

REGISTRATION REPORT

Part A

Risk Management

Product code: 11ELM-AC-PAL-3

Product name(s): NET-HERBE PAE

Active Substance(s):

Caprylic acid 39.8 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: SBM Développement

Date: 2018-10-03

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PART A – Risk Management

The company SBM DEVELOPPEMENT has requested marketing authorisation in France for the product NET-HERBE PAE (11ELM-AC-PAL-3) (amateur use), containing Caprylic acid 39.8 g/L for use as an herbicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 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 NET-HERBE PAE (11ELM-AC-PAL-3) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of NET-HERBE PAE (11ELM-AC-PAL-3) have been made using endpoints agreed in the EU peer review(s) of Caprylic acid.

This document describes the specific conditions of use and labelling required for France for the registration of NET-HERBE PAE (11ELM-AC-PAL-3).

Appendix 1 of this document provides a copy of the French Decision.

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

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

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of SBM DEVELOPPEMENT's application to market NET-HERBE PAE (11ELM-AC-PAL-3) 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.

1.2 Active substance approval

Caprylic acid (Fatty acids C7 to C20)

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.

Specific provisions of Regulation (EU) No 540/2011 were as follows :

PART A

Only uses as insecticide, acaricide, and herbicide and plant growth regulator may be authorised.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fatty acids (SANCO/2610/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.

Conditions of use shall include, where appropriate, risk mitigation measures.

An EFSA conclusion is available (EFSA Journal 2013;11(1):3023.)

A Review Report is available (SANCO/2611/08 – rev. 2, 16 July 2013)

1.3 Regulatory approach

The present application (2013-0187) 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”)¹ – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4th May 2017² provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight 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.

The current document (RR) based on Anses’s 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 recommendations are based and is not intended to show the assessment in detail.

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

Finally, the French Order of 26 March 2014⁵ 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 extrapolation⁶ 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.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of NET-HERBE PAE (11ELM-AC-PAL-3), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

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 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/AGRGI632554A/jo/texte>

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

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 <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

⁶ SANCO document “guidance document: - Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

1.5 Letter(s) of Access

The applicant SBM DEVELOPPEMENT is not the notifier at European level of the substance active Caprylic acid. SBM DEVELOPPEMENT has a letter of access from Oleon NV, the producer of Caprylic acid, who submitted a specification dossier in France (dossier 2011-1267 spe) that was accepted on 26 January 2012.

The applicant has provided letter(s) of access.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	NET-HERBE PAE (11ELM-AC-PAL-3)
Authorisation number	2180367
Function	herbicide
Applicant	SBM DEVELOPPEMNT
Composition	39.8 g/L Caprylic acid
Formulation type (code)	AL
Packaging	PET Trigger sprayer of 750 mL

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No1272/2008

Physical hazards	
Health hazards	
Environmental hazards	Aquatic chronic 3
Hazard pictograms	
Signal word	Danger
Hazard statements	H412 Harmful to aquatic life with long lasting effects.
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>

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

2.2.2 Other phrases in compliance with Regulation (EU) No 547/2011

The authorisation of the preparation is linked for professional and non-professional uses only to the following conditions:

Home and garden uses:
Do not discharge into the sink, gutter or any other water hole the non-used container leftovers and the sprayer washing water.

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment⁷: not relevant

⁷ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

Re-entry period: wait complete drying of the treated area.
Pre-harvest interval ⁸ : -
Other mitigation measures: -
The label may include the following recommendations: - The label must reflect the conditions of authorisation.

⁸ According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

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. 1, date: 2018-10-03

PPP (product name/code)	NET-HERBE PAE (11ELM-AC-PAL-3)	Formulation type:	AL
active substance 1	Caprylic acid	Conc. of as 1:	39.8 g/L
active substance 2	none	Conc. of as 2:	---
active substance	none	Conc. of as:	---
safener	none	Conc. of safener:	---
synergist	none	Conc. of synergist:	---
Applicant:	SBM Développement	professional use	<input type="checkbox"/>
Zone(s): South		non professional use	<input checked="" type="checkbox"/>

Verified by MS:

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G 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. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per treatment period c) per year	kg, L product / ha a) max. rate per appl. b) max. total rate per treatment period c) max total rate per year	g, kg as/ha a) max. rate per appl. b) max. total rate per treatment period c) max total rate per year	Water L/ha min / max		
1	France	Parks, public gardens or sidewalks/pavements	F	Weeds	Hand held trigger sprayer	Not relevant	b) 2 (spring-summer / autumn-winter) c) 4 (2 treatments period/year) (21 days within	a) max 100 mL product/m ² b)200 mL product/m ²	a) Max 39.8 kg as/ha b)79.6 kg as/ha c) 159.2	Not relevant	Not relevant	Acceptable

		PJT				treatment period ; 84 days between treatment periods)	c) 400 mL product/m ²	kg/sa/ha				
				Moss destruction		b) 2 (interval 5 days)	a) max 75 ml product/m ² b) max 150 ml product/m ²	a) max 29.85 kg as/ha b) max 59.7 kg as/ha				
2	France	Ornamental area Weeding before cultivation (annuals)	F	Weeds	Hand held trigger sprayer	Not relevant	a) 2 (interval 5 days)	a) max 100 mL product/m ² b) max 200 ml product/m ²	a) max 39.8 kg as/ha b) max 79.6 kg/sa/ha	Not relevant	Not relevant	Acceptable
				Moss destruction			a) max 75 ml product/m ² b) max 150 ml product/m ²	a) max 29.85 kg as/ha b) max 59.7 kg as/ha				
3	France	Ornamental area Weeding before cultivation (perennials)	F	Weeds	Hand held trigger sprayer	Not relevant	a) 2 (interval 5 days)	a)max 100 mL product/m ² b) max 200 ml product/m ²	a) Max 39.8 kg as/ha b) max 79.6 kg/sa/ha	Not relevant	Not relevant	Acceptable
				Moss destruction			a) max 75 ml product/m ² b) max 150 ml product/m ²	a) max 29.85 kg as/ha b) max 59.7 kg as/ha				
4	France	Ornamental area Weeding before cultivation (bi-annuals)	F	Weeds	Hand held trigger sprayer	Not relevant	a) 2 (interval 5 days)	a)max 100 mL product/m ² b) max 200 ml product/m ²	a) Max 39.8 kg as/ha b) max 79.6 kg/sa/ha	Not relevant	Not relevant	Acceptable
				Moss destruction			a) max 75 ml product/m ² b) max 150 ml product/m ²	a) max 29.85 kg as/ha b) max 59.7 kg as/ha				

5	France	Ornamentals (trees and shrubs) Plantations weeding	F	Weeds	Hand held trigger sprayer	Not relevant	b) 2 (spring-summer / autumn-winter) c) 4 (2 treatments period/year) (21 days within treatment period ; 84 days between treatment periods)	a) max 100 mL product/m ² b)200 mL product/m ² c) 400 mL product/m ²	a) Max 39.8 kg as/ha b)79.6 kg as/ha c) 159.2 kg/sa/ha	Not relevant	Not relevant	Acceptable
				Moss destruction			a) 2 (interval 5 days)	a) max 75 ml product/m ² b) max 150 ml product/m ²	a) max 29.85 kg as/ha b) max 59.7 kg as/ha			
6	France	Rose trees weeding	F	Weeds	Hand held trigger sprayer	Not relevant	b) 2 (spring-summer / autumn-winter) c) 4 (2 treatments period/year) (21 days within treatment period ; 84 days between treatment periods)	a) max 100 mL product/m ² b)200 mL product/m ² c) 400 mL product/m ²	a) Max 39.8 kg as/ha b)79.6 kg as/ha c) 159.2 kg/sa/ha	Not relevant	Not relevant	Acceptable
				Moss destruction			a) 2 (interval 5 days)	a) max 75 ml product/m ² b) max 150 ml product/m ²	a) max 29.85 kg as/ha b) max 59.7 kg as/ha			
7	France	Flowers (various) weeding	F	Weeds	Hand held trigger sprayer	Not relevant	b) 2 (spring-summer / autumn-winter) c) 4 (2 treatments period/year) (21 days within treatment period ; 84 days between treatment periods)	a) max 100 mL product/m ² b)200 mL product/m ² c) 400 mL product/m ²	a) Max 39.8 kg as/ha b)79.6 kg as/ha c) 159.2 kg/sa/ha	Not relevant	Not relevant	Acceptable
				Moss destruction			a) 2 (interval 5 days)	a) max 75 ml product/m ² b) max 150 ml product/m ²	a) max 29.85 kg as/ha b) max 59.7 kg as/ha			

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
 - (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
 - (f) All abbreviations used must be explained
 - (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at 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
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

NET-HERBE PAE (11ELM-AC-PAL-3) is a any other liquid (AL) ready-to-use formulation. 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 white, opaque milky, homogenous slightly viscous, foaming liquid like condensed milk, typical goatish odour of caprylic acid. It is not explosive and has no oxidizing properties. The product is not flammable. The self- ignition temperature has not been provided. In aqueous solution (1%), it has a pH value of 3.75 at room temperature. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The product NET-HERBE PAE (11ELM-AC-PAL-3) must be protected from frost and stored at temperature > 0°C. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in PET. Its technical characteristics are acceptable for an any other liquid (AL) formulation

A 2-year storage study with the new composition should be provided in post-registration.

The formulation is not classified for the physico-chemical aspect

The formulation must be kept from freezing

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

Analytical methods for the determination of residues of caprylic acid in plants or foodstuffs of animal origin are not necessary.

No validated analytical method is available for the determination of residues of caprylic acid in soil, water or 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.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

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

3.1.2.2 Analytical methods for residues

Analytical methods for the determination of residues of caprylic acid in plants or foodstuffs of animal origin are not necessary.

No validated analytical method is available for the determination of residues of caprylic acid in soil, water or 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.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active Substance: Caprylic acid		
ADI	Not applicable	EU agreed endpoint (2013)
ARfD	Not applicable	
AOEL	821 mg/kg bw/d	

Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012), in the absence of data:	
		Ready-to-use 39.8 g/L
	Dermal absorption endpoints %	75 %

3.1.3.1 Acute Toxicity

NET-HERBE PAE (11ELM-AC-PAL-3) containing 39.8 g/L caprylic acid has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

The proposed packaging has been described in sufficient detail, and its compliance can therefore be finalised. In summary, compliance with the provisions of French Decree No. 2010-1755 of 30 December 2010 and Orders of 30 December 2010 relating to the use of certain plant protection products by non-professional users is considered to be finalised.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G ⁹	Equipment	Application rate (kg as/ha)	Spray dilution (L/ha)	Model
Parks, public gardens or sidewalks/pavements Ornamentals, flowers, rose trees	F	Hand-held trigger sprayer	100 mL/m ² (39.8 kg as/ha)	Ready-to-use	UPJ home garden model

Considering proposed uses, operator systemic exposure was estimated using the French study 2005 dedicated to amateur use (UPJ home garden model):

Crop	Equipment	PPE and/or working coverall	% AOEL Caprylic acid
Parks, public gardens or sidewalks/pavements Ornamentals, flowers, rose trees	Hand-held trigger sprayer	No PPE	0.16 %

According to the model calculations, it can be concluded that the risk for the amator using NET-HERBE PAE (11ELM-AC-PAL-3) is acceptable.

3.1.3.3 Bystander Exposure

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

Resident Exposure

Residential exposure was assessed according to BREAM model. Exposure is estimated 1.34 % of the AOEL of caprylic acid for children.

It is concluded that there is no unacceptable risk to the resident exposed to NET-HERBE PAE (11ELM-AC-PAL-3).

⁹ Outdoor or field use (F), glasshouse application (G)

3.1.3.4 Worker Exposure

NET-HERBE PAE (11ELM-AC-PAL-3) is intended to be used by amateurs during home garden application. In this case of the non-professional user, the worker is also the user of the product. It will be necessary to ensure complete drying of the treated area or of treated plants before handling them.

3.1.4 Residues and Consumer Exposure

Not necessary.

3.1.5 Environmental fate and behaviour

Considering the packaging and the application method of the ready to use preparation NET-HERBE PAE (11ELM-AC-PAL-3) (low volume container (750 mL) with trigger spray), exposure of environmental compartments to active substance is considered negligible. Consequently, no risk assessment for environment and non-target organisms is deemed necessary.

3.1.6 Ecotoxicology

Considering the packaging and the application method of the ready to use preparation NET-HERBE PAE (11ELM-AC-PAL-3) (low volume container (750 mL) with trigger spray), exposure of environmental compartments to active substance is considered negligible. Consequently, no risk assessment for environment and non-target organisms is deemed necessary.

3.1.7 Efficacy

NET-HERBE PAE (11ELM-AC-PAL-3) is a dilution of DESHERB'NAT (coded 11-ELM-AC-3) proposed in a ready to use package. The assessment of DESHERB'NAT is done in the same time than this dossier. In the understanding of zRMS this product is intended in home garden considering the label draft submitted. However it is not specified by the applicant in any part of the section Efficacy.

Considering all the data submitted:

The level of efficacy of NET-HERBE PAE (11ELM-AC-PAL-3) is considered as acceptable for all the claimed uses, except for the use “moss destruction” for which no data was submitted.

NET-HERBE PAE (11ELM-AC-PAL-3) cannot be considered as selective due to its mode of action. As caprylic acid is a non-selective contact herbicide which removes plant cuticle, the product must not be directed to green parts of the crop and the adjacent crops.

In these conditions:

- the risk of negative impact on the yield and the quality can be considered as negligible.
- the risk of negative impact on parts of plants used for propagating purposes can be considered as negligible.

The risk of negative impact on succeeding crops is considered as negligible.

The risk of resistance development or appearance to caprylic acid is considered as very low.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation **can be granted** as proposed in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

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

- A complete shelf life study at ambient temperature in sales packaging with the new composition.

3.4.3 Label amendments

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision



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 **NET-HERBE PAE***

*de la société **SBM DEVELOPPEMENT***

enregistrée sous le n°2013-0187

Vu les conclusions de l'évaluation de l'Anses du 8 août 2018,

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 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.



Informations générales sur le produit	
Nom du produit	NET-HERBE PAE
Type de produit	Produit de référence
Titulaire	SBM DEVELOPPEMENT 160, route de la Valentine CS70052 13374 MARSEILLE Cedex 11 France
Formulation	Autre liquide (AL)
Contenant	39,8 g/L - acide caprylique
Numéro d'intrant	9883-2013.01
Numéro d'AMM	2180367
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 2021.

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

03 OCT. 2018

Françoise WEBER
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 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 téréphtalate (avec pulvérisateur à gâchette)	750 mL

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 arthropodes non cibles (mètres)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles	
14055905 Arbres et arbustes*Désherbage* Plantat. Pl. terre	100 mL/m ² Intervalle minimum entre les applications : 21 jours. 2 applications par période de traitement (printemps-été / automne-hiver). Intervalle minimum entre les périodes de traitement : 84 jours.	4/an	-	Non applicable	-	-	-	-	
17405901 Cultures florales et plantes vertes*Désherbage	100 mL/m ² Intervalle minimum entre les applications : 21 jours. 2 applications par période de traitement (printemps-été / automne-hiver). Intervalle minimum entre les périodes de traitement : 84 jours.	4/an	-	Non applicable	-	-	-	-	
17305901 Rosier*Désherbage*Pl. terre	100 mL/m ² Intervalle minimum entre les applications : 21 jours. 2 applications par période de traitement (printemps-été / automne-hiver). Intervalle minimum entre les périodes de traitement : 84 jours.	4/an	-	Non applicable	-	-	-	-	
11015924 Traitements généraux*Désherbage* Avt Mise Cult.	100 mL/m ² Intervalle minimum entre les applications : 5 jours.	2/an	-	Non applicable	-	-	-	-	
11015908 Traitements généraux* Destruct. Mousses	75 mL/m ² Intervalle minimum entre les applications : 5 jours.	2/an	-	Non applicable	-	-	-	-	
11015903 Usages non agricoles* Désherbage*PJT	100 mL/m ² Intervalle minimum entre les applications : 21 jours. 2 applications par période de traitement (printemps-été / automne-hiver). Intervalle minimum entre les périodes de traitement : 84 jours.	4/an	-	Non applicable	-	-	-	-	

NET-HERBE PAE
AMM n°2180367



Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
11015921 Traitements généraux*Désherbage* Zones Cult. Avt Plantat.	100 mL/m ²	2/an	-
Motivation du refus : L'usage est refusé puisque jugé non pertinent car déjà couvert par l'usage N°11015924.			

NET-HERBE PAE
AMM n°2180367



Conditions d'emploi du produit

Stockage et manipulation du produit

- Ne pas diriger l'application de la préparation vers les parties vertes des plantes non-cibles.

Délai de rentrée en application de l'arrêté du 4 mai 2017 :

- Attendre le séchage complet de la zone traitée.

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.

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)	Réurrence (mois)
Fournir les résultats de l'étude en cours de réalisation, concernant la stabilité au stockage pendant 2 ans, à température ambiante avec la nouvelle composition.	24	-

Appendix 2 – Copy of the draft product label as proposed by the applicant



PRÉSENTATION
Une substance active issue d'huiles végétales !
La substance active de NET-HERBE® PAE est naturellement présente dans certaines huiles végétales et le lait. Il s'agit d'un acide gras faisant partie du régime alimentaire de l'homme et de nombreux animaux.
NET-HERBE® PAE est un désherbant de contact non sélectif.
Appliqué sur la partie verte des plantes, il provoque une dégradation des tissus allant jusqu'à un dessèchement complet de la plante visible dans les 24 heures suivant le traitement.

INFORMATIONS RÉGLEMENTAIRES
Nom homologué : NET-HERBE® PAE - N° AMM : ... (Emploi autorisé dans les jardins) - Détenteur de l'Autorisation de mise sur le marché : SBM DEVELOPPEMENT (160 route de la Valentine 13011 MARSEILLE)
Composition : acide caprylique 39,8 g/L (soit 4 % p/p) • Formulation : liquide prêt-à-l'emploi (AL) • Type d'action du produit : herbicide • Volume de produit : 750 ml • Numéro de lot : voir sur l'emballage.

TABLEAU DES USAGES

Usages	Dose	Nombre maximum d'applications par an
Traitements généraux, désherbage des allées de parcs, jardins publics, trottoirs (Surfaces perméables uniquement)	100 ml / m² (soit, à la limite du ruissellement sur le feuillage)	4 applications par an (2 au printemps + 2 en automne) - intervalle minimum de 3 semaines entre 2 applications et de 12 semaines entre les 2 périodes
Désherbage des Arbres et arbustes d'ornement, rosiers, cultures florales		
Traitements généraux, désherbage (plantes annuelles, bisannuelles et vivaces) des zones cultivées avant mise en cultures		2 applications par an avec un intervalle mini-maxi de 5-21 jours

PÉRIODE D'EMPLOI
J F M A M J J A S O N D Ideal Possible

MODE D'EMPLOI
Bien agiter avant emploi!
Traiter dans des conditions de températures supérieures à 12°C • sur feuillage sec, sans risque de pluie dans les 24 heures minimum et en l'absence de vent. Pour une bonne efficacité, bien mouiller les mauvaises herbes. Prendre soin de ne pas toucher pas de plantes cultivées. Éviter les projections sur métaux et matières plastiques.
A stocker à une température supérieure à 8°C. En dessous, des pailettes peuvent se former • ce phénomène est réversible après mise à bonne température et n'affecte pas l'efficacité du produit.
Emballage : réemploi interdit. Éliminer les emballages avec ou sans reliquat de produit, dans une déchèterie.

NET-HERBE® PAE
Contient de l'acide octanoïque (caprylique)
P101 : En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette. P302 : Tenir hors de portée des enfants. P303 : Lire l'étiquette avant utilisation.
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.
Distribué par : NOVAJARDIN - 160, route de la Valentine 13011 MARSEILLE - Tél : 04 91 24 44 40
En cas d'urgence, appeler le 15 ou le centre anti-poison

NOVAJARDIN
160, route de la Valentine - 13011 MARSEILLE
Tél : 04 91 24 44 40
www.solabiol.com

Volume : **750 ml**

FACTICE
356 156 XXX XXX X
SOHERPAL750 - XXXXX-12A

SOLABIOI • Date : 26/11/12 • Ref : SOHERPAL750 - XXXXX-12A • Dim : 90x117 mm • Couleurs : CMJN - P:4625C

Appendix 3 – Letter(s) of Access

Provided upon request.