

REGISTRATION REPORT

Part A

Risk Management

Product code: 102000031427

Product name(s): HERBICLEAN CONCENTRE

Chemical active substance:

Pelargonic acid, 250 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: SBM Développement SAS

Date: 30/08/2021

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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 an herbicide for non-professional uses.

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

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

1.1 Application background

The present registration report concerns the evaluation of SBM Développement SAS's application submitted on 05/07/2017 to market HERBICLEAN CONCENTRE (102000031427) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone. The updated version concerns the evaluation of new data submitted by SBM Développement S.A.S on 11/09/2020 for the Toxicology and Ecotoxicology sections (application 2020-1244).

The present application (2017-1957) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of HERBICLEAN CONCENTRE (102000031427) has been made using endpoints agreed in the EU peer review of pelargonic acid. 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.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

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

¹ COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.

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

³ SANCO document "risk envelope approach", European Commission (14 March 2011). [Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5](#)

⁴ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

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

1.2 Letters of Access

The applicant has provided a letter of access for active substance and PPP data. This letter of access is available upon request.

1.3 Justification for submission of tests and studies

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.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 3.

2 Details of the authorisation decision

2.1 Product identity

Product code	102000031427
Product name in MS	HERBICLEAN CONCENTRE
Authorisation number	2210563
Kind of use	Non-professional use
Function	Herbicide
Applicant	SBM Développement SAS
Active substance(s) (incl. content)	Pelargonic acid, 250 g/L
Formulation type	Emulsifiable concentrate [EC]
Packaging	<p>Bottle HDPE/EVOH⁵ or HDPE/PA⁶ with dosing cap (0.125 L, 0.250 L, 0.5 L, 1 L)</p> <p>Other packagings proposed by the applicant are not accepted by ZRMS for non-professional users :</p> <ul style="list-style-type: none"> • Bottle HDPE/EVOH or HDPE/PA with a dosing cap above a non dosing cap • Bottle HDPE/EVOH (3 and 5 L)

⁵ HDPE/EVOH : high density polyethylene / alcohol vynilique ethylene

⁶ HDPE/PA : high density polyethylene / polyamide

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

2.2 Conclusion

The evaluation of the application for HERBICLEAN CONCENTRE (102000031427) resulted in the decision **to grant** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	No classification for human health. Hazardous to the aquatic environment - Chronic Hazard, category 3.
Hazard pictograms:	-
Signal word:	-
Hazard statement(s):	H412: Harmful to aquatic life with long-lasting effects.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>

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

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

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
	For other restrictions refer to 2.5

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

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017⁷ provides that:

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

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

Finally, the French Order of 26 March 2014⁸ provides that:

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁹ 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:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	

⁷ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

⁸ <https://www.legifrance.gouv.fr/loda/id/JORFTEXT000028792733>

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

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	Do not discharge into the sink, gutter or any other water hole the non-used container leftovers and the sprayer washing water.
	To protect groundwater, following an application on permeable surfaces, do not apply this or any other product containing pelargonic acid between August and February.
	To protect aquatic organisms, do not apply at least 5 meters away from any surface water bodies (well, pond, stream, river,...).
	To protect aquatic organisms, do not apply on impermeable surfaces such as asphalt, concrete, cobblestones and slabs.
	Do not apply when pollinating insects (bees, bumble bees...) and beneficial organisms are present (ladybirds, lacewings, hoverflies, ground beetles...).
	Avoid spray drift to nearby plants.
Other specific restrictions	
Re-entry period	Wait until the treated zone or plants have dried.
Storage	The spray mixture must be stirred during the application.

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.

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2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

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

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 2, date: 2021-08

PPP (product name/code): HERBICLEAN CONCENTRE / 102000031427

Formulation type: EC ^(a, b)

Active substance 1: Pelargonic acid

Conc. of a.s. 1: 250 g/L ^(c)

Safener: -

Conc. of safener: - ^(c)

Synergist: -

Conc. of synergist: - ^(c)

Applicant: SBM Développement SAS

Professional use: ☐Zone(s): Southern Zone ^(d)Non-professional use: ☒

Verified by MS: Yes

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 or situation (crop destination/purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS concluisions
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	mL product/10 m² a) max. rate per appl. b) max. total rate per crop/season	g a.s./10 m² 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 place Soft (permeable) surfaces	F	Weeds (annual biannual perennial), moss, liverwort	spraying knapsack, or hand- held sprayer, ready-to- dilute trigger bottle	March-July	8	3 weeks	120	30	500- 1000	N/a	Acceptable

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS conclusions
					Method/Ki nd	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		
2	FR	Around Ornamental Shrubs, Berryfruit, Pomefruit, Stonefruit	F	Weeds (annual biannual perennial), moss, liverwort	Spraying: knapsack spot treatment or hand- held sprayer, ready-to- dilute trigger bottle	Mars-July	8	3 weeks	120	30	500- 1000	N/a	Acceptable
3	FR	Ways and place Hard (impermeable) surfaces	F	Weeds (annual biannual perennial), moss, liverwort	Spraying: knapsack spot treatment or hand- held sprayer, ready-to- dilute trigger bottle	Mars-July	8	3 weeks	120	30	500- 1000	N/a	Acceptable

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.

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Remarks columns:	1	Numeration necessary to allow references	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	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.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of 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, it has a pH value around 4.2 at ambient temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicating a shelf life of 2 years at ambient temperature when stored in HDPE/EVOH and HDPE/PA bottles. Its technical characteristics are acceptable for an emulsifiable concentrate (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)

Considering the data provided:

- HERBICLEAN CONCENTRE (102000031427)'s efficacy is considered limited but acceptable for all intended uses.
- HERBICLEAN CONCENTRE (102000031427) cannot be considered as 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 desired plants during application.
- The risk of negative impact on propagation, succeeding crops is considered acceptable.
- The risk of resistance appearing or developing can be considered to be very low.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 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.

3.3.2 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.

3.4 Mammalian toxicology (Part B, Section 6)

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Endpoints used in risk assessment

Active substance: pelargonic acid			
ADI	Not applicable		EU (2009)
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>		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2017):		
		Concentrate (used in formulation) 250 g/L	Spray dilution (used in formulation) 30 g/L
	Dermal absorption endpoints %	25	70

Methanol			
ADI	2 mg/kg bw/d*		ANSES
ARfD	2 mg/kg bw*		
AOEL	2 mg/kg bw/d*		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2017):		
		Concentrate (used in formula- tion)35.9 g/L	Spray dilution (used in formulation) 4.31 g/L
	Dermal absorption endpoints %	75	70

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Supplementary information	<p>According to the Conclusion on the peer review of the active substance fatty acids C7 to C18¹⁰, it was concluded that methanol could be a potential degradation product of fatty acid methyl esters. Therefore, “[...] <i>since operators, workers and bystanders might be exposed to methanol, a non-consumer exposure risk assessment for methanol is needed</i> [...]”.</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 $39\,540 \times 0.1090 = 4.31$ 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 additive¹¹, 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 EPA¹². 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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3.4.1 Acute toxicity

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

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

¹⁰ 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 2013;11(1):3023)

¹¹ 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

¹² 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>

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Crop	F/G	Equipment	Application rate ml HERBICLEAN CONCENTRE/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 2009-2010¹³ 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.

The proposed packaging has been described in sufficient detail, and its compliance can therefore be finalised.

In summary, compliance with the provisions of French regulation relating to the conditions of authorisation

¹³ 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

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of plant protection products by non-professional users¹⁴ is considered to be finalised only for the following packaging :

Bottle HDPE/EVOH or HDPE/PA with dosing cap (0.125 L, 0.250 L, 0.5 L, 1 L)

Other packaging proposed by the applicant are not accepted by ZRMS for non-professional users :

- **Bottle HDPE/EVOH or HDPE/PA with a dosing cap above a non dosing cap**
- **Bottle HDPE/EVOH (3 and 5 L)**

were not acceptable for non professional user.

3.4.3 Worker exposure

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

3.4.4 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

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

According to Reg. (EU) No 839/2008 of 31 July 2008 as regards pelargonic acid, the Authority 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).

¹⁴ Arrêté du 6 avril 2020 relatif aux conditions d'autorisation d'un produit phytopharmaceutique pour la gamme d'usages « amateur » JORF n°0088 du 10 avril 2020

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Information on HERBICLEAN CONCENTRE (102000031427)

Crop	PHI for HERBI- CLEAN CON- CENTRE pro- posed by ap- plicant	PHI/ Withholding period* sufficiently supported for	PHI for NONANOIC ACID EC250 proposed by zRMS	zRMS Com- ments (if different PHI proposed)
		Pelargonic acid		
Ways and place Soft Surfaces	NR	Yes	NR	
Ornamental Shrubs, Berryfruit, Pomefruit, Stonefruit	NR	Yes	NR	
Ways and place Hard Surfaces	NR	Yes	NR	

NR: not relevant as pelargonic acid is included in Annex IV of regulation (EC) No 396/2005.

* 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

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

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substance metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of pelargonic acid in surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models or specific approaches for home and garden uses, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

Considering the home and garden intended uses for the formulated product no PEC_{soil} calculation is required.

PEC_{sw} derived for the active substance are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PEC_{gw} calculations are not deemed necessary for uses on hard surfaces.

For soft surfaces, PEC_{gw} for pelargonic acid do not occur at levels exceeding those mentioned in regulation EC 1107/2009 provided the product is applied between March and July. Therefore, no unacceptable risk of groundwater contamination is expected when the product is applied between March and July.

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.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of

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Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance 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 home and garden uses and since the product is used as a foliar spray, only the risk assessment for birds, aquatic organisms and bees was considered relevant by the zRMS.

The risk to birds is considered acceptable for the intended uses. For aquatic organisms, the risk to pelargonic acid following the intended uses of the product HERBICLEAN CONCENTRATE (102000031427) on permeable surfaces can be considered as acceptable, with the following mitigation:

To protect aquatic organisms do not apply at least 5 meters away from any surface water bodies (well, pond, stream, river,...).

Moreover, since an acceptable risk for aquatic organisms cannot be demonstrated for applications on impermeable surface, the following safety phrase might be added on the label:

To protect aquatic organisms do not apply on impermeable surfaces such as asphalt, concrete, pavements and slabs.

For other non-target organisms, the following safety phrases might be added on the label:

Do not apply when pollinating insects (bees, bumble bees...) and beneficial organisms are present (ladybirds, lacewings, hoverflies, ground beetles...).

Avoid spray drift to nearby plants.

3.8 Relevance of metabolites (Part B, Section 10)

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

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

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

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

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

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None.

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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 la demande d'autorisation de mise sur le marché du produit phytopharmaceutique **HERBICLEAN CONCENTRE***

*de la société **SBM DEVELOPPEMENT***

*enregistrée sous le **n°2020-1244***

Vu les conclusions de l'évaluation de l'Anses du 23 juin 2021,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et son annexe.

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	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 pélargonique
Numéro d'intrant	9990-2020.01
Numéro d'AMM	2210563
Fonction	Herbicide
Gamme d'usage	Amateur / emploi autorisé dans les jardins

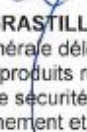
L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 août 2023.

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.

A Maisons-Alfort, le

30 AOÛT 2021


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



ANNEXE : 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 / éthylène alcool vinylique munies d'un bouchon doseur	125 mL ; 250 mL ; 500 mL ; 1 L
Bouteilles en polyéthylène haute densité / polyamide munies d'un bouchon doseur	125 mL ; 250 mL ; 500 mL ; 1 L

Les emballages de 3 et 5 L, ainsi que les emballages munis d'un capot doseur, sont refusés car ils ne permettent pas de garantir une exposition minimale de l'utilisateur.

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Dangers pour le milieu aquatique - Danger chronique, catégorie 3	H412 : Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme
Pour les phrases P se référer à la réglementation en vigueur.	
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.	

Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
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)
14055905 Arbres et arbustes* Désherbage*Plantat. Pl. terre	120 mL/10 m ² Application de mars à juillet. Intervalle minimum entre les applications : 21 jours. Les applications de février et d'août à octobre sont refusées en raison d'un risque inacceptable de contamination des eaux souterraines.	8/an	-	Non applicable	5	-	-
17405901 Cultures florales et plantes vertes* Désherbage	120 mL/10 m ² Application de mars à juillet. Intervalle minimum entre les applications : 21 jours. Les applications de février et d'août à octobre sont refusées en raison d'un risque inacceptable de contamination des eaux souterraines.	8/an	-	Non applicable	5	-	-
12555902 Fruits à noyau* Désherbage*Cult. Installées	120 mL/10 m ² Application de mars à juillet. Intervalle minimum entre les applications : 21 jours. Les applications de février et d'août à octobre sont refusées en raison d'un risque inacceptable de contamination des eaux souterraines.	8/an	-	3	5	-	-
12605905 Fruits à pépins* Désherbage*Cult. Installées	120 mL/10 m ² Uniquement sur pommier et poirier. Application de mars à juillet. Intervalle minimum entre les applications : 21 jours. Les applications de février et d'août à octobre sont refusées en raison d'un risque inacceptable de contamination des eaux souterraines.	8/an	-	3	5	-	-

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Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
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)
10015908 JEVI* Désherbage*PJT	120 mL/10 m² Application de mars à juillet. Intervalle minimum entre les applications : 21 jours. Les applications de février et d'août à octobre sont refusées en raison d'un risque inacceptable de contamination des eaux souterraines.	8/an	-	Non applicable	5	-	-
12155901 Petits fruits* Désherbage*Cult. Installées	120 mL/10 m² Application de mars à juillet. Intervalle minimum entre les applications : 21 jours. Les applications de février et d'août à octobre sont refusées en raison d'un risque inacceptable de contamination des eaux souterraines.	8/an	-	3	5	-	-
17305901 Rosier* Désherbage*PI, terre	120 mL/10 m² Application de mars à juillet. Intervalle minimum entre les applications : 21 jours. Les applications de février et d'août à octobre sont refusées en raison d'un risque inacceptable de contamination des eaux souterraines.	8/an	-	Non applicable	5	-	-
11015924 Traitements généraux* Désherbage*Avt Mise Cult.	120 mL/10 m² Application de mars à juillet. Intervalle minimum entre les applications : 21 jours. Les applications de février et d'août à octobre sont refusées en raison d'un risque inacceptable de contamination des eaux souterraines.	8/an	-	Non applicable	5	-	-

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Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
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)
11015932 Traitements généraux* Désherbage* Cult. Installées	120 mL/10 m² Application de mars à juillet. Intervalle minimum entre les applications : 21 jours. Les applications de février et d'août à octobre sont refusées en raison d'un risque inacceptable de contamination des eaux souterraines.	8/an	-	Non applicable	5	-	-
11015933 Traitements généraux* Désherbage* Zones agricoles non cult.	120 mL/10 m² Application de mars à juillet. Intervalle minimum entre les applications : 21 jours. Les applications de février et d'août à octobre sont refusées en raison d'un risque inacceptable de contamination des eaux souterraines.	8/an	-	Non applicable	5	-	-
11015906 Traitements généraux* Destruct. Algues	120 mL/10 m² Application de mars à juillet. Intervalle minimum entre les applications : 21 jours. Les applications de février et d'août à octobre sont refusées en raison d'un risque inacceptable de contamination des eaux souterraines.	8/an	-	Non applicable	5	-	-
11015908 Traitements généraux* Destruct. Mousses	120 mL/10 m² Application de mars à juillet. Intervalle minimum entre les applications : 21 jours. Les applications de février et d'août à octobre sont refusées en raison d'un risque inacceptable de contamination des eaux souterraines.	8/an	-	Non applicable	5	-	-

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Liste des usages refusés				
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	
18555901 Jardin d'amateur*Désherbage	120 mL/10 m²	8/an	-	
	Motivation du refus : L'usage est refusé car transitoire et supprimé du catalogue national des usages phytopharmaceutiques.			
00301054 Jardin d'amateur*Désherbage* All. PJT, Abords non plant.	120 mL/10 m²	8/an	-	
	Motivation du refus : L'usage est refusé car transitoire et supprimé du catalogue national des usages phytopharmaceutiques.			



Conditions d'emploi du produit

Stockage et manipulation du produit

- Agiter pendant l'application.

Délai de rentrée

- Attendre le séchage complet de la zone traitée.

Respect des limites maximales de résidus (LMR)

Le délai avant récolte est fixé à 3 jours pour les usages sur cultures consommables, conformément à la réglementation en vigueur.

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 d'emballages non utilisés et les eaux de lavage du pulvérisateur.
- Pour protéger les eaux souterraines, ne pas appliquer ce produit entre août et février pour les usages sur des surfaces perméables.

Protection de la faune

- Ne pas appliquer en présence d'insectes pollinisateurs et/ou auxiliaires (abeilles, bourdons, coccinelles, chrysopes ...).
- Pour protéger les organismes aquatiques, ne pas appliquer à moins de 5 mètres d'un point d'eau (puits, bassin, mare, ruisseau, rivière, fossé...).
- Pour protéger les organismes aquatiques, ne pas appliquer sur des jardins en pente ou des surfaces imperméables situées à proximité de point d'eau telles que le bitume, le béton, les pavés et les dalles.

Protection de la flore

- Éviter toute dérive de pulvérisation vers les plantes voisines.

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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.



FACE AVANT

Principe actif d'origine végétale
HERBICLEAN CONCENTRE

DESIGNATION COMMERCIALE

- Efficace sur Mauvaises herbes, Mousses et Algues
- Effet visible en 1 heure* (*Pour des températures supérieures ou égales à 20°C)
- Longue durée : jusqu'à 3-4 semaines

Produit de biocontrôle, au titre des articles L.253-5 et L.253-7 du code rural et de la pêche maritime : TBC

DESCRIPTION DU PRODUIT

Le nouveau Désherbant Herbiclean Concentré permet d'éliminer les principales mauvaises herbes annuelles, bi-annuelles et vivaces, avec une efficacité contre les mousses et algues. Il peut être utilisé, sous et autour des arbustes ornementaux, y compris les rosiers, les arbres fruitiers (petits fruits, pommier, fruits à noyau).

INFORMATIONS REGLEMENTAIRES

Nom homologué : Herbiclean Concentré
N°AMM : XXX – Emploi autorisé dans les jardins
Détenteur de l'AMM : SBM Développement (69)
Composition : 250 g/L Acide pélargonique (27,2 % m/m)
Formulation : EC (Concentré émulsionnable)
Type d'action : Herbicide non sélectif (traitement des parties aériennes)
Mode d'action : Contact
Numéro de lot et date de fabrication : voir sur l'emballage

PAVE DE SECURITE

HERBICLEAN CONCENTRE

Contient de l'acide pélargonique

H412 Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme.

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.

EUH401 Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

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

SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau (puits, bassin, mare, ruisseau, rivière, fossé...).

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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, appeler le 15 / 112 ou le centre antipoison.

Distribué par :
 SBM Life Science SAS - 60 Chemin des Mouilles - 69130 Ecully –
 Tél: 04 37 64 32 00

PRECAUTIONS D'EMPLOI

Porter des gants est recommandé pendant toutes les phases de manipulation.

Lors de l'application :

Ne pas appliquer sur gazon.

Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.

Éviter le contact avec toutes les parties vertes des plantes non ciblées.

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.

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.

Conserver le produit uniquement dans le récipient d'origine bien fermé à l'abri du gel et de l'humidité dans un endroit sec, frais et bien ventilé à l'écart des aliments et boissons y compris ceux pour animaux.

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.

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PERIODE D'EMPLOI

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



Période optimale

MODE 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 éliminer.

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.

Bien agiter le bidon avant emploi. Pour une efficacité optimale, traiter par temps clair les mauvaises herbes en croissance (de moins de 10 cm de hauteur) et appliquer la bouillie de façon à couvrir entièrement et uniformément les surfaces à traiter. Les mauvaises herbes ou mousses doivent être bien imbibées. • Agiter énergiquement la préparation avant et pendant l'application. • Retraiter en cas de nouvelle levée de mauvaises herbes.

A adapter selon l'emballage et fonctionnement de la bouteille

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USAGES

Dose : 120 ml/10m²

Intervalle minimum entre deux applications : 3 à 4 semaines

8 applications maximum par an

Zone non traitée aquatique : 5 mètres.

Usages	Dose d'emploi
Usages non agricoles * Désherbage * Allées de PJT, cimetières, voies	120 ml/10m ²
Traitements généraux * Désherbage * Avant Mise en Culture	
Traitements généraux * Désherbage * Cultures Installées	
Traitements généraux * Désherbage * Zones non cultivées	
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	
Jardin d'amateur * Désherbage	
Jardin d'amateur * Désherbage * Allées de PJT, Abords non plantés	
Traitements généraux * Destruction Mousses	120 ml/10m ²
Traitements généraux * Destruction Algues	

Volume net : 0,125 mL / 0,250 mL / 0.500mL / 1 litre / 3 litres / 5 litres

Référence : xxxx

Gencod : xxxx

PROD : xxxx

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