

REGISTRATION REPORT

Part A

Risk Management

Product code: 102000031427

Product names: HERBICLEAN CONCENTRE

Chemical active substance:

pelargonic acid (nonanoic acid), 250 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: SBM Développement SAS

Date: 22/06/2019

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PART A

RISK MANAGEMENT

1 Details of the application

The company SBM Développement SAS has requested a marketing authorisation in France for the product HERBICLEAN CONCENTRE (formulation code: 102000031427), containing 250 g/L pelargonic acid¹, as a herbicide for non-professional use.

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 information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to HERBICLEAN CONCENTRE (102000031427) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of HERBICLEAN CONCENTRE (102000031427) have been made using endpoints agreed in the EU peer review of pelargonic acid.

This document describes the specific conditions of use and labelling required for France for the registration of HERBICLEAN CONCENTRE (102000031427).

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).

Appendix 3 of this document contains 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 HERBICLEAN CONCENTRE (102000031427) in France as a herbicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

The present application (2017-1957) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")² – the highest application rates applied for in the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

The current document (RR) based on Anses assessment of the application submitted for this product is in compliance with Regulation (EC) No 1107/2009³, implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which

¹ Synonym nonanoic acid. The European Commission encompasses it as an active substance in the form of "Fatty acids C7 to C20" (<http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1676>)

² 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](http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1676)

³ REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

recommendations are based and is not intended to show the assessment in detail.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

1.2 Letters of Access

The applicant has provided letter(s) of access for active substance or PPP data.

1.3 Justification for submission of tests and studies

According to the applicant: “*The tests and study reports are necessary in order to support the first of authorisation for*”.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of HERBICLEAN CONCENTRE (102000031427), 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	102000031427
Product name in MS	HERBICLEAN CONCENTRE
Authorisation number	N/A : no marketing authorisation granted in France
Function	Herbicide
Applicant	SBM Développement SAS
Active substance(s) (incl. content)	Pelargonic acid (nonanoic acid), 250 g/L
Formulation type	Emulsifiable concentrate [EC]
Packaging	Bottle in HDPE/EVOH holding 1L. Container in HDPE/EVOH holding 3L, 5L. The packagings proposed by the applicant are not accepted by ZRMS for non-professional users in France
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None.
Recommended tank mixtures	None.

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

2.2 Conclusion

The evaluation of the application for HERBICLEAN CONCENTRE (102000031427) resulted in the decision **to refuse the authorisation**, as the packaging is not considered as compliant with a non-professional user in France (it does not allow reducing enough user's exposure).

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:	Skin Irritation, category 2 Hazardous to the aquatic environment, Chronic, Hazard Category 3.
Hazard pictograms:	
Signal word:	Warning
Hazard statement(s):	H315 : Causes skin irritation. H412 : Harmful to aquatic life with long-lasting effects.
Precautionary statement(s):	<i>For the P phrases, refer to the extant legislation</i>
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 4 May 2017⁵ provides that:

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

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

Finally, the French Order of 26 March 2014⁶ provides that:

- an authorisation granted for a “reference” crop applies also for “linked” crops, unless formally stated in the Decision
- the “reference” and “linked” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁷ 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:	
-	N/A : no marketing authorisation granted
Worker protection:	
-	N/A : no marketing authorisation granted
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
	N/A : no marketing authorisation granted
Other specific restrictions	
Re-entry period	N/A : no marketing authorisation granted
Storage	N/A : no marketing authorisation granted

⁵ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjutants 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/AGR1632554A/jo/texte>

⁶ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

⁷ 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.

PPP (product name/code):	HERBICLEAN CONCENTRE / 102000031427	Formulation type:	GAP rev. 1, date: 2019-06-22
Active substance 1:	Pelargonic acid	Emulsifiable concentrate (EC) ^(a, b)	
Safener:	-	Conc. of a.s. 1:	250 g/L ^(c)
Synergist:	-	Conc. of safener:	- ^(c)
Applicant:	SBM Développement SAS	Conc. of synergist:	- ^(c)
Zone(s):	southern ^(d)	Professional use:	<input type="checkbox"/>
Verified by MS:	Yes	Non-professional use:	<input checked="" type="checkbox"/>
Field of use:	Herbicide		

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)	mL product/10 m ² a) max. rate per appl. b) max. total rate per crop/season	g a.s./10 m ² a) max. rate per appl. b) max. total rate per crop/season	Water L/10 m ² min / max		

Zonal uses (field or outdoor uses, certain types of protected crops)

1	FR	Ways and places Soft (permeable) surfaces	F	Weeds (annual, biennial perennial), moss, liverwort	Spraying knapsack, or hand- held sprayer, ready-to- dilute trigger bottle	Post-emergence of weeds ^(*) (Feb - Oct)	1-8	21	120	30	500- 1000	N/a	Not Acceptable (pack- aging not acceptable for non-professional uses in France)
2	FR	Around ornamental shrubs, berry fruit bushes,	F	Weeds (annual, biennial perennial), moss, liverwort	Spraying: knapsack spot	Post-emergence of weeds ^(*) (Feb - Oct)	1-8	21	120	30	500- 1000	N/a	Not Acceptable (pack- aging not acceptable for non-professional

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)	mL product/10 m ² a) max. rate per appl. b) max. total rate per crop/season	g a.s./10 m ² a) max. rate per appl. b) max. total rate per crop/season	Water L/10 m ² min / max		
		pome and stone fruit trees			treatment or hand- held sprayer, ready-to- dilute trigger bottle								uses in France)
3	FR	Ways and places Hard (impermeable) surfaces	F	Weeds (annual, biennial perennial), moss, liverwort	Spraying knapsack spot treatment or hand- held sprayer, ready-to- dilute trigger bottle	Post-emergence of weeds(*) (Feb - Oct)	1-8	21	120	30	500- 1000	N/a	Not Acceptable (packaging not ac- ceptable for non- professional uses in France)

N/A = not applicable

Remarks (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
table (b) Catalogue of pesticide formulation types and international coding system CropLife
heading: (c) 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/homelacatures 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)

HERBICLEAN CONCENTRE (102000031427) is an emulsifiable concentrate (EC). 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 a clear yellow liquid. It is not explosive and has no oxidising properties. The product has a flash point of 143 °C and a self-ignition temperature of 330 °C. In aqueous solution (1 % dilution), it has a pH value of 4.2 at ambient temperature. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and 14 days at 54 °C, neither the active substance content nor the technical properties were changed. The stability data indicating a shelf life of at least two years at ambient temperature when stored in HDPE/PA and HDPE/EVOH packaging must be provided in post-authorisation. The technical characteristics are acceptable for an EC formulation.

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

The spray mixture must be shaken or stirred during the application.

3.2 Efficacy (Part B, Section 3)

3.3 Efficacy data

Considering the data provided:

- HERBICLEAN CONCENTRE (102000031427)'s efficacy is considered limited but acceptable for all the intended uses.
- HERBICLEAN CONCENTRE (102000031427) cannot be considered a selective product given pelargonic acid's mode of action (a contact and non-selective foliar herbicide). Therefore, it is recommended not to direct on to green parts of desired plants during application.
- The risk of negative impact on, propagation, succeeding and is considered acceptable.
- The risk of resistance appearing or developing can be considered to be very low.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Analytical methodology for the determination of the active substance in the formulation is available and validated. As the active substance pelargonic acid does not contain any relevant impurity, no pertinent analytical method is required.

3.4.2 Analytical methods for residues

The active substance is a naturally occurring compound and it would be impossible to distinguish between what occurs naturally and what occurs as a result of pesticide usage. Hence no analytical

methods are required for the determination of residues in plants, foodstuffs of animal origin, soil, water and air.

The active substance is neither toxic nor very toxic, hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.5 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active substance: pelargonic acid			
ADI	Not applicable		
ARfD	Not applicable		
AOEL	Not applicable <i>As no reference values for fatty acids are available for fatty acids, a quantitative risk assessment has been performed comparing the non-dietary exposure to fatty acids arising from the use as a plant protection product with the normal dietary intakes of fatty acids.</i>		EU (2009)
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 250 g/L	Spray dilution (used in formulation) 30 g/L
	Dermal absorption endpoints %	25	75

methanol			
ADI	2 mg/kg bw/d*		
ARfD	2 mg/kg bw*		ANSES
AOEL	2 mg/kg bw/d*		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 35.9 g/L	Spray dilution (used in formulation) 4.31 g/L
	Dermal absorption endpoints %	75	75

Supplementary information	<p>According to the Conclusion on the peer review of the active substance fatty acids C7 to C18⁸, it was concluded that methanol could be a potential degradation product of fatty acid methyl esters. Therefore, “[...] since operators, workers and bystanders might be exposed to methanol, a non-consumer exposure risk assessment for methanol is needed [...]”.</p> <p>However since no data are available on the conversion factor of fatty acid methyl esters into methanol, the following estimate is proposed:</p> <ul style="list-style-type: none">- the hydrolysis of the fatty acid methyl esters cannot be excluded under alkaline conditions,- the hydrolysis of the fatty acid methyl esters could occur in water in a tank after mixing/loading is done,- the operator (user) could be thus exposed to methanol during mixing/loading and application ,- a mixture of fatty acid methyl esters with a molar mass of 293.5 g/mol may be considered as a worst case,- likewise it will be supposed that total hydrolysis (100 %) occurs, giving rise to one mole of methanol (CH₃OH) with a molar mass of CH₄O = 32 g/mol,- the molar ratio being 32/293.5 = 0.1090, the maximum application rate of 39 540 g/ha esterified fatty acids corresponds to a worst-case rate of 39 540 x 0.1090 = 4.31 kg methanol/ha. <p>Taking into account this conversion factor, the expected methanol concentration is 35.9 g methanol/L in the formulated product.</p> <p>EFSA did not produce any toxicological review on methanol as an active substance; little toxicological information is available on this substance, essentially as a degradation product of aspartame. In the Scientific Opinion on the re-evaluation of aspartame as a food additive⁹, a Reference Dose (RfD) for exogenous methanol of 2 mg/kg bw/day was defined based on the Toxicological review of methanol by the US EPA¹⁰. This RfD was set using a mouse developmental study where formation of extra-cervical ribs was observed.</p> <p>Therefore this RfD of 2 mg/kg bw/day is relevant to be used as AOEL, ADI and ARfD in the following assessment.</p>
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3.5.1 Acute toxicity

HERBICLEAN CONCENTRE (102000031427) containing 250 g/L nonanoic acid has a low acute oral, inhalational and dermal toxicity, and is irritating to the rabbit skin, not irritating to eye and is not a skin sensitizer.

3.5.2 Operator exposure

Summary of critical use patterns (worst cases):

⁸ Conclusion on the peer review of the pesticide risk assessment of the active substance Fatty acids C7 to C18 (approved under Regulation (EC) No.1107/2009 as Fatty acids C7 to C20) (EFSA Journal 213;11(1):3023)

⁹ Scientific opinion - Statement on two reports published after the closing date of the public consultation of the draft Scientific Opinion on the re-evaluation of aspartame (E 951) as a food additive, EFSA Journal 2013;11(12):3504

¹⁰ Toxicological review of methanol (non-cancer) in support of summary information on the integrated risk information system (IRIS), September 2013, EPA/635/R-11/001Fa <http://www.epa.gov/iris/toxreviews/0305tr.pdf>

Crop	F/G ¹¹	Equipment	Application rate ml 102000031427/10 m ² (g/10m ²)	Spray dilution (mL/10m ²)	Model
Non-cultivated area - ornamentals, flowers.	Fn	Manual knapsack	120 mL/10 m ² 30 g pelargonic acid/10 m ² or 30 kg/ha (250 g pelargonic acid/L in the formulated product) 0.431 g methanol/10 m ² or 4.31 kg/ha (35.9 g methanol/L in the formulated product)	500 mL	French amateur model (UPJ)

Considering the proposed uses, operator (user) systemic exposure was estimated using the French study from UPJ 2009-2010¹² dedicated to non-agricultural areas:

Crop	Equipment	PPE and/or working coverall	% of normal dietary intake pelargonic acid 821 mg/kg/d	% AOEL methanol 2 mg/kg/d
Flower bed, vegetable crop (< 60 cm tall)	Pre-pressure sprayer or trigger sprayer	Not applicable, non-professional use.	UPJ : 0.20	UPJ : 15.9
Lawn	Pre-pressurised sprayer	Not applicable, non-professional use.	UPJ: 0.52	UPJ: 34.1
	Trigger sprayer		UPJ: 0.03	UPJ: 5.9
Non-cultivated area	Pre-pressurised sprayer or trigger sprayer	Not applicable, non-professional use.	UPJ : 0.27	UPJ : 20.1

According to the model calculations, it may be concluded that the risk for the operator (user) employing HERBICLEAN CONCENTRE (102000031427) is acceptable during mixing/loading and application for both pelargonic acid and methanol, a metabolite which could be generated from hydrolysis of the co-formulant fatty acid methyl esters.

3.5.3 Worker exposure

HERBICLEAN CONCENTRE (102000031427) is intended to be used by non-professionals for home

¹¹ Open field or glasshouse

¹² 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

garden application.

In this case of the non-professional user, 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.

3.5.4 Bystander and resident exposure

In the context of use by non-professionals, it may be considered that the assessment for bystanders and residents is covered by that for the operator (user).

However, residential exposure was assessed according to EFSA model (worst-case situation: professional uses) and an acceptable risk was determined for residents (adult and child).

Model (AOEM) - All pathways (mean) Hand held spray application outdoors to low crops	% normal dietary intakes of fatty acids for pelargonic acid	% AOEL methanol
Resident (children)	13	44
Resident (adults)	4.3	15

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

According to Reg. (EU) No 839/2008 of 31 July 2008 as regards maximum residue levels *inter alia* for pelargonic acid, EFSA concluded that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 is appropriate. Pelargonic acid is listed on Annex IV to Regulation (EC) No 396/2005 and therefore has an MRL exemption. No further assessment is required on metabolism and residues and no safety concern was identified regarding the use of HERBICLEAN CONCENTRE (102000031427).

Summary for pelargonic acid

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?	Comments
1	Ways and places Soft (permeable surfaces)	Not required	Not required	Not required	Not required	Not applicable	No	No	
2	Ornamental shrubs, berry fruit bushes, pome and stone fruit trees	Not required	Not required	Not required	Not required	Not applicable		No	
3	Ways and places Hard (impermeable) surfaces	Not required	Not required	Not required	Not required	Not applicable		No	

Information on HERBICLEAN CONCENTRE (102000031427)

Crop	PHI for HERBI-CLEAN CONCEN-TRE (102000031427) requested by applicant	PHI/withholding period* sufficiently supported for	PHI for HERBI-CLEAN CONCEN-TRE (102000031427) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Pelargonic acid		
Ways and place Soft (permeable) surfaces	NR	Yes	NR	PHI is not relevant as pelargonic acid is included in Annex IV of Regulation (EC) No 396/2005.
Ornamental shrubs, berry fruit bushes, pome and stone fruit trees	NR	Yes	NR	PHI is not relevant as pelargonic acid is included in Annex IV of Regulation (EC) No 396/2005.
Ways and place Hard (impermeable) surfaces	NR	Yes	NR	PHI is not relevant as pelargonic acid is included in Annex IV of Regulation (EC) No 396/2005.

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

Not relevant.

Pelargonic acid is included in Annex IV of Regulation (EC) No 396/2005 that regroups active substances for which no MRL is necessary and no specific studies are required. Therefore, no additional data are required to support the intended uses of HERBICLEAN CONCENTRE (102000031427).

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

Given the home and garden use of the preparation HERBICLEAN CONCENTRE (102000031427), PEC_{soil} values are not needed for the ecotoxicological risk assessment.

PEC_{sw} values (from spray drift only) derived for the active substance are used for the ecotoxicological risk assessment.

PEC_{gw} calculations are not deemed necessary for uses on hard surfaces. Significant exposure of groundwater is not expected.

However, although PEC_{gw} values for pelargonic acid are deemed necessary for uses on soft (permeable) surfaces, none were provided. In addition, PEC_{gw} calculations from the EFSA conclusions do not allow finalisation of the risk assessment for the intended uses at national level. Therefore, the risk assessment of groundwater contamination cannot be finalised for the uses on soft (permeable) surfaces.

Based on vapour pressure, information on volatilisation from plants and soil, and DT₅₀ calculation, no significant contamination of the air compartment is expected for the intended uses.

3.8 Ecotoxicology (Part B, Section 9)

Effects on birds and on terrestrial vertebrates other than birds:

Based on a weight-of-evidence approach, the acute and long-term dietary risk for both birds and mammals is considered acceptable for the intended non-professional use of HERBICLEAN CONCENTRE (102000031427).

Effects on aquatic organisms:

Based on the risk assessments for the active substance and HERBICLEAN CONCENTRE (102000031427), an acceptable risk to aquatic organisms is demonstrated from the proposed use, subject to the following precautionary measures:

- To protect aquatic organisms, do not apply within 5 metres of any surface water bodies (well, pond, stream, river...);
- To protect aquatic organisms, do not apply in sloping gardens or impermeable surfaces such as asphalt, concrete, pavements and slabs located near to a water point.

Erreur ! Source du renvoi introuvable.:

Pelargonic acid is also registered according to the EFSA Journal for fatty acid, as an insecticide/acaricide and can be used in formulation for insecticide uses.

Moreover, according to the new data requirement, for submissions after 1 January 2013, chronic and larval toxicity studies are required for formulations and active substances. On this basis the risk assessment for bees and other pollinators when HERBICLEAN CONCENTRE (102000031427) is applied cannot be finalised.

Effects on arthropods other than bees:

Based on a weight-of-evidence approach, overall it may be concluded that there is an acceptable risk to populations of non-target arthropods from the proposed non-professional use of HERBICLEAN CONCEN TRE (102000031427).

Effects on non-target soil meso- and macrofauna:

Based on a weight-of-evidence-approach, it may be concluded that there is an acceptable risk to earthworms and other soil non-target macro organisms and to soil microbial processes.

Effects on non-target terrestrial plants:

A tier 2 risk assessment based on dose-response data demonstrated an acceptable risk to non-target terrestrial plants for all non-professional uses of HERBICLEAN CONCENTRE (102000031427).

3.9 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 substance pelargonic acid is not approved as a candidate of substitution, therefore a comparative assessment is not anticipated.

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

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

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

- None

Appendix 1 Copy of the product authorisation



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 réglementaire,

Vu l'arrêté du 30 décembre 2010 relatif aux conditions d'emballage des produits phytopharmaceutiques pouvant être employés par des utilisateurs non professionnels,

Vu la demande d'autorisation de mise sur le marché et la demande associée du produit phytopharmaceutique HERBICLEAN CONCENTRE

de la société **SBM DEVELOPPEMENT**
enregistrées sous les n°**2017-1957 et 2019-1130**

Vu les conclusions de l'évaluation de l'Anses du 26 mars 2019,

Considérant que les emballages du produit ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel, conformément à l'article 1 de l'arrêté du 30 décembre 2010,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.



Informations générales sur le produit

Nom du produit	HERBICLEAN CONCENTRE
Type de produit	Produit de référence
Titulaire	SBM DEVELOPPEMENT 60 chemin des Mouilles, 69130 Ecully, France
Formulation	Concentré émulsionnable (EC)
Contenant	250 g/L - acide péragonique
Numéro d'intrant	648-2017.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Amateur / emploi autorisé dans les jardins

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)

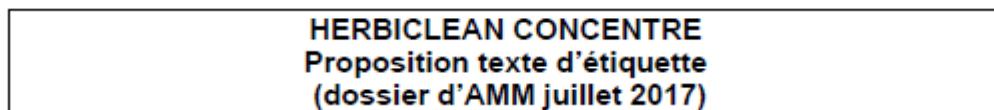
Appendix 2 Copy of the product label

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

Herbiclean Concentré

SBM Développement SAS



En sélectionnant des matières premières d'origine naturelle et végétale, Solabiol s'inscrit dans une démarche éthique de développement durable. Solabiol s'engage à vous proposer des produits respectueux de vos plantations et de l'environnement, et vous garantit d'avoir des plantes belles et saines, tout en restant en harmonie avec la nature.

Le nouveau Désherbant Herbiclean Concentré permet d'éliminer les principales mauvaises herbes annuelles, bi-annuelles et vivaces, avec une efficacité contre les mousses.

- Longue durée : jusqu'à 4 semaines
- Effet visible en 1 heure*
pour des températures supérieures ou égales à 20°C.

INFORMATIONS REGLEMENTAIRES

Nom homologué : HERBICLEAN CONCENTRE
A.M.M. n° xxxxxxxx – Emploi autorisé dans les jardins
Déteur de l'A.M.M. : SBM Développement SAS (69)
Composition : 250 g/L Acide pélargonique (27,2 % m/m)
Type d'action : Herbicide non sélectif contact
Formulation : Concentré émulsionnable (EC)
Dose : 120 ml/10 m²
Nombre maximal d'application : 8 applications par an.

EPOQUE D'EMPLOI

J	F	M	A	M	J	J	A	S	O	N	D
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 Période possible
 Période optimale

MODE ET DOSE D'EMPLOI

Herbiclean Concentré s'utilise en pulvérisation lorsque les mauvaises herbes sont jeunes et en croissance (de 5 à 10 cm), par temps chaud, sec et sans vent.
Appliquer le produit directement et uniformément sur les mauvaises herbes à détruire.
Il peut être nécessaire de retraiter si de nouvelles mauvaises herbes lèvent. Si une pluie intervient 1 heure après l'application l'efficacité sera réduite et il sera nécessaire de traiter à nouveau.

Dose d'application pour l'ensemble des usages : 120 ml pour 1 litre d'eau pour 10m²

Usages	Nombre maximal d'applications
Usages non agricoles * Désherbage * Allées de PJT, cimetières, voies	Ne pas dépasser 8 applications par an, en respectant un intervalle de 3 à 4 semaines entre chaque application
Traitements généraux * Désherbage * Avant Mise en Culture	
Traitements généraux * Désherbage * Cultures Installées	
Arbres et arbustes * Désherbage * Plantations pleine terre	
Rosier * désherbage * Pleine terre	
Cultures florales et plantes vertes * Désherbage	
Pommier*Désherbage*Cultures Installées (dont poirier)	
Fruits à noyau*Désherbage*Cultures Installées	
Petits fruits*Désherbage* Cultures, Installées	
Traitements généraux* Destruction Mousses	

E.BELADE

Herbiclean Concentré

SBM Développement SAS

PRÉCAUTIONS D'EMPLOI

Porter des gants est recommandé pendant toutes les phases de manipulation.
Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.

Lors de l'application :

Ne pas appliquer sur gazon.
Ne pas appliquer après une pluie ou s'il y a risque de pluie dans l'heure qui suit le traitement.
Ne pas traiter par temps venté.
Eviter toute dérive de pulvérisation et de ruissellement vers les plantes voisines.

Après l'application :

Délai de rentrée : Ne pas rentrer sur la zone traitée (animaux compris) avant le séchage complet de celle-ci.
Conserver le produit dans son emballage d'origine, à l'abri de l'humidité et hors gel.
Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidon non utilisés.
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.

Herbiclean Concentré

Contient acide pélargonique

H412 Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme.
EUH401 Respectez les instructions d'utilisation pour 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.

P501 Eliminer le contenu/récipient dans une déchèterie ou par un organisme agréé.

Spe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

SP1 : Ne pas polluer l'eau avec le produit ou son emballage

Premiers soins :

En cas d'inhalation : amener la victime à l'air libre. La garder au chaud et au repos • En cas de contact avec les yeux : laver immédiatement et abondamment avec de l'eau pendant au moins 15 minutes. Si besoin, retirer les lentilles de contact après les 5 premières minutes. • En cas de contact avec la peau : laver immédiatement et abondamment avec de l'eau et du savon • En cas d'ingestion : Rincer la bouche. Ne PAS faire vomir. • 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 appelez le 15 ou le centre anti poison.

Distribué par :

SBM LifeScience

Les 4 M – 111 Chemin du Petit Bois

69180 Ecully

Tel

Volume net : 1 litre / 3 litres / 5 litres

Réf. : XXXXX

Gencod : XXXXX

Internet+ N°Vert

N° lot et date de fabrication : voir indications sur l'emballage.

Logo SBM

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.