptahydrate), 430 g/kg**

**2,4-D, 2 g/kg**

**Dicamba, 1 g/kg**

**COUNTRY: FRANCE**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(New application)**

**Applicant:**

**AGRONUTRITION**

**Date:**

**2020/10/28**

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## PART A – Risk Management

The company AGRONUTRITION has requested marketing authorisation in France for the product FABRIMOUS+2<sup>1</sup>, containing 430 g/kg iron sulphate (heptahydrate), 2 g/kg 2,4-D and 1 g/kg dicamba, as a herbicide and fertiliser.

The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to FABRIMOUS+2 where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of FABRIMOUS+2 have been made using endpoints agreed in the EU peer reviews of iron sulphate, 2,4-D and dicamba.

This document describes the specific conditions of use and labelling required for France for the registration of FABRIMOUS+2.

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

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

Appendix 3 of this document contains 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 AGRONUTRITION's application to market FABRIMOUS+2 in France as a herbicide and 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 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.

Specific provisions of Regulation (EU) No 540/2011 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 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 shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.

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

A review report is available (SANCO/2616/08 – rev 6, 09 October 2015).

## 2,4-D

<sup>1</sup> An identical formulation, for non-professional use, is HOBBYMOUS+2.

Commission Implementing Regulation (EU) 2015/2033 of 13 November 2015 renewing the approval of the active substance 2,4-D in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Specific provisions of Regulation (EU) No 2015/2033 were as follows:

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 2,4-D, and in particular Appendices I and II thereof, shall be taken into account.

In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms, terrestrial organisms and consumers in cases of uses above 750 g/ha.

Conditions of use shall include risk mitigation measures, where appropriate.

The notifier shall submit to the Commission, the Member States and the Authority:

- (1) confirmatory information in the form of the submission of the complete study results from the existing extended one-generation study;
- (2) confirmatory information in the form of the submission of the Amphibian Metamorphosis Assay (AMA) (OECD (2009) Test No 231) as to verify the potential endocrine properties of the substance.

The information set out in point (1) shall be submitted by 4 June 2016 and the information set out in point (2) by 4 December 2017.

An EFSA conclusion is available (EFSA Journal 2014; 12(9):3812).

A review report is available in the form of a Revised Renewal report (SANCO/11961/2014 Rev 4 final 6 October 2017).

### **Dicamba**

Commission Implementing Regulation (EU) No 1100/2011 of 31 October 2011 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances dicamba, difenoconazole, and imazaquine.

Specific provisions of Regulation (EU) No 540/2011 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 review report on dicamba, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.

Specific provisions of Regulation (EU) No 1100/2011 were to amend Part B as follows:

#### **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 review report on dicamba, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011 shall be taken into account.

In this overall assessment Member States shall pay particular attention to the protection of non-target plants.

Conditions of use shall include adequate risk mitigation measures, where appropriate.

The notifier shall submit confirmatory information as regards:

- (a) the identification and quantification of a group of soil transformation products formed in a soil incubation study;
- (b) the potential for long range transport through the atmosphere.

The notifier shall submit this information to the Member States, the Commission and the Authority by 30 November 2013.

An EFSA conclusion is available (EFSA Journal 2011; 9(1): 1965) plus the outcome of the consultation on confirmatory data used in the risk assessment (Efsa technical report, 1 April 2016).

A review report is available (SANCO/829/08 – final rev. 2 12 July 2016).

### 1.3 Regulatory approach

The present application (2013-1330) were evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)<sup>2</sup> 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”)<sup>3</sup> – the highest application rates applied for in 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 4 May 2017<sup>4</sup> provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless otherwise 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, non-spraying 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 1107/2009<sup>5</sup>, 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 on the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011<sup>6</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

<sup>2</sup> French Food Safety Agency, Afssa, before 1 July 2010

<sup>3</sup> 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

<sup>4</sup> 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>

<sup>5</sup> 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

<sup>6</sup> 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

Finally, the French Order of 26 March 2014<sup>7</sup> 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 “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation<sup>8</sup> 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 FABRIMOUSS+2, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

#### **1.5 Letter(s) of Access**

The applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. The applicant has provided Letter(s) of Access for the active substances.

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<sup>7</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

<sup>8</sup> SANCO document “guidance document: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

## 2 DETAILS OF THE AUTHORISATION

### 2.1 Product identity


<b>Product name (code)</b>	FABRIMOUS+2
<b>Authorisation number</b>	2200862
<b>Function</b>	Herbicide, fertiliser. Professional use.
<b>Applicant</b>	AGRONUTRITION.
<b>Composition</b>	430 g/kg iron sulphate. 2 g/kg 2,4-D. 1 g/kg dicamba.
<b>Formulation type (code)</b>	Granule [GR].
<b>Packaging</b>	Bags in LDPE : 4 kg Bags in LDPE/PET: 6, 7, 12 and 20 kg.

### 2.2 Classification and labelling

#### 2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

<b>Physical hazards</b>	-	
<b>Health hazards</b>	Eye irritation cat. 2	
<b>Environmental hazards</b>	-	
<b>Hazard pictograms</b>		
<b>Signal word</b>	Warning	
<b>Hazard statements</b>	H319	Causes serious eye irritation
<b>Precautionary statements –</b>	<i>For the P phrases, refer to the extant legislation.</i>	
<b>Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)</b>	EUH208	Contains 2,4-D. May produce an allergic reaction

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

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe 2	To protect groundwater, do not apply this product to acidic soils (pH H <sub>2</sub> O < 6).
SPe 6	To protect birds and wild mammals, remove spillages.

#### 2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment <sup>9</sup> : refer to the Decision in Appendix 1 for the details.
Re-entry period <sup>10</sup> : Not applicable (spreading of granules).
Pre-harvest interval <sup>11</sup> : Not applicable.
Other mitigation measures: - Apply only with a vehicle-mounted spreader (a manual spreader is unacceptable on human health grounds).
The label should include the following recommendations: The phrase “EUH208 Contains 2,4-D. May produce an allergic reaction”. The product should not be directed on to adjacent ornamental crops. Due to the presence of dicamba, it is advisable not to use lawn mowings as mulch or compost.  The label must reflect the conditions of authorisation.

<sup>9</sup> If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

<sup>10</sup> The legal basis for this is **Titre I Article 3** of the French Order of 4 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]

<sup>11</sup> 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) **FABRIMOUS+2**  
active substance 1 **iron sulphate**  
active substance 2 **2,4-D**  
active substance 3 **dicamba**

Formulation type: **GR**  
Conc. of a.s. 1: **430 g/kg**  
Conc. of a.s. 2: **2 g/kg**  
Conc. of a.s. 2: **1 g/kg**

date: March 2020-10-28

Applicant: **AGRONUTRITION**  
Zone(s): **Southern EU**  
Verified by MS: **yes**

professional use ☒  
non-professional use ☐

1	2	3	4	5	6	7	8	10	11	12	13	14	15
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I (a)	Pests or Group of pests controlled (b)  (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)  (g)	Remarks:  e.g. g safener/synergist per ha  (h)	zRMS Conclusion
					Method / Kind (c-e)	Timing / Growth stage of crop & season (f)	Max. number (min. interval between applications) a) per use b) per crop/ season	kg product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
1	France	Turf	F	Broadleaf weeds	Suitable granular applicator	Post- emergence of the weeds (from mid- March to September)	a) 1 b) 1	a) 300 kg/ha b) 300 kg/ha	a) iron sulphate : 129000 2,4-D: 600 Dicamba: 300 b) iron sulphate : 129000 2,4-D: 600 Dicamba: 300	N/A	N/A	Professional uses. On established turf only.	Acceptable with a vehicle- mounted spreader only (risk to operators with manual spreader)
2	France	Turf	F	Moss	Suitable granular applicator	May to August	a) 1 b) 1	a) 300 kg/ha b) 300 kg/ha	a) iron sulphate : 129000 2,4-D: 600 Dicamba: 300 b) iron sulphate : 129000 2,4-D: 600 Dicamba: 300	N/A	N/A	Professional uses. On established turf only	Acceptable with a vehicle- mounted spreader only (risk to operators with manual spreader)

- Remarks:**
- (a) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
  - (b) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
  - (c) All abbreviations used must be explained
  - (d) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
  - (e) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
  - (f) 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
  - (g) PHI - minimum pre-harvest interval
  - (h) Remarks may include: Extent of use/economic importance/restrictions  
N/A: not applicable.

### 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

FABRIMOUS+2 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 that of grey/beige to a light orange in colour granules with a strong characteristic odour. It is not explosive and has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 370°C. In aqueous solution (1%), it has a pH value of 4.30 at ambient temperature. There is no effect of high temperature on the stability of the formulation, since 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in bag in PET/ PE. Its technical characteristics are acceptable for a granule formulation (GR). The formulation is not classified for the physical-chemical part.

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

##### 3.1.2 Methods of analysis

Analytical methods for the determination of the active substances are available and validated.

As the active substances do not contain relevant impurities, no pertinent analytical methods are required. The CIPAC method is not specific of divalent iron, which is in active substance (FeSO<sub>4</sub>). An analytical method for the determination of oxidation rate of Fe of the active substance in the product is required.

Analytical methods are available in the Renewal Assessment Report (RAR)/this dossier and validated for the determination of residues of iron sulphate, dicamba and 2,4-D in soil, water (surface and drinking) and air.

Considering the intended uses (turf), analytical methods for the determination of residues of dicamba and 2,4-D in plants and in foodstuffs of animal origin are not necessary.

##### 3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active substance: 2,4-D		
ADI	0.02 mg/kg bw/d	EU (2017)
ARfD	0.3 mg/kg bw	
AOEL	0.02 mg/kg bw/d	
AAOEL	Not determined	
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):	
		Concentrate (used in formulation) 2 g/kg
	Dermal absorption endpoints %	75

Active substance: <b>dicamba</b>		
ADI	0.3 mg/kg bw/d	EU (2009)
ARfD	0.3 mg/kg bw	

AOEL	0.3 mg/kg bw/d	
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):	
		Concentrate (used in formulation) 1 g/kg
	<b>Dermal absorption endpoints %</b>	<b>75</b>

Active Substance: <b>Iron sulphate</b>		
ADI	Ferrous ion : 0.8 mg kg bw/d Sulphate ion: 12.5 mg kg bw/d	EU (2009)
ARfD	Ferrous ion : Non applicable Sulphate ion: Non applicable	
AOEL	Ferrous ion : 0.38 mg kg bw/d Sulphate ion: 1.3 mg kg bw/d	
Dermal absorption	Based default values according to guidance on dermal absorption (Efsa 2012):	
		Concentrate (used in formulation) Ferrous ion : 86.4g/kg Sulphate ion: 427g/kg
	<b>Dermal absorption endpoints %</b>	Ferrous ion : 10

### 3.1.3.1 Acute Toxicity

FABRIMOUS+2, containing 2 g/kg of 2,4D, 1 g/kg of dicamba, 86.4g/kg of ferrous ion) has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin and is not a skin sensitizer. It is irritating to the rabbit eye.

### 3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G <sup>12</sup>	Equipment	Application kg product/ha rate	Model
<b>Crop Area and non-crop area</b> Turf and amenities including sport grounds, golf etc...Broadleaf weeds and moss	F	Micgranulator Or Manual application	300 kg product/ha (2,4D = 0.51 kg ea/ha Dicamba = 0.3 kg/ha Ferrous ion = 25.91 kg/ha	PHED

Considering proposed uses, operator systemic exposure was estimated using the PHED model:

<b>Actives Substances</b>	<b>Professional (crop and non-crop area) PHED model</b>					
	<i>Application rate: 300kg product/ha / Application volume : not applicable</i>					
	<i>Level of PPE gloves and normal workwear were worn during loading and application operation and mask FFP2 for vehicle-mounted (mixing and loading)</i>					
	<b>Vehicle-mounted equipment</b>			<b>Manual application</b>		
	<b>Total absorbed dose (mg/kg b.w./day)</b>	<b>% of AOEL</b>		<b>Total absorbed dose (mg/kg b.w./day)</b>	<b>% of AOEL</b>	

<sup>12</sup> Open field or glasshouse

Actives Substances	Professional (crop and non-crop area) PHED model <i>Application rate: 300kg product/ha / Application volume : not applicable</i> <i>Level of PPE gloves and normal workwear were worn during loading and application operation and mask FFP2 for vehicle-mounted (mixing and loading)</i>			
	2,4-D	0.0085	43	0.6023
Dicamba	0.0050	1.7	0.3543	118
Ferrous ion	0.1154	30	4.2548	1120

According to the model calculations, it can be concluded that the risk for the operator using FABRIMOUS+2 with a vehicle-mounted equipment is acceptable with gloves and normal workwear during mixing/loading and application and a respiratory mask FFP2 during mixing loading.

**According to the model calculations, it can be concluded that the risk for the operator using FABRIMOUS+2 with a hand held equipment equipment is unacceptable with gloves and normal workwear during mixing/loading and application.**

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

### 3.1.3.3 Bystander Exposure

FABRIMOUS+2 is a granular formulation; no drift is expected. Therefore estimating bystander exposure is considered to be not necessary.

### 3.1.3.4 Resident Exposure

FABRIMOUS+2 is a granular formulation; no drift is expected. Therefore estimating bystander exposure is considered to be not necessary.

### 3.1.3.5 Worker Exposure

Broadcast application of granules or [originally] manual application is intended for FABRIMOUS+2; no work is expected to be practised after application. Therefore worker exposure estimation is considered to be not relevant.

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

### 3.1.4 Consumer exposure

Given the proposed use, no exposure of consumers is anticipated.

### 3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate predicted environmental concentrations (PECs) for the active substances and their 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.

The PEC of 2,4-D, dicamba, sulfate irons and their metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PECsoil and PECsw derived for the active substances and their metabolites are used for the ecotoxicological risk assessment. PECgw for dicamba, 2,4-D, iron sulfate and their metabolites do not occur at levels exceeding those

mentioned in regulation EC 1107/2009, guidance document SANCO 221/2000<sup>13</sup>. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

As no further data was provided by the notifier to address the EFSA data gap concerning the behaviour of 2,4-D under acidic soils, FOCUS modeling cannot be extrapolated for soils having a soil  $\text{pH}_{\text{H}_2\text{O}} < 6.0$ . Therefore, a restriction measure is proposed: To protect groundwater, do not apply this product to acidic soils  $\text{pH}_{\text{H}_2\text{O}} < 6.0$ .

Based on vapour pressure, information on volatilisation from plants and soil, and  $\text{DT}_{50}$  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 active substances and their 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.

Based on the guidance documents, the risks for birds, mammals, aquatic organisms, bees and other non-target arthropods, earthworms and other soil macro- and micro-organisms are acceptable for the intended uses.

### 3.1.7 Efficacy

Considering the data submitted:

- ✓ the efficacy of FABRIMOUSS+2 is considered satisfactory on claimed uses. This preparation should be applied only under concomitance condition between weeds and mosses.
- ✓ the selectivity of FABRIMOUSS+2 is considered satisfactory on established turf only.
- ✓ the risk of negative impact on multiplication is considered acceptable.
- ✓ the risk of negative impact on succeeding crops is considered acceptable. Nevertheless, specific attention should be paid to susceptible replacement crops (turf) and to ornamental crops that can be associated with turf.
- ✓ the risk of negative impact on adjacent crops is considered acceptable. Nevertheless, specific attention should be paid to ornamental crops that can be associated with turf.

The product should not be directed on to adjacent ornamental crops. Due to the presence of dicamba, it is advisable not to use lawn mowings as mulch or compost.

- ✓ the risk of resistance developing or appearing does not require monitoring for the requested use.

<sup>13</sup> Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

### **3.2 Conclusions arising from French assessment**

Taking into account the above assessment, an authorisation can be granted with a vehicle-mounted spreader only, 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:

- An analytical method for the determination of oxidation rate of Fe of the active substance 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 et la demande associée du produit mixte **FABRIMOUS+2***

*de la société AGRONUTRITION*

*enregistrées sous les n°2013-1330 et 2019-0597*

*Vu les conclusions de l'évaluation de l'Anses du 19 octobre 2020,*

La mise sur le marché du produit mixte désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et 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	FABRIMOUS+2
Type de produit	Produit de référence
Titulaire	AGRONUTRITION PARC ACTIVESTRE 3 Avenue de l'Orchidée 31390 CARBONNE France
Formulation	Granulé (GR)
Contenant	2 g/kg - 2,4-D sel de diméthylamine 1 g/kg - dicamba sel de diméthylamine 430 g/kg - sulfate de fer heptahydraté Elément fertilisant (N) déclaré conforme à une norme d'application obligatoire
Numéro d'intrant	9876-2013.01
Numéro d'AMM	2200862
Fonction	Engrais (N), herbicide
Gamme d'usage	Professionnel

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 qui arrive à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 août 2022.

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

28 OCT. 2020

**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 :	
Emballage	Contenance
Sachets en polyéthylène basse densité	4 kg
Sacs en polyéthylène téréphtalate / polyéthylène basse densité	6 kg ; 7 kg ; 12 kg ; 20 kg

Teneurs garanties retenues en éléments fertilisants
Indiquer sur l'étiquette la teneur (en % MB) de l'élément fertilisant revendiqué : N (et ses différentes formes), 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 2	H319 : Provoque une sévère irritation des yeux
EUH208 : Contient du 2,4-D. Peut produire une réaction allergique.	
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	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	
<b>18505901</b> Gazons de graminées* Désherbage	300 kg/ha	1/an	-	Non applicable	-	-	-	-	
Application en post-levée des adventices, de mi-mars à septembre. Uniquement sur gazons installés avec un épandeur mécanisé. L'application avec un épandeur manuel est refusée en raison d'un risque d'effet nocif pour les opérateurs.									
<b>18505902</b> Gazons de graminées* Trt Part.Aer.*Mousses	300 kg/ha	1/an	-	Non applicable	-	-	-	-	
Application de mai à août. Uniquement sur gazons installés avec un épandeur mécanisé. L'application avec un épandeur manuel est refusée en raison d'un risque d'effet nocif pour les opérateurs.									

FABRIMOUS+2  
AMM n°2200862





## Conditions d'emploi du produit

### Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

### Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un tracteur équipé d'un micro-granulateur

#### • pendant le chargement du matériel d'épandage

- Gants en nitrile certifiés EN ISO 374-1/A1 et EN 16523-1+A1 (type A);
- EPI vestimentaire conforme à la norme NF EN ISO 27065;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
- Masque FFP2 (EN149)
- Lunettes certifiées norme EN 166 (CE, sigle 3);

#### • pendant l'épandage

- Gants en nitrile certifiés EN ISO 374-1/A1 et EN ISO 374-2 (types A, B ou C) à usage unique en cas d'intervention sur semoir, épandeur à engrais ou microgranulateur ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065 ;

#### • pendant le nettoyage du matériel d'épandage

- Gants en nitrile certifiés EN ISO 374-1/A1 et EN 16523-1+A1 (type A);
- EPI vestimentaire conforme à la norme NF EN ISO 27065;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
- Lunettes certifiées norme EN 166 (CE, sigle 3).

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

- 24 heures.

### Respect des limites maximales de résidus (LMR)

- Non applicable.



### **Protection de l'environnement (milieux, faune et flore)**

#### **Protection de l'eau**

- SPe 2 : Pour protéger les eaux souterraines et les organismes aquatiques, ne pas appliquer ce produit sur sols acides (pH- H<sub>2</sub>O <6).
- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

#### **Protection de la faune**

- SPe 6 : Pour protéger les oiseaux et les mammifères sauvages, récupérer tout produit accidentellement répandu.

### **Recommandations relatives à l'étiquette du produit**


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

- FABRIMOUS+2 est un produit mixte : engrais N conforme à une norme d'application obligatoire (à rappeler) et herbicide.
- Le produit ne doit pas être dirigé vers les cultures ornementales adjacentes au gazon.
- En raison de la présence de dicamba, il est conseillé de ne pas utiliser les déchets de tonte comme mulch ou compost.

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

Octobre 2016

**PROJET D'ETIQUETTE FABRIMOUS+ 2**  
**AMM N°**

<p><b>Nom homologué : FABRIMOUS+ 2</b> <b>AMM N° xxxxx</b> <b>Détenteur de l'AMM : AGRONUTRITION</b></p>		<p><b>PRECAUTIONS D'EMPLOI :</b></p>
<p><b>Composition :</b> 43% de sulfate de fer heptahydraté. 0,2% de 2,4D (sel de diméthylamine) 0,1% de Dicamba (sel de diméthylamine).  8,9% d'azote (N) total dont : 8,9% ammoniacal</p> <p><b>Formulation : granulés</b></p> <p><b>Type d'action du produit :</b> engrais gazon, désherbant, destruction des mousses.</p> <p><b>Usage :</b> gazons de graminées – désherbage gazons de graminées – mousses.</p> <p><b>Dose homologuée :</b> 300 Kg/ha ou 30g/m<sup>2</sup></p> <p><b>Eliminer les produits non utilisables dans une déchetterie et les emballages vides et rincés dans la poubelle ménagère.</b></p> <p style="text-align: right;"><b>Masse nette : kg</b></p> <p><b>N° de lot :</b> (voir sur l'emballage) <b>Date de fabrication :</b> (voir sur l'emballage) <b>N° en cas d'urgence :</b> appeler le 112 ou le centre antipoison <b>Accès FDS sur le serveur :</b> <a href="http://www.quickfds.fr">http://www.quickfds.fr</a></p>		<p><b>ATTENTION</b></p> <p><b>H319 : Provoque une sévère irritation des yeux.</b></p> <p>EUH208 : Contient du 2,4-D (sous forme de sel). Peut produire une réaction allergique.</p> <ul style="list-style-type: none"> <li>• P102 : Tenir hors de portée des enfants</li> <li>• P270 : Ne pas manger, boire ou fumer en manipulant ce produit</li> <li>• P272 : Les vêtements de travail contaminés ne devraient pas sortir du lieu de travail.</li> <li>• P281 : Utiliser l'équipement de protection individuel requis.</li> <li>• P264:Se laver les mains soigneusement après manipulation.</li> <li>• 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.</li> <li>• P337+P313 : Si l'irritation oculaire persiste: consulter un médecin.</li> <li>• P273 : Éviter le rejet dans l'environnement.</li> <li>• SP1 : Ne pas polluer l'eau avec le produit ou son emballage.</li> </ul> <p>EUH401 : Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.</p>
<p><b>AGRONUTRITION</b> Rue Albert EINSTEIN – ZI des Cauquillous 81500 LAVAUR <b>Tél. 05.63.83.12.00</b></p> <p><b>Distribué par : .....</b></p>		

### **Appendix 3 – Letter(s) of Access**

Provided upon request.