REGISTRATION REPORT
Part A
Risk Management

Product code: SBM 13/048
Product name(s): SHERPA 2 G C
Chemical active substance(s):
Cypermethrin, 2.0 g/kg

Southern Zone
Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(authorisation renewal according to Art. 43)

Applicant: SBM DEVELOPPEMENT
Date: 02/08/2024

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PART A
RISK MANAGEMENT

1 Details of the application

The company SBM DEVELOPPEMENT has requested a marketing authorisation in France for the product SHERPA 2 G C (SBM 13/048), containing 2 g/kg cypermethrin[1] as an insecticide for 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's application submitted on 26/04/2022 to market SHERPA 2 G C (SBM 13/048) 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 re-registration of authorisation after the renewal of approval of the active substance cypermethrin of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2014-2806, 2022-1416) 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 SHERPA 2 G C (SBM 13/048) has been made using endpoints agreed in the EU peer review of cypermethrin. It also includes assessment of data and information related to SHERPA 2 G C (SBM 13/048) 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 SHERPA 2 G C (SBM 13/048).

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1 Commission Implementing Regulation (EU) 2021/2049 of 24 November 2021 renewing the approval of the active substance cypermethrin as a candidate for substitution 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

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: the applicant is the owner of data which support the renewal of approval of the active substance.

1.3 Justification for submission of tests and studies

According to the applicant: « All the tests and studies submitted with this application were considered necessary for the fulfilment of the dossiers and risk assessments ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of SHERPA 2 G C (SBM 13/048), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation renewal decision

2.1 Product identity

Product code	SBM 13/048
Product name in MS	SHERPA 2 G C (SBM 13/048)
Authorisation number	8600664
Kind of use	Professional use
Low risk product (article 47)	No
Function	Insecticide
Applicant	SBM DEVELOPPEMENT
Active substance(s) (incl. content)	Cypermethrin, 2 g/kg
Formulation type	MG Microgranuls
Packaging	Multilayered kraft / HDPE bag (15 kg and 25 kg)
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 SHERPA 2 G C (SBM 13/048) resulted in the decision **to refuse** the renewal 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:	Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	 GHS09
Signal word:	Warning
Hazard statement(s):	H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the existing legislation***
Additional labelling phrases:	"As the product contains cypermethrin, which is likely to cause paresthesias, the label should state that contact with the skin should be avoided, in accordance with the french arrêté du 9 November 2004".

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

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

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).
	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[5] provides that:

[5] 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

- unless otherwise stated in the product authorisation renewal, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation renewal, 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 renewal, 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.

Moreover, the French Order of 12 April 2021[6] 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[7] 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[8] 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 renewal 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.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	

[6] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456
[7] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9
[8] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734
[9] List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

Spe 8	Dangerous to bees/To protect bees and pollinating insects do not apply to crop plants when in flower or during the honeydew production period /Do not use where bees are actively foraging /Do not apply when flowering weeds are present.
Other specific restrictions	
Re-entry period	Not applicable.
Storage	-
Risk mitigation measures	-

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" 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: 02/08/2024

PPP (code):	SBM 13/048	Formulation type:	GR [a, b]
Active substance 1:	Cypermethrin	Conc. of as 1:	2 g/kg [c]
Applicant:	SBM Développement	Professional use:	☒
Zone:	Southern	Non professional use:	☐
Verified by MS:	Yes		
Field of use:	Insecticide		

SHERPA 2 G C (SBM 13/048)
Part A - National Assessment
FRANCE DEPR version

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	FR	Maïze	F	<u>European corn borer</u> *Ostrinia nubilalis* [PYRUNU]	Overall foliar spray Applied over the top with microgranule applicator using high clearance tractors	<u>Season</u>: Spring <u>Growth stage</u>: BBCH 51-55	a) 2 b) 2	21	a) 15 b) 30	a) 0.03 b) 0.06	Not applicable, product applied as a dry granule	**90 days (Grain)** **42 days (Silage)**	**Not acceptable** (consumer exposure, non-target terrestrial and aquatic species, non-target arthropods)
2	FR	Sweet corn	F	<u>European corn borer</u> *Ostrinia nubilalis* [PYRUNU]	Overall foliar spray Applied over the top with microgranule applicator using high clearance tractors	<u>Season</u>: Spring <u>Growth stage</u>: BBCH 51-55	a) 2 (21 d) b) 2 (21 d)	21	a) 25 b) 50	a) 0.05 b) 0.10	Not applicable, product applied as a dry granule	14	**Not acceptable** (consumer exposure, non-target terrestrial and aquatic species, non-target arthropods)

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 authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
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 nenewal 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 pink granule, without odour. It is not explosive, has no oxidising properties. The product is neither flammable nor auto-flammable. In aqueous solution, it has a pH value around 7 at 20°C. Its tap and pour densities are respectively 1.651 and 1.444 g/mL. 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 multilayered bag (kraft bag with a polyethylene (PE) inner barrier).
The requested packaging made on Multilayered paper / HDPE bag is considered as acceptable.
Its technical characteristics are acceptable for a ***MG*** formulation.
The supported concentration of use is 15-25 kg SBM 13/048 / ha (i.e 0.03-0.05 kg cypermethrin / ha).
The product is not intended to be mixed in the tank together with other product (tank mixture).

3.2 Efficacy (Part B, Section 3)

The efficacy level of SHERPA 2 G C (SBM 13/048) is considered satisfactory for the requested use on sweet corn where the dose of 25 kg/ha has an interest, especially in situation of high *Ostrinia nubilalis* pressure. For the use requested on maize, the efficacy level remains acceptable at the dose of 15 kg/ha requested on this pest.

The phytotoxicity level of SHERPA 2 G C (SBM 13/048) is considered negligible for all the requested uses.

The risks of negative impact on yield, quality, propagation, succeeding and adjacent crops are con-sidered negligible.

In the absence of specific data, a particular care should be given to the conditions of use of SHERPA 2 G C (SBM 13/048) in the frame of IPM in terms of compatibility with released biological control agents (trichograms).

There is a risk of resistance to cypermethrin for *Ostrinia nubilalis* requiring to set up a monitoring.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical method for the determination of active substance in the formulation is available and validated. As the active substance contain relevant impurity, analytical method for determination of relevant impurity in formulation should be provided.

3.3.2 Analytical methods for residues

Analytical methods are available in the monograph and validated for the determination of residues of active substance in plants, product of animal origin, soil, water and air. Nevetheless listed data gap below are required:

- An analytical method for the determination of Cypemethrin residue in body fluids and tissue in accordance with the residue definition as 4-OH-PBA sulfate and DCVA glucuronide is required.
- Extraction efficiency for fat and milk is required

Pre-registration analytical methods are available for the determination Cypermethrin residue in Maize. For some analytical methods, an uncertainties remain about theier validity as extraction efficiency was not demonstrated.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

Endpoints used in risk assessment

Active substance	**Cypermethrin**
AOEL systemic	0.0025
AAOEL	0.0025
Oral absorption	50%
Vapour pressure	6.78×10^{-6} Pa at 20°C
Reference	Peer review cypermethrin EFSA Journal 2018;16(8):5402 SANTE2018-11527 Rev 8 of 22 October 2021
Dermal absorption	6.8%

SBM 13/048 containing 2 g/kg cypermethrin has low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.4.2 Operator exposure

Considering the proposed uses, the operator systemic exposure was estimated using the EFSA model[10]:

Model data		**Cypermethrin**	
	Level of PPE	**% AOEL**	**% AAOEL**
Application : Tractor / *broadcast application* **outdoor** **Crops : Maize/ sweet Corn**			
Application rate: 25 kg SBM 13/048 /ha		0.05 kg SA / ha	

[10] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

Spray ap-plica-tion (AOEM; 75th percentile) Body weight: 60 kg	Working coverall, gloves, and RPE FP1, P1 and similar during mix/loading and application	11.75	42.03

According to the model calculations, it can be concluded that the risk for the operator using SBM 13/048 is acceptable with a working coverall, gloves and respiratory protective equipment FP1, P1 and similar equipment during mixing/loading and application.

3.4.3 Worker exposure

Considering the granular formulation, zRMS considers that no worker exposure is expected.

3.4.4 Bystander exposure

Bystander exposure was assessed according to the EFSA model without mitigation measures (i.e. without drift reduction technology and a buffer zone of 2-3 meters).

Model data		Cypermethrin
		% AAOEL
Scenario: vehicle-mounted, granule, broadcast application. Buffer zone: 2-3 (m) Drift reduction technology: no Number of applications : 2 Interval between treatments: 21 days		
DT_{50}		30 days
DFR		3 µg/cm²/kg a.s./ha
Bystander (children) Body weight: 10 kg	Spray drift (95th percentile)	-
	Vapour (95th percentile)	42.80
	Surface deposits (95th percentile)	1.12
	Entry into treated crops (95th percentile)	-
Bystander (adults) Body weight: 60 kg	Spray drift (95th percentile)	-
	Vapour (95th percentile)	9.20
	Surface deposits (95th percentile)	0.32
	Entry into treated crops (95th percentile)	-

An acceptable risk was determined for the bystander (adult and/or child).

3.4.5 Resident exposure

Resident exposure was assessed according to the EFSA model without mitigation measures, a distance of 3 metres from the spray boom and no drift reduction technology was considered.

Model data		Cypermethrin
		% AOEL
Scenario: Vehicle-mounted, granule, broadcast application Buffer zone: 2-3 (m) Drift reduction technology: no Number of applications : 2 Interval between treatments: 21 days		
DT_{50}		30 days
DFR		3 µg/cm²/kg a.s./ha
Resident (children) Body weight: 10 kg	Spray drift (75th percentile)	-
	Vapour (75th percentile)	42.80
	Surface deposits (75th percentile)	1.12
	Entry into treated crops (75th percentile)	-
	All pathways (mean)	-
Resident (adults) Body weight: 60 kg	Spray drift (75th percentile)	-
	Vapour (75th percentile)	9.20
	Surface deposits (75th percentile)	0.16
	Entry into treated crops (75th percentile)	-
	All pathways (mean)	-

An acceptable risk was determined for resident (adult and/or child).

3.4.6 Combined exposure

Not relevant.

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

The data available are considered sufficient for risk assessment for sweet corn and maize.

An exceedance of the current MRLs of 0.05* mg/kg on sweet corn and of of 0.3 mg/kg on maize for cypermethrin as laid down in Reg. (EU) 396/2005 is not expected.

The chronic intake of cypermethrin residues might present a public health concern.
As cypermethrin MRLs are currently being reviewed, FR zRMS cannot finalize the risk assessment for this product.

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

Information on SBM 13/048 (KCA 6.8)

Crop	PHI for SBM 13/048 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for SBM 13/048 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Cypermethrin		
Maize	14	No	Grain: 90 days Silage: 42 days	Based on residue trials
Sweet corn	14	Yes	-	

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for SBM 13/048
Crop group	Led by cypermethrin	
None	-	

3.6 NR: not relevantEnvironmental 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. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substance and its metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of cypermethrin and its 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.
PEC soil and PECsw derived for the active substance and its metabolites are not acceptable and not used for the ecotoxicological risk assessment. RMS has some concerns on the crop interception values that have been considered in soil and surface water exposure calculations since the formulated product SHERPA 2 G C (SBM 13/048) is a micro-granular formulation. **The crop interception factors are designed for spray drift applications (Beinum and Beulke, 2010; Olesen and Jensen, 2013). The use of these values in exposure calculations for broadcast microgranular application is hence questionable and might not be appropriate for regulatory purposes without any further detailed justification or additional data.** See section B8 for further details.
PECgw for cypermethrin and its metabolites do not occur at levels exceeding those mentioned in regulation EU No 546/2011. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

3.7 Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses. 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 and its metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The exposure levels related to the intended uses of the product SHERPA 2 G C (SBM 13/048), provided by the applicant cannot be used. Indeed, the crop interception value used for the cypermethrin's exposure calculations corresponds to a validated value for spray application (EFSA, 2014[11]), and its extrapolation to the mode of application of the product SHERPA 2 G C (SBM 13/048) (microgranules foliar application) has not been demonstrated. Therefore, the risk assessment for non-target terrestrial (birds, mammals and soil organisms) and aquatic organisms cannot be finalized.

Considering the mode of application of the product SHERPA 2 G C (SBM 13/048) (microgranules foliar application in the leaf axils and the horn of corn plant), and given the non-systemic nature of the active substance cypermethrin, the exposure to bees and non-target terrestrial plants is considered negligeable. Mitigation measures are required for bees.

The exposure levels estimated for non-target arthropods other than bees are higher than the toxicity reference value. The higher-tier study provided by the applicant for refining risk assessment cannot be used. Indeed, the applicant did not demonstrate that the mode of application used in this higher-tier study can be extrapolated to the indended uses and mode of application of SHERPA 2 G C (SBM 13/048) (microgranules foliar application). Thus, the risk assessment for non-target arthropods other than bees cannot be finalized.

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)

SHERPA 2 G C (SBM 13/048) contains cypermethrin active substance approved as a candidate for substitution due to a significant proportion of non-active isomers.
Step 1 (French guidance document 27 July 2015) :

- Taking into account minor uses according to the French National Plant Protection Uses Catalogue: In accordance with Articles 50(1)(d) 50.1(d) and 51 of Regulation (EC) No 1107/2009, in the framework of the consideration of minors uses, product substitution is not considered for use on the following crop: Sweet corn

[11] European Food Safety Authority, 2014. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., doi:10.2903/j.efsa.2014.3662

- Taking into account the management of resistance in accordance with Articles 50(1)(c) of Regulation (EC) No 1107/2009: As the number of alternative modes of action is not sufficient, the substitution is not considered for use on the following crop: Maize

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

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

5.1.1 Post-authorisation monitoring

It should be put in place monitoring of resistance to cypermethrin (one monitoring for all products based on cypermethrin) for *Ostrinia nubilalis*.
A report on the results of the monitoring put in place should be provided at the time of the demand of renewal for the product.

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation renewal

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.

SBM COMPANY

SHERPA® 2 GC

INSECTICIDE

UFI Code : 11G9-2SY7-G300-1C68

LUTTE CONTRE LA PYRALE DU MAÏS

Autorisation de Mise sur le Marché (A.M.M.) N° 8600664

Composition : Microgranulés (MG) Cyperméthrine : 0,2% p/p (2g/kg)

FABRIQUÉ EN FRANCE

QUANTITE NETTE : xx KG

Informations réglementaires
Nom commercial: SHERPA® 2 GC - AMM n°8600664.
®: Marque enregistrée SBM Développement
Détenteur et emballeur :
SBM Développement SAS, 60 Chemin des Mouilles – 69130 Ecully – France

USAGE EXCLUSIVEMENT PROFESSIONNEL

Distribué par xxxxx

Le n° de lot et la date de conditionnement sont indiqués sur l'emballage.

PREMIER SECOURS

S'éloigner de la zone dangereuse

En cas de contact cutanée : enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet. En cas d'irritation ou éruption cutanée, consulter un spécialiste.

En cas de projection dans les yeux : rincer abondamment pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Consulter un médecin.

En cas d'inhalation : en cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre antipoison.

En cas d'ingestion : rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir sans avis médical. Contacter sans délai les secours : le 15, le 112 ou un centre antipoison.
Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité.
En cas d'intoxication animale, contacter votre vétérinaire.

MODE D'ACTION – propriétés

SHERPA® 2 GC est un insecticide microgranulé, à base de cyperméthrine (Famille des pyréthrinoïdes (IRAC 3A)), et actif par contact et ingestion. Il présente une forte action de choc et une longue persistance d'action. Sa formulation microgranulés évite la formation de poussière lors de l'application localisée.

USAGES ET DOSES HOMOLOGUÉS

Usage homologué	Cultures couvertes	Ravageurs ciblés	Application		Dose	Délai avant récolte
			Nombre	Stade		
Maïs*Trt Parties aériennes*Pyrale	Maïs	Pyrale (Chenilles phytophages)	2*	BBCH 51-55	15 kg/ha	14 jours
Maïs doux*Trt Parties aériennes*Pyrale	Maïs doux	Pyrale (Chenilles phytophages)	2*	BBCH 51-55	25 kg/ha	14 jours

* Intervalle minimum entre les applications : 21 jours
L'utilisation du produit n'est préconisée que sur les cultures et cibles mentionnées dans le tableau des usages et, à ce titre, décline toute responsabilité concernant l'élargissement de son utilisation à d'autres usages tels que permis par la mise en œuvre du catalogue des usages (Arrêté du 12 avril 2021). L'utilisateur est mis en garde contre les risques éventuels de phytotoxicité et de manque d'efficacité pour toute utilisation sur des cultures non préconisées.

RECOMMANDATIONS D'EMPLOI

Appliquer SHERPA® 2 GC en traitement 1ère génération entre le début de floraison et 50% des panicules mâles visibles dans le cornet (en fonction des bulletins de santé du végétal). Dans tous les cas, intervenir au plus tard au stade pré-floraison « 50% des panicules mâles visibles ».

SHERPA® 2 GC est formulé pour maximiser l'efficacité contre les foreurs du maïs tout en minimisant les risques de pullulation de pucerons. Toutefois un risque de pullulation des populations de pucerons peut survenir suite à l'emploi de pyréthrinoïdes : surveiller l'évolution de ces populations et réaliser un traitement aphicide si nécessaire.

MODE D'UTILISATION

SHERPA® 2 GC s'applique directement sur la culture, sans dilution préalable, à l'aide d'enjambeurs. SHERPA® 2 GC est utilisable dans tous les types d'appareils destiné à l'épandage de granulés. Afin d'assurer une application de précision, homogène et régulière des microgranulés sur les rangs, le microgranulateur doit être obligatoirement équipé de diffuseur queue de carpe.

MISE EN ŒUVRE ET BONNES PRATIQUES

Stockage du produit

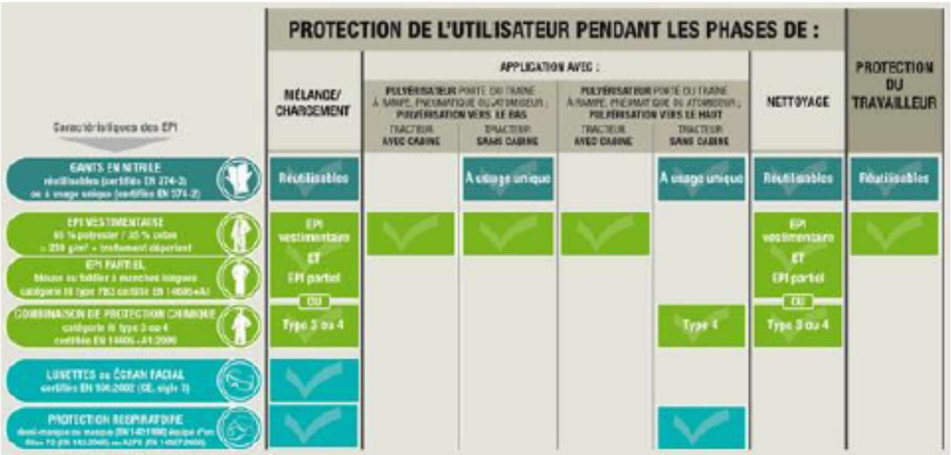
Conserver SHERPA® 2 GC dans son emballage d'origine, hermétiquement fermé, à l'abri de la lumière, à température ambiante, dans un endroit sec, aéré et fermant à clé.

Protection de l'opérateur et du travailleur

Il convient de rappeler que 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 complémentaires comme les protections individuelles. En tout état de cause, 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 étapes successives d'habillage/déshabillage doivent être évitées au maximum. Les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Ne pas manger, boire, téléphoner ou fumer lors de l'utilisation du produit.

Eviter le contact de ce produit à base de pyréthrinoïdes avec la peau, les pyréthrinoïdes étant susceptibles de provoquer des paresthésies. Porter des gants à usage unique lors d'une intervention extérieure au cours de l'application.



Rapporter les équipements de protection individuelle (EPI) usagés dans un sac translucide, à votre distributeur partenaire ECO EPI ou faire appel à une entreprise habilitée pour la collecte et l'élimination de produits dangereux.

Elimination du produit, de l'emballage

Réemploi de l'emballage interdit.
Apporter les emballages vidés et pliés à votre distributeur partenaire d'A.D.I. VALOR ou à un autre service de collecte spécifique. Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Interroger votre distributeur partenaire d'A.D.I. VALOR ou faire appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux.

IMPORTANT : Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez sur ces bases, la culture et les traitements selon les bonnes pratiques agricoles en tenant compte, sous votre responsabilité, de tous les facteurs particuliers concernant votre exploitation tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces... Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine, ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture.

SHERPA® 2 GC - AMM n° 8600664 – SBM Développement S.A.S
Composition : Microgranulés (MG) Cyperméthrine : 0,2% p/p (2g/kg)

H410	**Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.**
P102	Tenir hors de portée des enfants.
P262	Eviter tout contact avec les yeux, la peau ou les vêtements
P273	Éviter le rejet dans l'environnement.
P280	Porter des gants de protection et des vêtements de protection.
P391	Recueillir le produit répandu.
P501	Éliminer le contenu/récipient dans un centre de collecte de déchets agréé conformément à la réglementation locale/régionale/nationale et/ou internationale.
EUH401	Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.
SP1	Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.
SPe3	Pour protéger les organismes aquatiques, respecter un dispositif végétalisé permanent non traité de 10 m en bordure des points d'eau pour le maïs doux.
SPe8	Dangereux pour les abeilles. Pour protéger les abeilles et autres insectes pollinisateurs, appliquer au plus tard au stade BBCH 55 (stade pré-floraison). Ne pas utiliser en présence d'abeilles.

Délai de rentrée des travailleurs sur la parcelle (DRE) : 6 heures.

En cas d'urgence, composez le 15 ou le 112 ou contacter le centre antipoison le plus proche.

Puis signalez vos symptômes au réseau Phyt'attitude, N° vert 0 800 887 887 (service & appel gratuits).

Fiche de Données de Sécurité disponible sur internet : wwwquickfds.fr

REEMPLOI DE L'EMBALLAGE INTERDIT

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Décision relative à une demande de renouvellement de l'autorisation de mise sur le marché d'un produit phytopharmaceutique

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 règlementaire,

Vu la demande de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active cyperméthrine, et les données fournies en réponse aux demandes de post-autorisation, du produit phytopharmaceutique ***SHERPA 2 G C***

de la société	*SBM DEVELOPPEMENT*
enregistrées sous les	*n° 2014-2806 et 2022-1416*

Vu les conclusions de l'évaluation de l'Anses du 11 janvier 2024,

Considérant qu'un risque d'effet inacceptable pour les espèces non cibles terrestres (oiseaux, mammifères, arthropodes, et organismes du sol) et aquatiques, lié à l'utilisation du produit, ne peut être exclu,

Considérant par ailleurs qu'un risque d'effet nocif pour le consommateur, lié à l'utilisation du produit, ne peut être exclu,

Considérant qu'en conséquence, les exigences mentionnées à l'article 29 du règlement (CE) n° 1107/2009 ne sont plus remplies,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas renouvelée** en France.

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Informations générales sur le produit	
Nom du produit	SHERPA 2 G C
Type de produit	Produit de référence
Titulaire	SBM DEVELOPPEMENT 60 chemin des Mouilles 69130 ECULLY France
Formulation	Microgranulé (MG)
Contenant	2 g/kg - cyperméthrine
Numéro d'intrant	8600664
Numéro d'AMM	8600664
Fonction	Insecticide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 02/08/2024

DocuSigned by:
Charlotte Gratilleur
AE281A955A42454...

Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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ANNEXE : Conditions de mise sur le marché

Liste des usages retirés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Délai accordé pour la vente et la distribution	Délai accordé pour le stockage et l'utilisation des stocks
16663103 Maïs doux*Trt Part.Aer.*Chenilles phytophages	25 kg/ha	2/an	14	6 mois à compter de la présente décision	18 mois à compter de la présente décision
	Motivation du retrait : L'usage est retiré car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les espèces non cibles terrestres (oiseaux, mammifères, arthropodes, et organismes du sol) et aquatiques, ni un risque d'effet nocif pour les consommateurs.				
15553101 Maïs*Trt Part.Aer.*Pyrale(s)	15 kg/ha	2/an	14	6 mois à compter de la présente décision	18 mois à compter de la présente décision
	Motivation du retrait : L'usage est retiré car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les espèces non cibles terrestres (oiseaux, mammifères, arthropodes, et organismes du sol) et aquatiques, ni un risque d'effet nocif pour les consommateurs.				