REGISTRATION REPORT

Part A

Risk Management

Product code:

IRON SULFATE MONOHYDRATE GR 7,3 G

Product name(s): FAMOSS

Chemical active substance(s):

Iron sulphate monohydrate, 73.02 g/kg
(Iron sulphate anhydrous, 65.3 g/kg)

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: SBM DEVELOPPEMENT SAS

Date: 17/11/2025

Table of Contents

PART A

RISK MANAGEMENT

1 Details of the application

The company SBM DEVELOPPEMENT SAS has requested a marketing authorisation in France for the product FAMOSS (product code: IRON SULFATE MONOHYDRATE GR 7,3 G), containing 73.02 g/kg Iron sulphate[1] (monohydrate) as a herbicide and fertilizer for non-professional uses.

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

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

.

1.1 Application background

The present registration report concerns the evaluation of SBM DEVELOPPEMENT SAS's application submitted on 30/03/2023 to market FAMOSS in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2023-1268) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[2], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[3]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of FAMOSS has been made using endpoints agreed in the EU peer review of Iron sulphate. It also includes assessment of data and information related to FAMOSS where those data have not been considered in the EU peer review process.

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 risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of FAMOSS.

---

1 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

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

3 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

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

1.2 Letters of Access

Not necessary: active substance data are not protected any more.

1.3 Justification for submission of tests and studies

According to the applicant: « all tests performed, and study reports are necessary in order to support the first of authorisation for FAMOSS ».

1.4 Data protection claims

2 Where protection for data is being claimed for information supporting registration of FAMOSS. it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. » Details of the authorisation decision

2.1 Product identity

Product code	IRON SULFATE MONOHYDRATE GR 7,3 G
Product name in MS	FAMOSS
Authorisation number	2250521
Kind of use	Non-professional use
Low risk product (article 47)	No
Function	Herbicide and fertilizer
Applicant	SBM DEVELOPPEMENT SAS
Active substance(s) (incl. content)	Iron sulphate, 73.02 g/kg
Formulation type	Granule [GR]
Packaging	Bottle HDPE[5] (3.8 kg, 5 kg) with spreader system Box cardboard/PET[6] (3,2 kg) with spreader system Box cardboard/LDPE[7] (3,2 kg) with spreader system **only with a Lawn trolley** bag to refill PET/LDPE (10 kg, 12 kg) bag to refill LDPE (10 kg, 12 kg) cardboard/LDPE (10 kg, 12 kg) cardboard/BoPET[8] (10 kg, 12 kg) **Other packaging proposed by the applicant are not accepted by zRMS for non-professional users :** **Folding box with plastic sachet inside (3.2 kg) and zip bags with dosing cup (8, 10, 12, 14 kg)**

[5] HDPE : High Density Polyethylene
[6] PET : Polyethylene terephthalate
[7] LDPE : Low Density Polyethylene
[8] BoPET : bi-oriented polyethylene terephthalate

Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for FAMOSS resulted in the **decision to grant the authorisation**.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	None
Hazard pictograms:	None
Signal word:	None
Hazard statement(s):	None
Precautionary statement(s):	***For the P phrases, refer to the existing legislation***
Additional labelling phrases:	EUH 208 : Contains iron (III) IDHA. May produce an allergic reaction.

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

2.4.2 Standard phrases under Regulation (EU) No 547/2011

-	None
	For other restrictions refer to 2.5

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

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

The French Order of 4 May 2017[9] provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 12 April 2021[10] provides that:

- an authorisation granted for a "reference" crop applies also for "related" crops, unless formally stated in the Decision
- the "reference" and "related" 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[11] 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.

Finally, the French Order of 20 November 2021[12] on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop[9] when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.

[9] 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, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

[10] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

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

[12] Arrêté du 20 novembre 2021 relatif à la protection des abeilles et des autres insectes pollinisateurs et à la préservation des services de pollinisation lors de l'utilisation des produits phytopharmaceutiques - Légifrance (legifrance.gouv.fr)

Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
	Do not discharge into the sink, gutter or any other water source the non-used container leftovers and the washing water of the spreader.
	Avoid spreading the pellets to nearby plants.
	To protect aquatic organisms, do not spread the granules close to a water source (wells, pond, stream, river ...).
Other specific restrictions	
Re-entry period	Not applicable.
Storage	-
Risk mitigation measures	-
Agricultural recommendations	-

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable" , the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date:17/11/2025

PPP (product name/code):	FAMOSS / IRON SULFATE MONOHYDRATE GR 7,3 G	Formulation type:	GR [a, b]
Active substance 1:	Iron sulphate	Conc. of a.s. 1:	73.02 g/kg [c] (monhydrate) 65.28 g/kg [c] (anhydrous)
Applicant:	SBM DEVELOPPEMENT SAS	Professional use:	☐
Zone(s):	Southern Zone [d]	Non-professional use:	☒
Verified by MS:	Yes		
Field of use:	Herbicide and fertilizer		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f] RMS Conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	**Lawn (species)**	**Fn**	**Mosses in lawn**	Spread	Feb to May Oct. to Dec	a) 2 b) 2	40	a) 400 b) 800	a) 26.1 ($FeSO_4$) b) 52.2 ($FeSO_4$)	Not applicable	Not applicable	**Acceptable**

* As some standards may have undergone changes, it is the responsibility of the applicant to update the references.
** The application is possible during the flowering period in line with the application of the French Order of November 20, 2021 (arrêté du 20 novembre 2021 relatif à la protection des abeilles et des autres insectes pollinisateurs et à la préservation des services de pollinisation lors de l'utilisation des produits phytopharmaceutiques).

Remarks table heading:
(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

IRON SULFATE MONOHYDRATE GR 7,3 G/FAMOSS
Part A - National Assessment
FRANCE

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of brown granules heterogeneous in size and colour, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature above 400 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active substance 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 cardboard/LDPE and PE/PET packagings. Its technical characteristics are acceptable for a granule formulation.

3.2 Efficacy (Part B, Section 3)

The dose of 0.4 kg/10m² (2.6 g iron sulphate/m²), which is lower than the dose of the reference product used (5.4 g iron sulphate/m²) to control moss in lawns, is still acceptable from an agronomic point of view. However, it does not guarantee optimum efficacy.

The level of selectivity of the FAMOSS product is considered satisfactory for the claimed use.

The risks of negative impact adjacent crops is considered negligible.

The risk of occurrence or development of resistance to the substance does not require monitoring for the claimed use.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical method for the determination of the total iron in the formulation is available and validated.

Analytical method for the determination of relevant impurities (arsenic, cadmium, chromium, lead and mercury) in the formulation is available. Analytical methods for residues

Iron sulphate as active substance on Annex IV of EC Regulation no 396/2005 is exempt from MRL setting.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

FAMOSS has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to skin or eye and is not a skin sensitiser.

3.4.2 Operator exposure

Considering the proposed uses, the operator exposure was estimated using the EFSA model[13]:and French study from UPJ 2009-2010[14] dedicated to non-agricultural areas.

At tier 1 level, according to the exposure assessment using the EFSA model, the operator exposure to FAMOSS is above the AOEL value of ferrous iron and sulphate ion,

At tier 2 level, according to the exposure assessment using the UPJ model, the operator exposure to FAMOSS is below the AOEL value of ferrous iron and sulphate ion.

Regarding the proposed packaging, only packaging that ensure minimal exposure for the non professional user[15] are considered acceptable (see table on 2.1 Product identity).
The other proposed packaging Folding box with plastic sachet inside (3.2 kg) and zip bags with dosing cup (8, 10, 12, 14 kg) are not accepted by zRMS for non-professional users.

3.4.3 Worker exposure

FAMOSS 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, the assessment of worker exposure is covered by that of the operator.

3.4.4 Bystander exposure

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

3.4.5 Resident exposure

According to the exposure assessment using the EFSA model, the estimation of resident (adults and child) exposure (including recreational exposure) to FAMOSS is below the AOEL values of ferrous iron and sulphate ion.

In addition, the risk assessment for direct ingestion of granules by infants provided by the applicant has been evaluated by zRMS. The maximum number of granules which can be ingested per day by a child, without exceeding the ADI and the AOEL of both ferrous iron and sulphate ion has been calculated.
The results show that respectively 6 and 2 granules are required to achieve an intake of iron sulphate which would be equivalent to the reference doses ADI and AOEL.

Considering the presence of a potent bittering agent in the product, there is no unacceptable risk by ingestion of granules by infants (bystanders / residents).

---

13 AOEM – Agricultural Operator Exposure Model (EFSA Journal 2022;20(1):7032)

14 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

15 Arrêté du 6 avril 2020 relatif aux conditions d'autorisation d'un produit phytopharmaceutique pour la gamme d'usages « amateur »

3.4.6 Combined exposure

A cumulative assessment for operators, residents (adult and child) and workers was performed. At the first tier, combined exposure was calculated as the sum of the component exposures, without regard to the mode of action or mechanism/target of toxicity.

The combined exposure to ferrous iron and sulphate ion in FAMOSS (Hazard Index) is < 1.

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

The data available are considered sufficient for risk assessment. The active substance has been included in Annex IV of Regulation (EC) 396/2005. Therefore, no MRL are necessary and no specific studies are required to support the intended use.

Furthermore the use of IRON SULFATE MONOHYDRATE GR 7,3 G is intended on lawn only and therefore no consumer exposure is expected.

As far as consumer health protection is concerned, France, zRMS, agrees with the authorization of the intended uses.

According to available data, no specific mitigation measures should apply.

3.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009.

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.
Compared to the natural contents of iron and sulphates in soil, the additional amounts resulting from the representative use of FAMOSS are negligible. Therefore, an estimation of PECgw values is not required.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance(s) and its/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.

Considering the intended uses (home and garden) and the formulation of the product (granular application), only the risk assessment for birds and mammals was performed. For the other organisms, safety sentences may be needed.

For birds and mammals, the risk is considered acceptable.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substance iron sulfate is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation

FAMOSS_MAMM_2023-1268_D.pdf

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.