

REGISTRATION REPORT

Part A

Risk Management

Product code: 11ELM-AC-3

Product name(s): NET-HERBE

Active Substance(s):

Caprylic acid 564 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: SBM Développement

Date: 2018-10-15

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PART A – Risk Management

The company SBM DEVELOPPEMENT has requested marketing authorisation in France for the product NET-HERBE (amateur uses) (11ELM-AC-3), containing 564 g/L Caprylic acid 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 (11ELM-AC-3) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of NET-HERBE (11ELM-AC-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 (11ELM-AC-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 Développement's application to market NET-HERBE (11ELM-AC-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 (2013-0202) 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

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

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

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 (11ELM-AC-3)
Authorisation number	not registered in France
Function	herbicide
Applicant	SBM DEVELOPPEMENT
Composition	564 g/L Caprylic acid
Formulation type (code)	oil-in-water emulsion EW
Packaging	NA: not registered in France

2.2 Classification and labelling

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

Physical hazards	
Health hazards	Skin irritation cat. 2, Serious eye damage cat. 1
Environmental hazards	Aquatic chronic 3
Hazard pictograms	
Signal word	Danger
Hazard statements	H315 Causes skin irritation H318 Causes serious eye damage 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

NA: not registered in France

2.2.3 Other phrases linked to the preparation

NA: not registered in France

2.3 Product uses

Please note:

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

GAP rev. 1, date: 2018-10-15

PPP (product name/code)	NET-HERBE (11ELM-AC-3)	Formulation type:	EW
active substance 1	Caprylic acid	Conc. of as 1:	564 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 DEVELOPPEMENT	professional use	<input type="checkbox"/>
Zone(s): southern		non professional use	<input checked="" type="checkbox"/>

Verified by MS: y

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			Water L/ha min / max	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 crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season			
1	FR	Parks, public gardens or sidewalks/pavements PJT	F	Weeds	Manual hand-held sprayer or knapsack with flat spray and spray shield when used near a culture	2 treatment periods: spring- early summer & autumn-early winter	2	a)max 8 mL product/m ² b)16 mL product/m ² / crop/ treatment period	a) Max 45.12 kg as/ha per application b)90.24 kg as/ha per season	500-1000	Not relevant	Not acceptable (classification of the product for non- professional users)
2	FR	Ornamental cultivated area Weeding before cultivation (annuals)	F	Weeds	Manual hand-held sprayer or knapsack with flat spray and spray shield when used near a culture	Not relevant	a) 2/treatment period (interval 5 - 21 days)	a)max 8 mL product/m ²	a) Max 45.12 kg as/ha per application	500-1000	Not relevant	Not acceptable (classification of the product for non- professional users)

3	FR	Ornamental cultivated area Weeding before cultivation (bi-annuals)	F	Weeds	Manual hand-held sprayer or knapsack with flat spray and spray shield when used near a culture	Not relevant	a) 2/treatment period (interval 5 - 21 days)	a)max 8 mL product/m ²	a) Max 45.12 kg as/ha per application	500-1000	Not relevant	Not acceptable (classification of the product for non- professional users)
4	FR	Ornamental cultivated area Weeding before cultivation (perennials)	F	Weeds	Manual hand-held sprayer or knapsack with flat spray and spray shield when used near a culture	Not relevant	a) 2/treatment period (interval 5 - 21 days)	a)max 8 mL product/m ²	a) Max 45.12 kg as/ha per application	500-1000	Not relevant	Not acceptable (classification of the product for non- professional users)
5	FR	Ornamentals (trees and shrubs) Plantations weeding	F	Weeds	Manual hand-held sprayer or knapsack with flat spray and spray shield culture	Not relevant	2	a)max 8 mL product/m ² b)16 mL product/m ² / crop/ treatment period	a) Max 45.12 kg as/ha per application b)90.24 kg as/ha per season	500-1000	Not relevant	Not acceptable (classification of the product for non- professional users)
6	FR	Rose trees Weeding	F	Weeds	Manual hand-held sprayer or knapsack with flat spray and spray shield	Not relevant	2	a)max 8 mL product/m ² b)16 mL product/m ² / crop/ treatment period	a) Max 45.12 kg as/ha per application b)90.24 kg as/ha per season	500-1000	Not relevant	Not acceptable (classification of the product for non- professional users)
7	FR	Flowers (various) Weeding	F	Weeds	Manual hand-held sprayer or knapsack with flat spray and spray shield.	Not relevant	2	a)max 8 mL product/m ² b)16 mL product/m ² / crop/ treatment period	a) Max 45.12 kg as/ha per application b)90.24 kg as/ha per season	500-1000	Not relevant	Not acceptable (classification of the product for non- professional users)

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 (11ELM-AC-3) is an oil-in-water emulsion EW. 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 white homogenous opaque liquid. The product is not flammable. Self- ignition temperature has not been determined, but is expected to be above 99.9 °C. In aqueous solution (1%), it has a pH value of 3.6 at 20°C. There is no effect of low temperature on the stability of the formulation, since after 7 day at 0°C the technical properties were not changed. The formulation is moderately affected by high temperature, since after 14 days at 54°C, the active ingredient content was not changed, but emulsion stability has lowered. Its technical characteristics are acceptable for an EW formulation.

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

A test of pourability is required for the new formulation and should be provided in post authorization.

The formulation is not classified for the physico-chemical aspect

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 methods are 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:		
		Concentrate (used in formulation) 564 g/L	Spray dilution (used in formulation) 45 g/L

	Dermal absorption endpoints %	25 %	75 %
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3.1.3.1 Acute Toxicity

NET-HERBE (11ELM-AC-3) containing 564 g/L caprylic acid has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is irritating to the rabbit skin and the eye and is not a skin sensitiser.

NET'HERBE (11ELM-AC-3): 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 not acceptable. It cannot be considered that the exposure of the non-professional user, regarding the classification (ocular risk), will be minimal.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G ⁷	Equipment	Application rate (kg as/ha)	Spray dilution (L/ha)	Model
Parks, public gardens or sidewalks/pavements Ornamentals, flowers, rose trees	F	Hand-held sprayer	8 mL/m ² (45.12 kg as/ha)	1000	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 sprayer	No PPE	0.08 %

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

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

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.

3.1.3.4 Resident Exposure

Residential exposure was assessed according to BREAM model (only for PJT uses). Exposure is estimated 1.5 % of the AOEL of caprylic acid for children.

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

3.1.3.5 Worker Exposure

⁷ Open field or glasshouse

NET-HERBE (11ELM-AC-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.
For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

3.1.4 Residues and Consumer Exposure

Not necessary.

3.1.5 Environmental fate and behaviour

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 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 caprylic acid in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

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

PEC_{gw} for caprylic acid do not occur at levels exceeding those mentioned in regulation EC 1107/2009 for uses with 2 applications per year when the product is applied between March and August. However these levels are exceeded when the product is applied in September. Therefore, no unacceptable risk of groundwater contamination is expected for uses involving 2 applications per year when the product is applied between March and August.

PEC_{gw} for caprylic acid considering spot treatment application are not available for all relevant FOCUS scenarios for uses with 4 applications per year. Therefore, based on the results provided by the applicant, unacceptable risk of groundwater contamination cannot be excluded and the risk assessment cannot be finalized for uses involving 4 applications per year.

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.

3.1.6 Ecotoxicology

For home and garden uses, only birds and aquatic assessment is considered relevant for ecotoxicologic evaluation. The risk to birds is considered acceptable for the intended uses. For aquatic organisms, the risk to Caprylic acid following the intended uses of the formulation NET-HERBE (11ELM-AC-3) can be considered as acceptable, with the following mitigation measure:

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

Moreover, the risk for aquatic organisms cannot be performed for applications on impermeable surface. The following safety phrase might be added on the label:

To protect aquatic organisms do not apply in sloping gardens or impermeable surfaces located near a waterhole such as asphalt, concrete, pavements and slabs.

For other non-target organisms, the following precaution sentence will be applied:

Do not treat when beneficial organisms are visiting the area.

Avoid spray drift and runoff to nearby plants.

Do not treat when bees are visiting the area.

3.1.7 Efficacy

NET'HERBE (11ELM-AC-3) is an oil emulsion in water formulation (EW) containing 564 g/l of caprylic acid.

Considering all the data submitted:

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

NET-HERBE (11ELM-AC-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

The product NET'HERBE (11ELM-AC-3) is classified H318 causes serious eye damage that is not acceptable for a product intended to be used by non-professional users. The product is not compliant with the French regulations relating to the use by non-professional users.

Taking into account the above assessment, an authorisation cannot 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

NA: not registered in France.

3.4.2 Post-authorisation data requirements

NA: not registered in france

3.4.3 Label amendments

NA: not registered in France.

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

Vu l'avis de l'Anses du 16 février 2016 (saisine 2013-SA-0128) relatif à la modification ou à l'apport de précision de 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 du produit phytopharmaceutique **NET-HERBE***

*de la société **SBM DEVELOPPEMENT***

*enregistrée sous le **n°2013-0202***

Vu les conclusions de l'évaluation de l'Anses du 19 juin 2018,

Considérant que la classification du produit ne permet pas la délivrance d'une autorisation pour un emploi par des utilisateurs non professionnels,

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.

NET-HERBE
AMM n°-

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Informations générales sur le produit		
Nom du produit	NET-HERBE	
Type de produit	Deuxième gamme	
Titulaire	SBM DEVELOPPEMENT 160, route de la Valentine CS70052 13374 MARSEILLE Cedex 11 France	
Formulation	Emulsion de type aqueux (EW)	
Contenant	564 g/L - acide caprylique	
Produit de référence	Nom commercial	DESHRB'NAT
	N° AMM	2180369
Numéro d'intrant	9884-2013.01	
Numéro d'AMM	-	
Fonction	Herbicide	
Gamme d'usage	Amateur / emploi autorisé dans les jardins	

A Maisons-Alfort le,

15 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)

NET-HERBE
AMM n°-

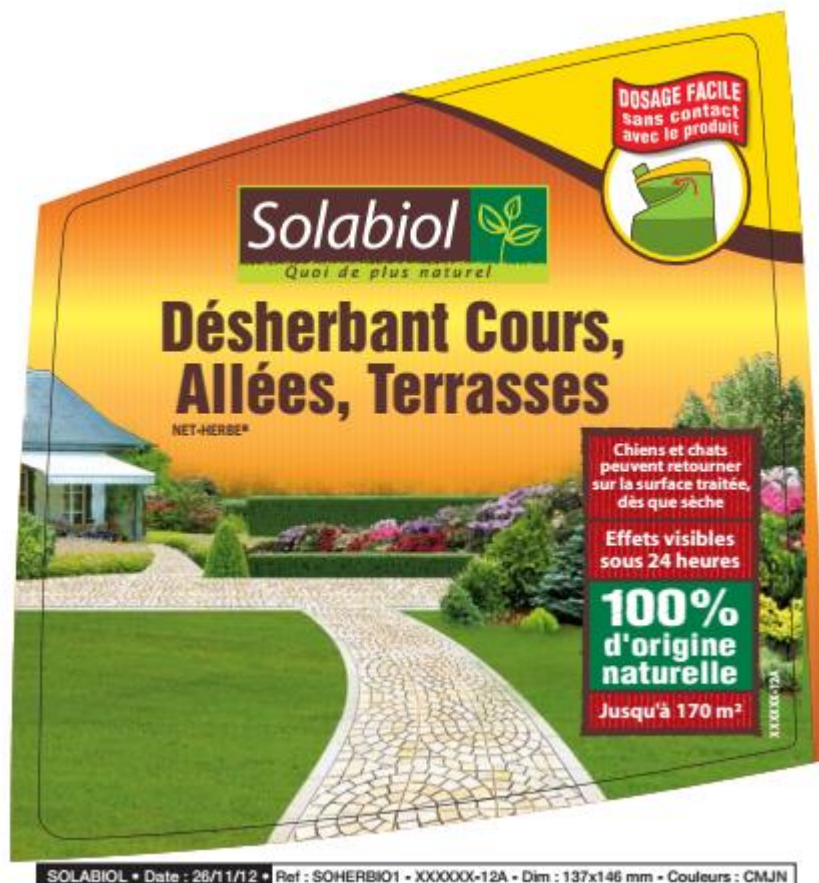
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ANNEXE I : Classification du produit

Classification du produit	
Catégorie de danger	Mention de danger
Corrosion cutanée/irritation cutanée - Catégorie 2	H315 : Provoque une irritation cutanée
Lésions oculaires graves et irritation oculaire - Catégorie 1	H318 : Provoque des lésions oculaires graves
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.	

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



[illegible]

Appendix 3 – Letter(s) of Access

Provided upon request.