REGISTRATION REPORT

Part A

Risk Management

Product code: 102000028980

Product name: BOTAVER (102000028980)

Chemical active substances:

Pyrethrins, 4.2 g/L

Azadirachtin, 4.1 g/L

Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: SBM DEVELOPPEMENT SAS

Date: 22/05/2019

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PART A
RISK MANAGEMENT

1 Details of the application

The company SBM DÉVELOPPEMENT SAS has requested marketing authorisation in France for the product BOTAVER (formulation code: 102000028980), containing 4.2 g/L pyrethrins and 4.1 g/L azadirachtin [LJ1]A for use as an insecticide for non-professional uses.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to BOTAVER (102000028980) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of BOTAVER (102000028980) have been made using endpoints agreed in the EU peer reviews of pyrethrins and azadirachtin.

This document describes the specific conditions of use and labelling required for France for the registration of BOTAVER (102000028980).

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

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

Appendix 3 of this document is a copy of the letter(s) of Access.

1.1 Application background

The present registration report concerns the evaluation of SBM DÉVELOPPEMENT SAS's application to market BOTAVER (102000028980) in France as an insecticide (product uses described under point 2.3). France acted as an interzonal and zonal Rapporteur Member State (izRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the European Union.

The present application (2016-3721) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone for field uses and for all Member States of the European Union for greenhouse uses, taking into account the worst-case uses ("risk envelope approach")[1] – the highest application rates over the Southern zone for field uses and the European Union for greenhouse uses. When risk mitigation measures were necessary, they are adapted to the situation in France.

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[2], 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.

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[1] SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

[2] 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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[3], and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

1.2 Letters of Access

The applicant has provided letters of access for active substances and product data.

1.3 Justification for submission of tests and studies

Justification not submitted by the applicant.

1.4 Data protection claims

. Where protection for data is being claimed for information supporting registration of BOTAVER (102000028980), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	102000028980
Product name in MS	BOTAVER
Authorisation number	2190143
Low risk (article 47)	No
Function	Insecticide
Applicant	SBM DÉVELOPPEMENT SAS
Active substances (incl. content)	Pyrethrins, 4.2 g/L Azadirachtin, 4.1 g/L
Formulation type	Emulsionable Concentrate [EC]
Packaging	HDPE: 125 mL, 250 mL, 500 mL HDPE/PA: 125 mL, 250 mL, 500 mL HDPE/EVOH: 125 mL, 250 mL, 500 mL non-professional user
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

[3] 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

2.2 Conclusion

The evaluation of the application for BOTAVER (102000028980) resulted in the decision to grant the authorization.

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 classes, categories:	Skin Sens. 1A Aquatic Chronic 1
Hazard pictograms:	
Signal word:	Warning
Hazard statements:	H317 : May cause an allergic skin reaction. H410 : Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the extant legislation***
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

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

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

	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 4th May 2017 [4] provides that:

[4] 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

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally 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, drift buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 26 March 2014[5] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] 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.

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
-	
Worker protection:	
-	
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
	Do not discharge into the sink, gutter or any other water hole the non-used container leftovers and the sprayer washing water.
	Do not treat when bees and beneficial organisms are visiting the area.
Other specific restrictions	
Re-entry period	Wait for complete drying of the treated area.
Storage	Do not store in a room where temperatures may exceed 40 °C.
Risk mitigation measures	- Do not use the by-products of ornamental crops for human or animal consumption.

[5] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo
[6] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

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:
When the conclusion is "not acceptable"", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 1, date: 2019-05-22

PPP (product name/code):	BOTAVER (102000028980)	Formulation type:	EC [a, b]
Active substance 1:	Pyrethrins	Conc. of as 1:	4.2 g/L [c]
Active substance 2:	Azadirachtin	Conc. of as 2:	4.1 g/L [c]
Applicant:	SBM DÉVELOPPEMENT SAS	Professional use:	☐
Zone:	Interzonal [d]	Non professional use:	☒
Verified by MS:	**Yes**		

Field of use: Insecticide

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:** **izRMS conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

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:** **izRMS conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or 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	S-Zone: FR, PT, IT	Apple	Fn	Aphids	Foliar spray	69-75	a) 2	4	a) 5	a) 0.0210 Py/ha + 0.0205 Aza/ha	500 L/ha/m Canopy Height	-	**Not acceptable** (Risk for consumer, groundwater and non-target species)
2	S-Zone: FR, PT, IT	Tomato	Fn	Lepidoptera	Foliar spray	10-89	a) 2	4	a) 7.5	a) 0.0315 Py/ha + 0.0308 Aza/ha	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	3	**Not acceptable** (Risk for consumer, groundwater and non-target species,
3	S-Zone: FR, PT, IT	Potato	Fn	Colorado PB	Foliar spray	10-85	a) 2	4	a) 6	a) 0.0252 Py/ha + 0.0246 Aza/ha	Max. 1200 L/ha	-	**Not acceptable** (Risk for consumer, groundwater and non-target species)
4	S-Zone: FR, PT, IT	Roses	Fn	Aphids	Foliar spray	31 - 89	a) 4	4	a) 7.5	a) 0.0315 Py/ha + 0.0308 Aza/ha	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	-	**Not acceptable** (risk for groundwater and non-target species)
5	S-Zone: FR, PT, IT	Ornamentals (green plants et flower crops)	Fn	Aphids	Foliar spray	31 - 89	a) 4	4	a) 7.5	a) 0.0315 Py/ha + 0.0308 Aza/ha	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	-	**Not acceptable** (risk for groundwater and non-target species)
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													

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:** **izRMS conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
6	S-Zone: FR, PT, IT	Tomato~~,~~	Gn	Spider mites,	Foliar spray	10-89	a) 2	4	7.5	a) 0.0315 Py + 0.0308 Aza	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	3	**Not acceptable** (risk for the consumer and for groundwater)
7	S-Zone: FR, PT, IT	Tomato~~,~~	Gn	Whiteflies	Foliar spray	10-89	a) 2	4	7.5	a) 0.0315 Py + 0.0308 Aza	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	3	**Not acceptable** (risk for the consumer and for groundwater)
8	S-Zone: FR, PT, IT	Tomato Eggplant	Gn	Aphids	Foliar spray	10-89	a) 2	4	7.5	a) 0.0315 Py + 0.0308 Aza	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	3	**Not acceptable** (risk for the consumer and for groundwater)
9	S-Zone: FR, PT, IT	Tomato~~,~~	Gn	Lepidoptera	Foliar spray	10-89	a) 2	4	7.5	a) 0.0315 Py + 0.0308 Aza	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	3	**Not acceptable** (risk for the consumer, and for groundwater)
10	S-Zone: FR, PT, IT	Cucumber Cucumber, Zuchini	Gn	spider mites,	Foliar spray	10-89	a) 2	4	7.5	a) 0.0315 Py + 0.0308 Aza	900 (< 50cm) 1200	3	**Not acceptable** (risk for the consumer and for groundwater)

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:** **izRMS conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
											(50-125cm) 1500 (>125cm)		
11	S-Zone: FR, PT, IT	Cucumber Cucumber, Zuchini	Gn	, whiteflies	Foliar spray	10-89	a) 2	4	7.5	a) 0.0315 Py + 0.0308 Aza	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	3	**Not acceptable** (risk for the consumer and for groundwater)
12	S-Zone: FR, PT, IT	Cucumber Cucumber, Zuchini	Gn	Aphids	Foliar spray	10-89	a) 2	4	7.5	a) 0.0315 Py + 0.0308 Aza	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	3	**Not acceptable** (risk for the consumer and for groundwater)
13	S-Zone: FR, PT, IT	Roses	Gn	Aphids	Foliar spray	10-89	a) 4	4	7.5	b) 0.0315 Py + 0.0308 Aza	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	-	**Acceptable** Only in non-soil crops
14	S-Zone: FR, PT, IT	Roses	Gn	Spider mites	Foliar spray	10-89	a) 4	4	7.5	b) 0.0315 Py + 0.0308 Aza	900 (< 50cm) 1200 (50-125cm) 1500	-	**Acceptable** Only in non-soil crops

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:** **izRMS conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
											(>125cm)		
15	S-Zone: FR, PT, IT	Roses	Gn	Whiteflies	Foliar spray	10-89	a) 4	4	7.5	b) 0.0315 Py + 0.0308 Aza	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	-	**Acceptable** Only in non-soil crops
16	S-Zone: FR, PT, IT	Ornamentals (green plants et flower crops)	Gn	Aphids	Foliar spray	10-89	a) 4	4	7.5	b) 0.0315 Py + 0.0308 Aza	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	-	**acceptable** Only in non-soil crops
17	S-Zone: FR, PT, IT	Ornamentals (green plants et flower crops)	Gn	Whiteflies	Foliar spray	10-89	a) 4	4	7.5	b) 0.0315 Py + 0.0308 Aza	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	-	**acceptable** Only in non-soil crops
18	S-Zone: FR, PT, IT	Ornamentals (green plants et flower crops)	Gn	Spider mites, mites	Foliar spray	10-89	a) 4	4	7.5	b) 0.0315 Py + 0.0308 Aza	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	-	**acceptable** Only in non-soil crops

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:** **izRMS conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
19	S-Zone: FR, PT, IT	Ornamentals (house plants and balconies)	I, Gn	Spider mites	Foliar spray	10-89	a) 4	4	7.5	b) 0.0315 Py + 0.0308 Aza	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	-	Acceptable Only in non-soil crops
20	S-Zone: FR, PT, IT	Ornamentals (house plants and balconies)	I, Gn	Whiteflies	Foliar spray	10-89	a) 4	4	7.5	b) 0.0315 Py + 0.0308 Aza	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	-	Acceptable Only in non-soil crops
21	S-Zone: FR, PT, IT	Ornamentals (house plants and balconies)	I, Gn	Aphids	Foliar spray	10-89	a) 4	4	7.5	b) 0.0315 Py + 0.0308 Aza	900 (< 50cm) 1200 (50-125cm) 1500 (>125cm)	-	Acceptable Only in non-soil crops

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.

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)

BOTAVER (102000028980) is an emulsifiable concentrate (EC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a yellow slightly turbid homogeneous liquid, with a weak oily odour. It is not explosive and has no oxidising properties. The product has a flash point of 230 °C and a self-ignition temperature of 375 °C. In 1 % aqueous solution, it has a pH value around 6.1 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 8 weeks at 40 °C, neither the active substances' content nor the technical properties were changed. The stability data indicate a shelf life of at least one year at ambient temperature when stored in HDPE. As the stability was demonstrated in HDPE packaging, HDPE/PA and HDPE/EVOH packaging can be considered acceptable. A two years stability study at ambient temperature is under progress and will be submitted when the report will be available in March 2019. Its technical characteristics are acceptable for an EC formulation.

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

The formulation must be stored at a temperature below 40 °C.

3.2 Efficacy (Part B, Section 3)

Considering the data provided:

- The efficacy of BOTAVER (102000028980) is considered acceptable for all intended uses.
- The risk of phytotoxicity of BOTAVER (102000028980) is considered acceptable.
- A specific attention should be paid regarding the use of BOTAVER (102000028980) in the frame of IPM programs.
- The risk of resistance appearance or development does not require a monitoring for the claimed uses.

3.3 Methods of analysis (Part B, Section 5)

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

No analytical method for the determination of relevant impurities of azadirachtin in the formulation was submitted, and is required.

Analytical methods are available in the Draft Assessment Report (DAR) and this dossier, and validated for the determination of azadirachtin residues in plants (apple, tomato, eggplant, potato, cucumber and zucchini), soil, water (surface and drinking) and air.

Analytical methods are available in the DAR and this dossier and validated for the determination of pyrethrins residues in soil, water (surface and drinking) and air.

As MRLs were set, analytical methods for the determination of pyrethrins and azadirachtin residues in foodstuffs of animal origin will be required during the renewal process of these substances.

Analytical methods for the determination of pyrethrins and azadirachtin residues in tissues and biological

fluids will also be required during the renewal process.

3.4 Mammalian toxicology (Part B, Section 6)

The endpoints used in risk assessment are shown below:

Active substance: **azadirachtin**			
ADI	0.1 mg kg bw/d		UE (2011)
ARfD	0.75 mg/kg bw		
AOEL	0.1 mg/kg bw/d		
Dermal absorption	Based default values according to guidance on dermal absorption (EFSA 2012):		
		Concentrate (used in formulation) 4.1 g/L	Spray dilution (used in formulation) 0.02 g/L
	Dermal absorption endpoints %	**75 %**	**75 %**

Active substance: **pyrethrins**			
ADI	0.04 mg kg bw/d		EU (2009)
ARfD	0.2 mg/kg bw		
AOEL	0.07 mg/kg bw/d		
Dermal absorption	Based default values according to guidance on dermal absorption (EFSA 2012):		
		Concentrate (used in formulation) 4.2 g/L	Spray dilution (used in formulation) 0.02 g/L
	Dermal absorption endpoints %	**75 %**	**75 %**

3.4.1 Acute toxicity

BOTAVER (102000028980) has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and a skin sensitizer.

3.4.2 Operator exposure

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

Crop	F/G[7]	Equipment	Application rate L product/ha	Spray dilution	Model
Vegetables	F	Pre-pressure sprayer	7.5 L/ha	900 L/ha	UPJ
Ornamentals / Apple	F	Pre-pressure sprayer	7.5 L/ha	500 L/ha	UPJ

Considering proposed uses, operator systemic exposure was estimated using the French study from UPJ 2009-2010[8] dedicated to non-agricultural areas:

[7] Open field or glasshouse

[8] 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

Crop	Equipment	PPE and/or working coverall	% AOEL pyrethrins	% AOEL azadirachtin
Vegetables	Pre-pressure sprayer	No PPE	21	14
Ornamentals / Apple	Pre-pressure sprayer		21	14

According to the model calculations, it may be concluded that the risk for the operator using BOTAVER (102000028980) is acceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application.

3.4.3 Worker exposure

BOTAVER (102000028980) is intended to be used by non-professionals during home garden application. In this case, the worker is also the user of the product. It will be necessary to ensure complete drying of the treated area or of treated plants before handling them.

3.4.4 Bystander exposure

For a product intended to non-professional users, it is considered that the assessment for bystanders is covered by that for the operator.

3.4.5 Combined exposure

A cumulative assessment for operators and bystanders has been performed. At the first tier, combined exposure was calculated as the sum of the components exposures without regard to the mode of action or mechanism/target of toxicity.

Hazard quotients (HQ) for each active substance and the hazard index (HI: sum of hazard quotients) are reported below.

Model data	**Active substance**	**PPE**	**Total absorbed dose (mg/kg/day)**	**Estimated exposure / AOEL* (HQ)**
Operator Low crop spraying UK-POEM Body weight: 60 kg	pyrethrins	No PPE[1)]	0.0081	0.12
	azadirachtin	No PPE[1)]	0.0079	0.08
	Cumulative risk Operators (HI)			**0.20**
Operator Low crop spraying French home garden Body weight: 60 kg	pyrethrins	No PPE[1)]	0.0143	0.20
	azadirachtin	No PPE[1)]	0.0140	0.14
	Cumulative risk Operators (HI)			**0.34**
Operator High crop spraying French home garden Body weight: 60 kg	pyrethrins	No PPE[1)]	0.0148	0.20
	azadirachtin	No PPE[1)]	0.0144	0.14
	Cumulative risk Operators (HI)			**0.34**

The Hazard Index is < 1. Thus combined exposure to both active substances in BOTAVER (102000028980) is not expected to present a risk for operators or bystanders.

Residues and consumer exposure (Part B, Section 7)

The data available are considered sufficient for risk assessment purposes. Any exceedance of the current MRLs for pyrethrins and azadirachtin is not expected.

The chronic and acute intakes are unlikely to present a public health concern regarding the provisional residue definition for both active substances.

According to the available data, the following specific mitigation measure is recommended: apple pomace and potatoes should not be fed to livestock.

Confirmatory data regarding uncertainties were further submitted and assessed for both active substances. However, no firm conclusion may be reach for the intended uses of the preparation BOTAVER (102000028980).

Data gap for azadirachtin: metabolism and feeding studies covering the dietary burden of livestock.

Toxicological reference values for the dietary risk assessment of pyrethrins and azadirachtin:

Reference value	Source	Year	Value	Study relied upon	Safety factor
Pyrethrins					
ADI	EFSA	2013	0.04 mg/kg bw/day[1]	Rat, long-term toxicity	100
ARfD	EFSA	2013	0.2 mg/kg bw[1]	Rat, acute neurotoxicity	100
Azadirachtin A					
ADI	EFSA	2011	0.1 mg/kg bw/day	Rat, 90-day (Trifolio and Sipcam extracts)	300[2]
ARfD	EFSA	2011	0.75 mg/kg bw	Rat, teratogenicity (Trifolio extract)	300[3]

[1] The ADI and ARfD values are referring to the extract containing 57 % of pyrethrins (mixture including 6 components)

[2] Higher safety factor to account for missing long term/carcinogenicity studies and developmental study in rabbit with Trifolio and Sipcam sources

[3] Higher safety factor to account for missing developmental study in rabbit with Trifolio and Sipcam sources.

3.4.5.1 Summary for Pyrethrins

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Apple	Yes	Yes	Yes	No	Yes	Not possible to conclude	Not possible to conclude
2	Potato	Yes	Yes	Yes	Yes	Yes		
3	Tomato	Yes	Yes	Yes	Yes	Yes		
4	Aubergine	Yes	Yes	Yes	Yes	Yes		
5	Cucumber	Yes	Yes	Yes	Yes	Yes		
6	Zucchini	Yes	Yes	Yes	Yes	Yes		
7	Roses + Ornamentals	Not relevant for dietary risk assessment						

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

As pyrethrins residues do not exceed the trigger values defined in Regulation (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Since residue definitions in plants are still provisional, dietary burden as well as consumer risk assessment was not conducted for pyrethrins. Therefore the risk assessment regarding the intended uses cannot be finalized.

Considering that:

- **Confirmatory data were not considered sufficient by EFSA to address in general the fate of the pyrethrolone moiety or the hydroxy-chrysanthemic acid metabolites in treated crops and to demonstrate that metabolites residues would be regularly below LOQ or not even formed**.
- **Information on the toxicity (including genotoxicity) of the metabolites was not considered sufficient by EFSA to conclude on their toxicological profile**.

EFSA considered that a firm conclusion on the consumer risk assessment is still not possible and further evidence is necessary to ascertain the actual exposure and risk potential for the consumer related to the use of pyrethrins (EFSA, 2017).

Therefore the risk assessment regarding the intended uses cannot be finalized.

3.4.5.2 Summary for azadirachtin

Use-No.	Crop	Plant metabolism covered?*	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Apple	No	Yes	Yes	Yes	Yes	No	No
2	Potato	No	Yes	Yes	Yes	Yes		No
3	Tomato	No	Yes	Yes	Yes	Yes		No
4	Aubergine	No	Yes	Yes	Yes	Yes		No
5	Cucumber	No	Yes	Yes	Yes	Yes		No
6	Zucchini	No	Yes	Yes	Yes	Yes		No
7	Roses + Ornamentals	Not relevant for dietary risk assessment						

As residues of azadirachtin do not exceed the trigger values defined in Regulation (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

The threshold of 0.004 mg/kg body weight/day is exceeded for all ruminants and for poultry. However, neither livestock metabolism nor feeding study is available. Without additional data, RMS is of opinion that by products should not be fed to livestock to avoid any exposure.

Based on the available confirmatory data, azadiracthin A may be considered as a relevant analytical marker component to characterize residue levels in field samples (Addendum 08, confirmatory information, DE, Sept.2017). Therefore, France has used the same approach in this evaluation as RMS DE which means that the evaluation is performed considering azadirachtin A as the main compound. However these data were only assessed by RMS but not peer reviewed by EFSA.

3.4.5.3 Summary for BOTAVER (102000028980)

Crop	PHI for BOTAVER (102000028980) proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for BOTAVER (102000028980) proposed by izRMS
		pyrethrins	azadirachtin	
Apple	F	Y	Y	F
Potato	F	Y	Y	F
Tomato	3	Y	Y	3
Aubergine	3	Y	Y	3
Cucumber	3	Y	Y	3
Zucchini	3	Y	Y	3

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).

3.5 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. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for 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.

For **home** uses, exposure of environmental compartments to the active substances can be considered negligible. Therefore, no additional risk assessment for environment and non-target organisms is deemed necessary.

For other non-professional uses (i.e. greenhouse, walk-in tunnel or in-filed), the conclusions of risk assessment are reported below.

3.5.1.1 Azadirachtin

Note that according to the EU review of azadirachtin, further data on the relationship between azadirachtin A and other active components in the neem seeds extract with respect to amount, biological activity and persistence, shall be submitted in order to confirm the lead active compound approach with regard to azadirachtin A and to confirm specification of the technical material. No such data were submitted by the applicant. **Therefore, the risk exposure for all intended uses cannot be finalized**. However, a provisional risk assessment based on azadirachtin A and its metabolite azadirachtin H* has been conducted (see below).

Considering home and garden uses, risk assessment for soil organisms is not deemed necessary.

PECsw values based on the basic drift values (BBA) derived for azadirachtin A can be used for the ecotoxicological risk assessment. However, no conclusions can be drawn for other potential components that may be formed. **Therefore, the risk assessment for all intended uses cannot be finalized (for more detail, please refers to RR part B/ section 8)**.

PECgw values for azadirachtin A and its metabolite azadirachtin H* do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000 on

metabolites in groundwater.

Therefore, no unacceptable risk of groundwater contamination by azadirachtin A and its metabolite azadirachtin H* is expected for the intended uses. **However, no conclusions can be drawn for other potential components that may be formed. Therefore, the risk assessment for all intended uses cannot be finalized (for more detail, please refers to RR part B/ section 8)**.

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 azadirachtin A within the intended uses.

3.5.1.2 Pyrethrins

According to RMS Italy, confirmatory data assessed in addendum of July 2016 demonstrate that pyrethrin 1 is representative with respect to the environmental assessment of all pyrethrins components. However, for pyrethrin 1, studies are available only with material labelled at the cyclopropane ring only. Therefore, a data gap has been identified to address the fate and behaviour of the cyclopentelone moiety after the rupture of the ester bridge in the pyrethrins (normally first degradation step). Despite RMS' request, this data gap has not been addressed in the current submission. Therefore in agreement with EFSA conclusions, France consider that the environmental risk assessment cannot be finalized based on the available data.

Considering home and garden uses, risk assessment for soil organisms is not deemed necessary.

PECsw values based on the basic drift values (BBA) derived for pyrethrin 1 can be used for the ecotoxicological risk assessment. **However, since complete information on the fate and behaviour of pyrethrins in soil is not available, it is considered that the groundwater assessments cannot be finalized (for more detail, please refers to RR part B/ section** 8).

PECgw values for pyrethrin 1 were < 0.001 µg/l. According to the confirmatory data evaluated by RMS Italy, they cover all pyrethrins (pyrethrin 1, cinerin 1, jasmolin 1, pyrethrin 2, cinerin 2, and jasmolin 2). There is therefore no unacceptable risk of groundwater contamination by pyrethrins for the intended uses. **However, since complete information on the fate and behaviour of pyrethrins in soil is not available, it is considered that the groundwater assessments cannot be finalized (for more detail, please refers to RR part B/ section 8**).

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 pyrethrin 1 within the intended uses.

3.6 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 substances were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Given the non-professional uses of BOTAVER (102000028980), the exposure of mammals, bees and other non-target arthropods, earthworms and other soil macro-organisms, soil micro-organisms and non-target terrestrial plants is considered negligible. In addition, the exposure of birds and aquatic organisms is considered negligible for the intended uses of BOTAVER (102000028980) in non-professional glasshouse and at home. Since BOTAVER (102000028980) is an insecticide, the following precaution statement shall be reported: Do not treat when bees and beneficial organisms are visiting the area.

Based on the guidance documents, the risks for birds from pyrethrins are acceptable for the intended non-professional field uses of BOTAVER (102000028980).

For aquatic organisms, the available data in the environmental fate section are not sufficient to determine a complete degradation scheme in water for pyrethrins. Therefore, the risk assessment of pyrethrins for aquatic organisms cannot be finalized for the non-professional field uses as it is not possible to determine that all the metabolites of pyrethrins have been identified.

For azadirachtin, a provisional risk assessment for birds and aquatic organisms based on azadirachtin A and its metabolite **has been conducted for the intended non-professional field uses.**

Based on the guidance documents, the risks for birds and aquatic organisms would be acceptable for the intended non-professional field uses.

However, according to the EU review of azadirachtin, further data on the relationship between azadirachtin A and the rest of the active components in the neem seeds extracts with respect to amount, biological activity and persistence, shall be submitted in order to confirm the lead active compound approach with regard to azadirachtin A and to confirm specification of the technical material. The confirmatory data have been submitted by the applicants and have been assessed by the RMS, but the peer review of these data at EU level is still ongoing. Pending this assessment, the risk assessment for azadirachtin is not finalized for the non-professional field uses.

3.7 Relevance of metabolites (Part B, Section 10)

Not relevant.

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

The active substances pyrethrins and azadirachtin are not approved as candidate of 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 Post-authorisation monitoring

None.

5.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 6 and 24 months respectively regarding:

- A validated analytical method for the determination of relevant impurities of azadirachtin in the product.

- The final report of the 2 years shelf-life study;

Appendix 1 Copy of the product authorisation

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Décision relative à une demande d'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 d'autorisation de mise sur le marché et les demandes associées du produit phytopharmaceutique ***BOTAVER***

de la société *SBM DEVELOPPEMENT*

enregistrées sous les *n°2016-3721, 2018-1582 et 2019-1129*

Vu les conclusions de l'évaluation de l'Anses du 12 mars 2019,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

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Informations générales sur le produit	
Nom du produit	BOTAVER
Type de produit	Produit de référence
Titulaire	SBM DEVELOPPEMENT 60 chemin des Mouilles, 69130 Ecully, France
Formulation	Concentré émulsionnable (EC)
Contenant	4,1 g/L - azadirachtine A 4,2 g/L - pyréthrines
Numéro d'intrant	925-2016.01
Numéro d'AMM	2190143
Fonction	Insecticide
Gamme d'usage	Amateur / emploi autorisé dans les jardins

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera 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 2023.

Le dépôt d'une demande de 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, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance 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.

Attention : à compter du 01/01/2019, la mise sur marché, la délivrance, l'utilisation et la détention des produits de la gamme d'usages « amateur » sont exclusivement réservées aux utilisateurs professionnels, en application de l'article L. 253-7-III du Code rural et de la pêche maritime, à l'exception des produits de la gamme amateurs inscrits sur la liste des produits de biocontrôle, des produits utilisables en agriculture biologique ou des produits à faible risque. Cette interdiction ne s'applique pas aux traitements et mesures nécessaires à la destruction et à la prévention de la propagation des organismes nuisibles mentionnés à l'article L. 251-3, en application de l'article L. 251-8 du même Code.

A Maisons-Alfort le, 22 MAI 2019

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)

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ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	**Contenance**
Bouteilles en polyéthylène haute densité munies d'une chambre de dosage	125 mL ; 250 mL ; 500 mL
Bouteilles en polyéthylène haute densité / éthylène alcool vinylique munies d'une chambre de dosage	125 mL ; 250 mL ; 500 mL
Bouteilles en polyéthylène haute densité / polyamide munies d'une chambre de dosage	125 mL ; 250 mL ; 500 mL

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Sensibilisants cutanés - Catégorie 1 sous-catégorie A	H317 : Peut provoquer une allergie cutanée
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
Pour les phrases P se référer à la règlementation 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.**	

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Liste des usages autorisés
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	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
17403101 Cultures florales et plantes vertes*Trt Part.Aer.* Acariens, phytoptes et tarsonèmes	**5 mL/L**	**4/an**	entre les stades BBCH 10 et BBCH 89	Non applicable	-	-	-	-
	Uniquement autorisé sous abri hors sol. L'usage en pleine terre est refusé en raison de l'absence de données permettant d'exclure un risque de contamination des eaux souterraines. Intervalle minimum entre les applications : 4 jours							
17403102 Cultures florales et plantes vertes*Trt Part.Aer.* Aleurodes	**5 mL/L**	**4/an**	entre les stades BBCH 10 et BBCH 89	Non applicable	-	-	-	-
	Uniquement autorisé sous abri hors sol. L'usage en pleine terre est refusé en raison de l'absence de données permettant d'exclure un risque de contamination des eaux souterraines. Intervalle minimum entre les applications : 4 jours							
17403104 Cultures florales et plantes vertes*Trt Part.Aer.* Pucerons	**5 mL/L**	**4/an**	entre les stades BBCH 10 et BBCH 89	Non applicable	-	-	-	-
	Uniquement autorisé sous abri hors sol. Les usages en plein champ et en pleine terre sous abri sont refusés en raison de l'absence de données permettant d'exclure un risque de contamination des eaux souterraines et un risque inacceptable pour les espèces non cibles. Intervalle minimum entre les applications : 4 jours							

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Liste des usages autorisés
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	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
00701016 Plantes d'intérieur et balcons*Trt Part.Aer.* Acariens	**5 mL/L**	**4/an**	entre les stades BBCH 10 et BBCH 89	Non applicable	-	-	-	-
	Intervalle minimum entre les applications : 4 jours							
00701017 Plantes d'intérieur et balcons*Trt Part.Aer.* Aleurodes	**5 mL/L**	**4/an**	entre les stades BBCH 10 et BBCH 89	Non applicable	-	-	-	-
	Intervalle minimum entre les applications : 4 jours							
00701020 Plantes d'intérieur et balcons*Trt Part.Aer.* Pucerons	**5 mL/L**	**4/an**	entre les stades BBCH 10 et BBCH 89	Non applicable	-	-	-	-
	Intervalle minimum entre les applications : 4 jours							
17303101 Rosier*Trt Part.Aer.* Acariens	**5 mL/L**	**4/an**	entre les stades BBCH 10 et BBCH 89	Non applicable	-	-	-	-
	Uniquement autorisé sous abri hors sol. L'usage en pleine terre est refusé en raison de l'absence de données permettant d'exclure un risque de contamination des eaux souterraines. Intervalle minimum entre les applications : 4 jours							

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Liste des usages autorisés
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	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
17303117 Rosier*Trt Part.Aer.* Aleurodes	**5 mL/L**	**4/an**	entre les stades BBCH 10 et BBCH 89	Non applicable	-	-	-	-
	Uniquement autorisé sous abri hors sol. L'usage en pleine terre est refusé en raison de l'absence de données permettant d'exclure un risque de contamination des eaux souterraines. Intervalle minimum entre les applications : 4 jours							
17303108 Rosier*Trt Part.Aer.*Pucerons	**5 mL/L**	**4/an**	entre les stades BBCH 10 et BBCH 89	Non applicable	-	-	-	-
	Uniquement autorisé sous abri hors sol. Les usages en plein champ et en pleine terre sont refusés en raison de l'absence de données permettant d'exclure un risque de contamination des eaux souterraines et un risque inacceptable pour les espèces non cibles. Intervalle minimum entre les applications : 4 jours							

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Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
16323101 Concombre*Trt Part.Aer.* Acariens	5 mL/L	2/an	3
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque pour le consommateur. L'usage en pleine terre est également refusé en raison de l'absence de données permettant d'exclure un risque de contamination des eaux souterraines.		
16323103 Concombre*Trt Part.Aer.* Aleurodes	5 mL/L	2/an	3
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque pour le consommateur. L'usage en pleine terre est également refusé en raison de l'absence de données permettant d'exclure un risque de contamination des eaux souterraines.		
16323106 Concombre*Trt Part.Aer.* Pucerons	5 mL/L	2/an	3
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque pour le consommateur. L'usage en pleine terre est également refusé en raison de l'absence de données permettant d'exclure un risque de contamination des eaux souterraines.		

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agence nationale de sécurité sanitaire alimentation, environnement, travail

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15653101 Pomme de terre*Trt Part.Aer.* Coléoptères phytophages	5 mL/L	2/an	5
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque pour le consommateur L'usage est également refusé en raison de l'absence de données permettant d'exclure un risque de contamination des eaux souterraines et un risque inacceptable pour les espèces non cibles.		
12603150 Pommier*Trt Part.Aer.* Pucerons	5 mL/L	2/an	5
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque pour le consommateur L'usages est également refusé en raison de l'absence de données permettant d'exclure un risque de contamination des eaux souterraines et un risque inacceptable pour les espèces non cibles.		
16953109 Tomate*Trt Part.Aer.* Acariens	5 mL/L	2/an	3
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque pour le consommateur. L'usage en pleine terre sous abri est également refusé en raison de l'absence de données permettant d'exclure un risque de contamination des eaux souterraines.		

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Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
16953101 Tomate*Trt Part.Aer.* Aleurodes	5 mL/L	2/an	3
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque pour le consommateur. L'usage en pleine terre sous abri est également refusé en raison de l'absence de données permettant d'exclure un risque de contamination des eaux souterraines.		
16953113 Tomate*Trt Part.Aer.* Chenilles phytophages	5 mL/L	2/an	3
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque pour le consommateur. Les usages en plein champ et en pleine terre sont également refusés en raison de l'absence de données permettant d'exclure un risque de contamination des eaux souterraines et un risque inacceptable pour les espèces non cibles.		
16953104 Tomate*Trt Part.Aer.* Pucerons	5 mL/L	2/an	3
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque pour le consommateur. L'usage en pleine terre sous abri est également refusé en raison de l'absence de données permettant d'exclure un risque de contamination des eaux souterraines.		

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Conditions d'emploi du produit

Stockage et manipulation du produit

Ne pas stocker le produit dans un local où la température peut dépasser 40°C.

Délai de rentrée :

- Attendre le séchage complet de la zone traitée.

Respect des limites maximales de résidus (LMR)

- Ne pas utiliser les sous-produits des cultures ornementales traitées en alimentation humaine ou animale.

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

Protection de l'eau

- Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidon non utilisés et les eaux de lavage du pulvérisateur.

Protection de la faune

- Ne pas appliquer en présence d'insectes pollinisateurs et/ou auxiliaires (abeilles, bourdons, coccinelles, ...).

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir le rapport final de l'étude de stabilité au stockage de 2 ans.	24	-
Fournir une méthode d'analyse validée pour la détermination des impuretés pertinentes de l'azadirachtine dans le produit.	6	-

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.

E. Belade 06/09/2017

PROJET DE TEXTE D'ÉTIQUETTE

Texte Recto

Titre	**Insecticide Polyvalent** Cultures légumières, rosiers, plantes d'intérieur
Nom homologué	**BOTAVER**
Litrage	125 ml - 25 litres de préparation ou 250 m² 250 ml – 50 litres de préparation ou 500 m² 500 ml - 100 litres de préparation ou 1000 m²
Picto	Logo UAB* *Conformément au règlement CE n°834/2007
1er picto « pb »	Pucerons / Doryphore
2ème picto « pb »	Aleurodes / acariens
1er plus produit	Large spectre d'action
2ème plus produit	Effets visible rapidement Elimine oeufs, larves et adultes
3ème plus produit	Efficace contre les doryphores
VISUEL AMBIANCE	Pommier, pomme de terre, tomate, aubergine, concombre, rosiers, cultures florales, plantes d'intérieur
Code couleur	Insecticide – Natria

Texte Verso

BOTAVER – Insecticide Polyvalent est un nouvel insecticide à base de 2 matières actives d'origine naturelle, les pyréthrines et l'azadirachtine Il est efficace sur un grand nombre d'insectes tels que pucerons, acariens, aleurodes sur de nombreuses cultures. Il lutte également contre le fléau des pommes de terre : le doryphore. Le produit est également utilisable sous serre pour les cultures légumières et en intérieur pour les plantes ornementales.

Les pyréthrines sont un ensemble de substances dérivées des fleurs de pyrèthre de Dalmatie ou de certains chrysanthèmes. Les pyréthrines agissent par contact et ont la propriété d'attaquer le système nerveux des insectes.
L'azadirachtine est un composé d'origine naturelle présent dans l'huile extraite des graines *d'Azadirachta indica* (aussi appelé margousier ou neem). Son action permet de limiter le développement des insectes, avec une efficacité à tous les stades de développement des insectes.

- ✓ **Large spectre d'action**
- ✓ **Efficacité longue durée***
- ✓ **Effet visible 3 à 7 jours après le traitement***
- ✓ **Dose unique pour tous les usages**
- ✓ **Utilisation intérieure (sous serre) et extérieure**
- ✓ **Utilisable en agriculture biologique** (conformément au Règlement CE 834/2007)

II/ EPOQUE D'EMPLOI

J	F	M	A	M	J	J	A	S	O	N	D

Période possible

Période optimale

*en fonctions des ravageurs et des cultures

E. Belade 06/09/2017

III/ MODE ET DOSE D'EMPLOI

Remplir la cuve du pulvérisateur à la moitié du volume d'eau nécessaire. Verser la quantité requise de produit dans l'eau du pulvérisateur, puis agiter pour mélanger la préparation. Compléter avec de l'eau jusqu'au volume final. Agiter une seconde fois avant application.
Appliquer la préparation pour mouiller les faces supérieures et inférieures des feuilles et des tiges. Appliquer jusqu'à la limite de ruissellement.

Les applications doivent être réalisées dès l'apparition des premiers symptômes, en renouvellement le traitement 4 à 7 jours après la première application.
Sur pommier, ne pas appliquer pendant la floraison mais à la chute complète des pétales ou lorsque les fruits ont atteint la moitié de leur taille finale. Sur pommier, éviter des applications sous un fort ensoleillement et avec des températures élevées (supérieur à 25°C).

La dose d'application pour l'ensemble des cultures est de **5 ml pour 1 litre d'eau pour 10 m².**

Cultures	Insectes	Extérieur / Intérieur (sous serre)	Délai avant récolte	Nombre max. d'application et jours d'intervalle entre les applications
Pommier	pucerons	Extérieur	5	2 4-7 jours
Tomate, aubergine	Chenilles phytophages, acariens, aleurodes	Extérieur / Intérieur (Sous serre)	3	
Aubergine	Pucerons	Intérieur (Sous serre)	3	
Concombre	Acariens, aleurodes, pucerons	Intérieur (Sous serre)	3	
Pomme de terre	Doryphores	Extérieur	5	
Rosiers, Cultures florales et plantes vertes, Plantes d'intérieur et balcons	Acariens, aleurodes, pucerons	Extérieur / Intérieur	-	2 à 4 4-7 jours

Respecter une zone non traitée de 5 mètres par rapport aux points d'eau.
Il est recommandé de ne pas appliquer sur cresson de fontaine (*Nasturtium*) et sur capucines (*Tropaeolum spp.*).

IV/ PRÉCAUTIONS D'EMPLOI
Protéger votre peau (gants, vêtements couvrants) pendant toutes les phases de manipulation du produit.
Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.

Lors de la préparation du pulvérisateur :
Ne préparer que la quantité de bouillie nécessaire au traitement.
Lors de l'application :
Ne pas traiter par temps venté ou par forte chaleur.
Ne pas traiter sur un terrain risquant un entraînement vers un point d'eau : ruisseaux, étangs, mares, puits ..., en particulier si le terrain est en pente.
Ne pas traiter en présence d'abeilles.
Attention : ce produit peut porter atteinte à la faune auxiliaire
Après l'application :
Délai de rentrée : attendre le séchage complet de la zone traitée.
Nettoyer et rincer très soigneusement le pulvérisateur aussitôt après le traitement.
L'eau de rinçage du pulvérisateur (rincé 3 fois lors de la dernière utilisation) doit être pulvérisée à proximité de la zone traitée.
Conserver le produit dans son emballage d'origine, à l'abri de l'humidité.
Réemploi de l'emballage interdit. Ne pas jeter dans les poubelles ménagères, mais éliminer l'emballage avec ou sans produit en déchèterie ou par un organisme agréé.

Nom homologué : BOTAVER

E. Belade 06/09/2017

A.M.M. n° xxxxxxxxx – Emploi autorisé dans les jardins
Détenteur de l'A.M.M. : SBM Développement SAS (69 - Ecully)
Composition : 4,1 g/l Azadirachtine (xx % m/m) 4,2 g/l Pyréthrines (xx % m/m)
Formulation : Concentrée émulsionnable (EC)
Insecticide
Usages et doses autorisés : voir tableau des usages dans mode et dose d'emploi

BOTAVER
Contient pyréthrines/pyréthroides et azadirachtin
Attention

H317 Peut provoquer une allergie cutanée.
H411 Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
EUH401 Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

P101 En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette.
P102 Tenir hors de portée des enfants.
P280 Porter des gants de protection/ des vêtements de protection/ un équipement de protection des yeux/ du visage.
P333 + P313 En cas d'irritation ou d'éruption cutanée: consulter un médecin.
P501 Eliminer le contenu/récipient dans une déchèterie ou par un organisme agréé.

SP1 : Ne pas polluer l'eau avec le produit ou son emballage.
Spe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.
Spe8 : Dangereux pour les abeilles. Pour protéger les abeilles et autres insectes pollinisateurs, ne pas appliquer durant la floraison ou en période de production d'exsudats.

Premiers soins :
En cas d'inhalation : Amener la victime à l'air libre, la garder au repos et la maintenir au chaud • En cas de contact avec la peau : Laver immédiatement avec beaucoup d'eau et de savon pendant au moins 15 minutes. En cas d'irritation de la peau, envisager l'application d'une huile ou d'une lotion contenant de la vitamine E. • En cas de contact avec les yeux : Rincer immédiatement et abondamment à l'eau, y compris sous les paupières, pendant au moins 15 minutes. Après les 5 premières minutes, enlever les lentilles cornéennes, si présentes, continuer à rincer l'œil. • En cas d'ingestion : Rincer la bouche et faire boire de l'eau par petites gorgées. Ne PAS faire vomir. Appeler immédiatement un médecin ou centre antipoison. Rincer la bouche. • 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'urgence appeler le 15 ou le centre anti-poison.

Distribué par :
SBM Life Science SAS
Les 4 M - 111 Chemin du Petit bois
69130 Ecully
Tél : 04 37 64 32 00

Volume net : 125 ml / 250 ml / 500 ml
Réf. : xxx
Gencod : xxxxxxxx
Emb. : xxxxx
Internet+ N°Vert Logo SBM
N° de lot et date de fabrication : voir indications sur l'emballage.

Appendix 3 Letter of Access

Letter(s) of access and, if necessary, an argumentation according to art. 62.4 of Reg (UE) No 1107/2009 have been submitted and are available under request.