

REGISTRATION REPORT

Part A

Risk Management

Product code: UKS118A

**Product name: LANDSCAPER PRO WEED
CONTROL + FERTILIZER**

Active substances:

2,4-D 8 g/kg

dicamba 1.2 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(authorisation renewal according to Art. 43)

**Applicant: EVERGREEN GARDEN CARE France
SAS**

Date: 2021/01/22 (Decision)

Table of Contents

1	DETAILS OF THE APPLICATION.....	4
1.1	APPLICATION BACKGROUND.....	4
1.2	ACTIVE SUBSTANCE APPROVAL.....	4
1.3	REGULATORY APPROACH.....	5
1.4	DATA PROTECTION CLAIMS.....	6
1.5	LETTER(S) OF ACCESS.....	7
2	DETAILS OF THE AUTHORISATION.....	8
2.1	PRODUCT IDENTITY.....	8
2.2	CLASSIFICATION AND LABELLING.....	8
2.2.1	<i>Classification and labelling under Directive 99/45/EC.....</i>	<i>8</i>
2.2.2	<i>Classification and labelling in accordance with Regulation (EC) No 1272/2008.....</i>	<i>8</i>
2.2.3	<i>Other phrases in compliance with Regulation (EU) No 547/2011.....</i>	<i>8</i>
2.2.4	<i>Other phrases linked to the preparation.....</i>	<i>9</i>
2.3	PRODUCT USES.....	10
3	RISK MANAGEMENT.....	12
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	12
3.1.1	<i>Physical and chemical properties.....</i>	<i>12</i>
3.1.2	<i>Methods of analysis.....</i>	<i>12</i>
3.1.3	<i>Mammalian Toxicology.....</i>	<i>12</i>
3.1.4	<i>Consumer exposure.....</i>	<i>14</i>
	<i>Given the proposed use, no exposure of consumers is anticipated.</i>	<i>14</i>
3.1.5	<i>Environmental fate and behaviour.....</i>	<i>15</i>
3.1.6	<i>Ecotoxicology.....</i>	<i>15</i>
3.1.7	<i>Efficacy.....</i>	<i>15</i>
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT.....	17
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING.....	17
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.....	17
3.4.1	<i>Post-authorisation monitoring.....</i>	<i>17</i>
3.4.2	<i>Post-authorisation data requirements.....</i>	<i>17</i>
3.4.3	<i>Label amendments.....</i>	<i>17</i>
	APPENDIX 1 – COPY OF THE FRENCH DECISION.....	18
	APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT.....	24
	APPENDIX 3 – LETTER(S) OF ACCESS.....	25

zRMS NOTE

In order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, the risk assessment conclusions only applies for the active substance 2,4-D following its renewal of approval.

PART A – Risk Management

The company EVERGREEN GARDEN CARE FRANCE SAS has requested a renewal of marketing authorisation in France for the product LANDSCAPER PRO WEED CONTROL + FERTILIZER¹ (product code : UKS118A, marketing authorisation no 2150944; formulation code: GR), containing 8 g/kg 2,4-D and 1.2 g/kg dicamba, as a herbicide and a fertiliser.

The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-8 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to LANDSCAPER PRO WEED CONTROL + FERTILIZER (UKS118A) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of LANDSCAPER PRO WEED CONTROL + FERTILIZER (UKS118A) have been made using endpoints agreed in the EU peer reviews of both 2,4-D and dicamba.

This document describes the specific conditions of use and labelling required for France for the registration of LANDSCAPER PRO WEED CONTROL + FERTILIZER (UKS118A).

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

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

Appendix 3 of this document contains 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 EVERGREEN GARDEN CARE FRANCE SAS's application to market LANDSCAPER PRO WEED CONTROL + FERTILIZER (UKS118A) in France as a herbicide and a fertiliser (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 renewal of authorisation after approval of the active substance 2,4-D of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

2,4-D

Commission Implementing Regulation (EU) 2015/2033 of 13 November 2015 renewing the approval of the active substance 2,4-D in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Specific provisions of Regulation (EU) No 2015/2033 were as follows:

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 2,4-D, and in particular Appendices I and II thereof, shall be taken into account.

In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms, terrestrial organisms and consumers in cases of uses above 750 g/ha.

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

The notifier shall submit to the Commission, the Member States and the Authority:

(1) confirmatory information in the form of the submission of the complete study results from the existing extended

¹ An identical formulation, for non-professional use, is ENGRAIS DESHERBANT MU (marketing authorisation n° 2000390)

one-generation study;

(2) confirmatory information in the form of the submission of the Amphibian Metamorphosis Assay (AMA) (OECD (2009) Test No 231) as to verify the potential endocrine properties of the substance.

The information set out in point (1) shall be submitted by 4 June 2016 and the information set out in point (2) by 4 December 2017.

An EFSA conclusion is available (EFSA Journal 2014; 12(9):3812).

A review report is available in the form of a Revised Renewal report (SANCO/11961/2014 Rev 5 of 6 October 2017).

Dicamba

Commission Implementing Regulation (EU) No 1100/2011 of 31 October 2011 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances dicamba, difenoconazole, and imazaquine.

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

PART A

Only uses as herbicide 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 dicamba, 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.

Specific provisions of Regulation (EU) No 1100/2011 were to amend Part B as follows:

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 dicamba, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011 shall be taken into account.

In this overall assessment Member States shall pay particular attention to the protection of non-target plants.

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

The notifier shall submit confirmatory information as regards:

(a) the identification and quantification of a group of soil transformation products formed in a soil incubation study;

(b) the potential for long range transport through the atmosphere.

The notifier shall submit this information to the Member States, the Commission and the Authority by 30 November 2013.

An EFSA conclusion is available (EFSA Journal 2011; 9(1): 1965) plus the outcome of the consultation on confirmatory data used in the risk assessment (Efsa technical report, 1 April 2016).

A review report is available (SANCO/829/08 – final rev. 2 of 12 July 2016).

1.3 Regulatory approach

The present application (2016-1260 and 2019-6269) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)² in the context of the zonal procedure for all Member

² French Food Safety Agency, Afssa, before 1 July 2010

States of the Southern zone, taking into account the worst-case uses (“risk envelope approach”)³ – the highest application rates applied for in 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 2017⁴ provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless otherwise 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, non-spraying 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’ assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009⁵, 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 on the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011⁶, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁷ provides that:

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁸ 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 LANDSCAPER PRO WEED CONTROL + FERTILIZER (UKS118A), it is indicated in the reference lists in Appendix 1 of the Registration

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 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>

⁵ 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

⁶ 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

⁷ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

⁸ SANCO document “guidance document: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

Report, Part B Sections 1-7.

1.5 Letter(s) of Access

The applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-8. The applicant has provided Letter(s) of Access for active substance.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	LANDSCAPER PRO WEED CONTROL + FERTILIZER (UKS118A)
Authorisation number	2150944
Function	Herbicide, fertiliser Professional use
Applicant	EVERGREEN GARDEN CARE FRANCE SAS
Composition	8 g/kg 2,4-D 1.2 g/kg dicamba
Formulation type (code)	Granule [GR]
Packaging	Low-density polyethylene (LDPE) sacks containing 7.5 kg, 10 kg, 15 kg, 20 kg or 25kg product Bulk bag in PE/woven polypropylene containing 1000 kg product

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

2.2.2 Classification and labelling in accordance with Regulation (EC) No 1272/2008

Physical hazards	-	
Health hazards	-	
Environmental hazards	-	
Hazard pictograms	-	
Signal word	-	
Hazard statements	-	-
Precautionary statements –	<i>For the P phrases, refer to the existant legislation</i>	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH208	Contains 2,4-D. May produce an allergic reaction ⁹

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

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

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

⁹ LANDSCAPER PRO WEED CONTROL + FERTILIZER (UKS118A) contains $\geq 0,1$ % of 2,4-D acid (classified as a skin sensitiser category 1 in the CLP Regulation). This concentration limit for elicitation is used to protect already-sensitised individuals.

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).
SPe 6	To protect birds and wild mammals, remove spillages.
SPe 3	To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 5 metres to surface water bodies ¹⁰ .

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment ¹¹ : refer to the Decision in Appendix 1 for the details.
Re-entry period ¹² : Not applicable (spreading of granules).
Pre-harvest interval ¹³ : Not applicable.
Other mitigation measures: - -
<p>The label may include the following recommendations:</p> <p>Precise the conditions of use of mowing waste as mulch or compost.</p> <p>Precise the optimal conditions for using the product in order to limit the risk of phytotoxicity on adjacent crops.</p> <p>This product is a mixed product: NPK fertilizer complying with a mandatory application standard (to be recalled) and herbicide.</p> <p>The label must reflect the conditions of authorisation.</p>

¹⁰ to limit the risk of eutrophication

¹¹ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

¹² The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

¹³ 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.

date: 2021-01-22

PPP (product name/code) **LANDSCAPER PRO WEED CONTROL +
FERTILIZER/UKS118A**
active substance 1 **2,4-D**
active substance 2 **dicamba**

Formulation type: **GR**
Conc. of a.s. 1: **8 g/kg**
Conc. of a.s. 2: **1.2 g/kg**

Applicant: **EVERGREEN GARDEN CARE FRANCE SAS**
Zone(s): **Southern EU**
Verified by MS: **yes**

professional use ☒
non-professional use ☐

1	2	3	4	5	6	7	8	10	11	12	13	14	15
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I (a)	Pests or Group of pests controlled (b) (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days) (g)	Remarks: e.g. g safener/synergist per ha (h)	zRMS Conclusion
					Method / Kind (c-e)	Timing / Growth stage of crop & season (f)	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 a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
1	France	Managed amenity turf (professional uses) (non- agricultural zones: parks and municipal gardens, sports grounds, golf courses, cemeteries)	F	Broad-leaved weeds (BBBBB) including but not limited to: TAROF, <i>Taraxacum officinale</i> ; TREFRE, <i>Trifolium repens</i> L.; PLALA, <i>Plantago lanceolata</i> L.; PLAMA <i>Plantago major</i> L.; BELPE, <i>Bellis perennis</i> L.; RANRE, <i>Ranunculus repens</i> L. Post-emergent	Suitable granular applicator	During vegetation period (March to July)	a) 1 b) 1	a) 200 kg/ha b) 200 kg/ha	a) 2,4-D: 1600 g/ha Dicamba: 240 g/ha b) 2,4-D: 1600 g/ha Dicamba: 240 g/ha	N/A	N/A	Professional uses. On established lawns only. Because of the presence of dicamba, it is advisable not to use grass cuttings as mulch or compost.	Acceptable (with vehicle- mounted spreader) Unacceptable (risk to operators with manual spreader)

-
- Remarks:**
- (a) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (b) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
 - (c) All abbreviations used must be explained
 - (d) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (e) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (f) 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
 - (g) PHI - minimum pre-harvest interval
 - (h) Remarks may include: Extent of use/economic importance/restrictions
- N/A: not applicable.

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

LANDSCAPER PRO WEED CONTROL + FERTILIZER (UKS118A) is a granule formulation (GR). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is of light grey/brown pellets of approx. 0.5-2.0 mm diameter. It is not explosive, has no oxidising properties and is not flammable. It has a self-ignition temperature above 400 °C. In 1 % aqueous solution, it has a pH value of 3.39 at 20 °C. There is no effect of high temperatures on the stability of the formulation, since after 14 days at 54 °C and eight weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in LDPE. As the formulation is GR, all the different types of packaging can be considered acceptable. The technical characteristics are acceptable for a GR formulation.

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

3.1.2 Methods of analysis

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

The relevant impurities of the active substance 2,4-D (dioxins and furans expressed as TCDD equivalent toxic <10ppb) cannot be formed during the production of the preparation and the storage of the PPP. The contents of its relevant impurities are below the specifications in the active substance. The analytical methods for the determination of these impurities in the technical active substance are validated. However, no analytical method for the determination of these relevant impurities is submitted and is required in post-authorization.

Analytical methods are available in the Draft Assessment Report (DAR) and validated for the determination of residues of dicamba and 2,4-D in soil, water (surface and drinking) and air.

Analytical methods for the determination of residues of dicamba and 2,4-D in foodstuffs of plant and animal origin are not necessary.

The active substances are 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: 2,4-D		
AOEL	0.02 mg/kg bw/d	EFSA Journal 2014;12(9):3812
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2017):	
		Concentrate (used in formulation)
	Dermal absorption endpoints %	50

Active Substance: Dicamba		
AOEL	0.3 mg/kg bw/d	EFSA Journal 2011;9(1):1965
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2017):	
		Concentrate (used in formulation)
	Dermal absorption endpoints %	50

3.1.3.1 Acute Toxicity

LANDSCAPER PRO WEED CONTROL + FERTILIZER (UKS118A) containing 8 g/kg 2,4-D and 1.2 g/kg dicamba 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.

3.1.3.2 Operator Exposure

Only 2,4-D is subject to the renewal according to Art. 43, and as such has been assessed.

The plant protection product LANDSCAPER PRO WEED CONTROL + FERTILIZER (UKS118A) containing 8 g/kg of 2,4-D and 1.2 g/kg of dicamba is intended to be used on lawns as a weed eliminator once a year in order to improve the growth of the lawn and control broad-leaved weeds. LANDSCAPER PRO WEED CONTROL + FERTILIZER (UKS118A) is to be used for spreading (type of formulation GR).

Summary of critical use patterns (worst cases):

Crop type	F/G ¹⁴	Equipment <i>Application method</i>	Maximum application rate
Grassland and lawns	F	Vehicle mounted/Manual application of granules. <i>Downward spraying</i>	200 kg/ha (1.6 kg/ha of 2,4-D)

Considering proposed uses, operator systemic exposure was estimated using the EFSA model¹⁵:

Crop	Equipment	PPE and/or working coverall	% AOEL 2,4-D
Grassland and lawns	Manual application of granules	Gloves and coverall for mixing and loading, and application + FP2, P2 during mixing and loading, and application	6500%

Crop	Equipment	PPE and/or working coverall	% AOEL 2,4-D
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¹⁴ Open field or glasshouse

¹⁵ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

Grassland and lawns	Vehicule mounted (granules)	Gloves and coverall for mixing and loading, and application + FP2, P2 during mixing and loading	98%
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According to the model calculations, it can be concluded that the risk for the operator using LANDSCAPER WEED CONTROL + FERTILIZER (UKS118A) is not acceptable for manual application of granules.

It can be concluded that the risk for the operator using LANDSCAPER WEED CONTROL + FERTILIZER (UKS118A) is acceptable only for vehicle mounted equipment with gloves and coverall for mixing and loading, and application + FP2, P2 during mixing and loading for the active substance 2,4-D.

In order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, only the AS under review, 2,4-D, is evaluated.

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

3.1.3.3 Bystander Exposure

Due to the application technique for LANDSCAPER PRO WEED CONTROL + FERTILIZER (UKS118A), where the granular formulation is applied directly on to turf, no drift is expected. In addition, the active substances are not volatile in this formulation type and the formulation is a solid non-dusty granule. Consequently, it is considered that it is unnecessary to assess the risk of bystander exposure.

3.1.3.4 Resident Exposure

Due to the application technique for LANDSCAPER PRO WEED CONTROL + FERTILIZER (UKS118A), where the granular formulation is applied directly on the soil, no drift is expected. Moreover, there is no resident exposure for entry into treated crops. Results are presented in table below.

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and/or child) when mitigation measures such as a buffer zone of 2-3 meters are taken:

Model (AOEM) - All pathways (mean)	% AOEL 2.4-D (Vapour : 75 th percentile)	% AOEL 2.4-D (Deposits : 75 th percentile)
Resident (children)	5.4%	7.9%
Resident (adults)	1.2%	2.9%

3.1.3.5 Worker Exposure

Broadcast application of granules or Manual application is intended for LANDSCAPER PRO WEED CONTROL + FERTILIZER (UKS118A); no work is expected to be practiced after application. Therefore, worker exposure estimation is considered not relevant.

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

3.1.4 Consumer exposure

Given the proposed use, no exposure of consumers is anticipated.

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 and its 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.

In order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, this risk assessment report for the sections “Fate and behaviour in the Environment / Ecotoxicology” only applies for the active substance 2,4-D following its renewal of approval. For the other active substance, provisions of the initial authorization remain.

The PEC of 2,4-D and its metabolites in 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_{gw} for 2,4-D and its metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

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

In order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, this risk assessment report for the sections “Ecotoxicology” only applies for the active substance 2,4-D following its renewal of approval. For other active substances, provisions of the initial authorization remain.

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for active substances and their metabolites were used for the intended use patterns.

Based on the guidance documents, the risks for birds, mammals, aquatic organisms, bees and other non-target arthropods, earthworms and other soil macro-organisms, micro-organisms and non-target plants are acceptable for the intended uses of UKS 118A according to the intended GAP for intended uses by professional users. Risk mitigations are required to protect aquatic organisms.

3.1.7 Efficacy

Considering the data submitted:

- ✓ The efficacy of LANDSCAPER PRO WEED CONTROL + FERTILIZER (UKS118A) is considered satisfactory for the requested use.
- ✓ The selectivity of LANDSCAPER PRO WEED CONTROL + FERTILIZER (UKS118A) is considered satisfactory for the requested use, on established lawns only. Due to the presence of dicamba, it is advisable not to use grass cuttings as mulch or compost.
- ✓ The risk of negative impact on propagation is considered acceptable.
- ✓ The risk of negative impact on succeeding and adjacent crops is considered acceptable. Nevertheless, specific attention should be paid to susceptible adjacent crops and to the sowing/planting of succeeding and replacement crops.

-
- ✓ The risk of resistance developing or appearing to 2,4-D and dicamba is considered low and does not require monitoring for the requested use.

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.

However, application of LANDSCAPER PRO WEED CONTROL + FERTILIZER with manual spreader is concluded to result in unacceptable operator exposure, especially given the risk posed by 2,4-D.

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:

- Provide a confirmation of the applicability of the product, of the analytical method for the determination of relevant impurities in the technical active substance.

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 de renouvellement de l'autorisation de mise sur le marché d'un produit mixte et à la demande associée

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 les demandes de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active 2,4-D, et de modification de l'autorisation du produit mixte **LANDSCAPER PRO WEED CONTROL + FERTILIZER***

de la société EVERGREEN GARDEN CARE France SAS

enregistrées sous les n°2016-1260 et n°2019-6269

Vu les conclusions de l'évaluation de l'Anses du 1^{er} avril 2019, relatives à la demande de renouvellement du produit mixte,

Vu les conclusions de l'évaluation de l'Anses du 26 octobre 2020, relatives à la demande de modification de l'autorisation de mise sur le marché du produit mixte,

L'autorisation de mise sur le marché du produit mixte désigné ci-après **est renouvelée** en France 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.



Informations générales sur le produit	
Nom du produit	LANDSCAPER PRO WEED CONTROL + FERTILIZER
Type de produit	Produit de référence
Titulaire	EVERGREEN GARDEN CARE France SAS 4 allée des Séquoias 69760 LIMONEST France
Formulation	Granulé (GR)
Contenant	1,2 g/kg - dicamba 8 g/kg - 2,4-D Éléments fertilisants (NPK) déclarés conformes à une norme d'application obligatoire
Numéro d'intrant	974-2012.01
Numéro d'AMM	2150944
Fonction	Engrais (NPK) et herbicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 décembre 2022.

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

22 JAN. 2021

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



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
Sacs en polyéthylène basse densité	7,5 kg ; 10 kg ; 15 kg ; 20 kg ; 25 kg
Big-bags en polypropylène / polyéthylène basse densité	1000 kg

Teneurs garanties retenues en éléments fertilisants

Indiquer sur l'étiquette la teneur (en % MB) des éléments fertilisants revendiqués : N (et ses différentes formes), P₂O₅ (et ses différentes formes) et K₂O soluble dans l'eau, conformément à la norme d'application obligatoire qui encadre le produit.

Il est de la responsabilité du détenteur de s'assurer de la conformité à la norme à laquelle il se réfère.

Classification du produit

La classification retenue est la suivante :

Sans classement.

EUH208 : Contient du 2,4-D. Peut produire une réaction allergique.

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)	Mention abeilles
18505901 Gazons de graminées* Désherbage	200 kg/ha	1/an	-	Non applicable	DVP 5	-	-	-
Uniquement sur gazons installés avec un épandeur mécanique. Application durant la phase de croissance du gazon, de mars à juillet. L'application avec un épandeur manuel est refusée en raison d'un risque d'effet nocif pour les opérateurs.								

DVP : Dispositif Végétalisé Permanent.

LANDSCAPER PRO WEED CONTROL + FERTILIZER
AMM n°2150944



Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application mécanisée effectuée à l'aide d'un micro-granulateur

• pendant le chargement du matériel d'épandage

- Gants certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Blouse ou tablier à manches longues de catégorie III type 3 (PB) à porter par-dessus l'EPI vestimentaire précité ;

• pendant l'épandage

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, en cas d'intervention sur l'épandeur à engrais ou le microgranulateur ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;

• pendant le nettoyage du matériel d'épandage

- Gants certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Blouse ou tablier à manches longues de catégorie III type 3 (PB) à porter par-dessus l'EPI vestimentaire précité.

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

- 6 heures.

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

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

Protection de la faune

- SPe 6 : Pour protéger les oiseaux et les mammifères sauvages, récupérer tout produit accidentellement répandu.
- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau.

Le produit peut être utilisé sur les usages autorisés, conformément aux conditions d'emploi antérieures à la présente décision pendant une période de 6 mois.



Exigences complémentaires post-autorisation

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

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir la confirmation de l'applicabilité au produit de la méthode de détermination des impuretés pertinentes dans la substance active technique.	24	-

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer les informations suivantes sur l'étiquette :

- Préciser les conditions optimales d'utilisation du produit afin de limiter le risque de phytotoxicité sur les cultures adjacentes.
- Préciser les conditions d'utilisation des déchets de tonte comme le mulch ou le compost.
- Ce produit est un produit mixte : engrais NPK conforme à une norme d'application obligatoire (à rappeler) et herbicide.

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

Landscaper Pro Weed Control + Fertilizer 22-5-5+2,4D+Dicamba

Nom homologué : LANDSCAPER PRO WEEDCONTROL + FERTILIZER

AMM n°2000390 de Scotts France SAS (69).

Produit réservé à un usage exclusif par les professionnels

Composition : Produit mixte : Engrais NPK conforme à une norme d'application obligatoire et herbicides : 8 g/kg (0,8% p/p) 2,4-D acide, 12 g/kg (0,12% p/p) dicamba acide
ENGRAIS CE : Engrais NPK 22-5-5 contenant de l'urée formaldéhyde :

- 22% Azote (N) total, dont : 0,9% ammoniacal, 10,1% uréique, 11% urée formaldéhyde (dont : 3,6% soluble à 20°C, 3,2% insoluble à 20°C mais soluble à 100°C et 4,2% insoluble à 100°C),

- 5% d'Anhydride Phosphorique (P₂O₅) soluble dans le citrate d'ammonium neutre,

- 5% d'Oxyde de Potassium (K₂O) soluble dans l'eau

Formulation : Granulés

Type d'action du produit : Engrais gazon, désherbant systémique

Usages et doses homologués : Gazons de graminées *Désherbage : 20 g/m²

Gamme d'usages : Professionnel

P101: En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette.
P102: Tenir hors de portée des enfants. P103: Lire l'étiquette avant utilisation. P270: Ne pas manger, boire ou fumer en manipulant ce produit. P273: Éviter le rejet dans l'environnement.
P280: Porter des gants de protection / des vêtements de protection / un équipement de protection des yeux / du visage. P501: Éliminer le contenu / récipient conformément à la réglementation locale. EUH208: Contient du 2,4-D. Peut produire une réaction allergique. EUH401: Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

- * SP1: Ne pas polluer l'eau avec le produit ou son emballage. [Ne pas nettoyer le matériel d'application près des eaux de surface. / Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes].
- * SPe2: Pour protéger les eaux souterraines, ne pas appliquer ce produit sur gazons d'août à février.
- * SPe3: Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

NOTE:

La garantie de ce produit, explicite ou implicite, est limitée à la garantie de la composition telle que présentée sur l'étiquette, dans la mesure où les utilisations sont hors du contrôle du vendeur. Pour la même raison, le vendeur n'est pas responsable des préjudices contre des êtres vivants, des cultures, sols, substrats ou matériaux qui pourraient résulter de l'usage ou du stockage de ce produit si l'usage était différent de celui annoncé sur l'étiquette ou notre documentation.

Mode d'emploi:

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'applications	Délai avant récolte	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
18505901 Gazons de graminées* Désherbage	200 kg/ha	1/an	De mars à juillet	Non applicable	5	-	-	-
Ne pas épandre manuellement. Ne pas appliquer entre août et février en raison d'un risque pour les eaux souterraines. Uniquement sur gazons installés. Application sur zones non agricoles : pelouses ornementales dans les parcs et les jardins, terrains de golf, etc.								

Titulaire de homologation:

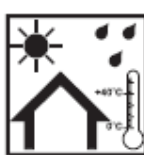
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Appendix 3 – Letter(s) of Access

Provided upon request.