REGISTRATION REPORT

Part A

Risk Management

Product code: S19321 R537.001

Product name(s): HERBATAK ULTRA

Chemical active substance:

Pelargonic acid, 565.49 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: Evergreen Garden Care France SAS

(ex Scotts France SAS)

Date: 2019/08/08

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PART A
RISK MANAGEMENT

1 Details of the application

The company Evergreen Garden Care France SAS (ex Scotts France S.A.S) has requested a marketing authorisation in France for the product HERBATAK ULTRA (EC: S19321 R537.001), containing 565.49 g/L pelargonic acid as a herbicide for non-professional uses.

The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the 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 HERBATAK ULTRA (EC: S19321 R537.001) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of HERBATAK ULTRA (EC: S19321 R537.001) have been made using endpoints agreed in the EU peer review of pelargonic acid.

This document describes the specific conditions of use and labelling required for France for the registration of HERBATAK ULTRA (EC: S19321 R537.001).

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

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

Appendix 3 of this document contains a copy of the Letter(s) of Access.

Appendix 4 of this document provides the list of data considered for national authorisation

1.1 Application background

The present registration report concerns the evaluation of Evergreen Garden Care France SAS (ex Scotts France S.A.S) 's application to market HERBATAK ULTRA (EC: S19321 R537.001) in France as a herbicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

The present application (2017-2965 and 2017-3199) 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 applied for in the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

The current document (RR) based on Anses assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[2], implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at

[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] 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

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 provided in Regulation (EU) No 546/2011[3], and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

1.2 Letters of Access

The applicant has provided a letter of access for active substance.

1.3 Justification for submission of tests and studies

According to the applicant: « Data submitted here have not been previously reviewed at EU level and are required to be provided to support this product authorisation at a national level. ».

1.4 Data protection claims

2 Where protection for data is being claimed for information supporting registration of HERBATAK ULTRA (EC: S19321 R537.001), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7Details of the authorisation decision

2.1 Product identity

Product code	S19321 R537.001
Product name in MS	HERBATAK ULTRA
Authorisation number	N/A : no marketing authorisation granted
Low risk (article 47)	No
Function	Herbicide
Applicant	Evergreen Garden Care France SAS
Active substance(s) (incl. content)	Pelargonic acid; 565.49 g/L
Formulation type	Emulsifiable concentrate (EC)
Packaging	N/A : not registered in France
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

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

2.2 Conclusion

The evaluation of the application for HERBATAK ULTRA (EC: S19321 R537.001) resulted in the decision to refuse the authorization.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Skin irritant cat. 2 Eye irritant cat. 2 Aquatic Chronic 3
Hazard pictograms:	
Signal word:	Warning
Hazard statement(s):	H315: Causes skin irritation H319: Causes serious eye irritation H412: Harmful to aquatic life with long lasting effects
Precautionary statement(s):	***For the P phrases, refer to the existent legislation***
Additional labelling phrases:	-

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

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

	For other restrictions refer to 2.5

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

None.

2.5 Risk management

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

The French Order of 4th May 2017 [4] provides that:
- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

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

Finally, the French Order of 26 March 2014[5] 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 extrapolation[6] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	no PPE for non professional users
Worker protection:	
-	no PPE for non professional users
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
	Do not discharge into the sink, gutter or any other water hole the non-used container leftovers and the sprayer washing water.
	To protect aquatic organisms do not apply at least 5 meters away from any surface water bodies (well, pond, stream, river,…).
	Do not apply when bees and beneficial organisms are present.

[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/AGRG1632554A/jo/texte

[5] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

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

	Avoid spray drift and runoff to nearby plants
Other specific restrictions	
Re-entry period	Wait until the treated zone or plants have dried
Storage	-

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

2.6 Intended uses (only NATIONAL GAP)

Please note: 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" or "not finalised", 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: 2019-08-08

PPP (product name/code):	S19321 R537.001/ HERBATAK ULTRA	Formulation type:	EC [a, b]
Active substance 1:	Pelargonic acid	Conc. of as 1:	565.49 g/L [c]
Safener:	Not applicable	Conc. of safener:	Not applicable [c]
Synergist:	Not applicable	Conc. of synergist:	Not applicable [c]
Applicant:	Evergreen Garden Care France SAS	Professional use:	☐
Zone(s):	southern [d]	Non professional use:	☒
Verified by MS:	**Yes**		

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Natural surfaces not intended to bear vegetation	F	Annual weeds **Monocotyledon**s e.g TTTMM including (*Poa annua* [POAAN]) **and dicotyledon**s e.g. TTTDD including (*Sonchus* sp. [SONSS]; *Matricaria* sp. [MATSS]; *Lamium* sp. [LAMSS]; *Veronica persica* [VERPE]; *Stellaria media* [STEME])	Knapsack foliar sprayer after dilution in water	Young weeds, optimally smaller than 10 cm April - November	Repeat as necessary a) 4 b) 4	7 - 21	a) 23 L product/ ha b) 92 L product / ha	a)12.99 kg/ha b) 51.96 kg/ha	Min 300 L/ha Max 500 L/ha	n.a.	**Not acceptable** (groundwater)
2	FR	Natural surfaces not intended to bear vegetation	F	Perennial weeds **Monocotyledon**s e.g. TTTMM including (*Elymus repens [AGRRE])* **and dicotyledon**s e.g. TTTDD including (*Cirsium arvense [CIRAR];Epilobium angustifolium [CHAAN]; Urtica dioica [URTDI]; Rumex obtusifolius [RUMOB])*	Knapsack foliar sprayer after dilution in water	Young weeds, optimally smaller than 10 cm April - November	Repeat as necessary a) 4 b) 4	7 - 21	a) 23 L product/ ha b) 92 L product / ha	a)12.99 kg/ha b) 51.96 kg/ha	Min 300 L/ha Max 500 L/ha	n.a.	**Not acceptable** (groundwater)
3	FR	Permeable surfaces overlaying soil	F	Annual weeds **Monocotyledon**s e.g. TTTMM including (*Poa annua* [POAAN]) **and dicotyledon**s e.g. TTTDD including (*Sonchus* sp. [SONSS]; *Matricaria* sp. [MATSS]; *Lamium* sp. LAMSS]; *Veronica persica* [VERPE]; *Stellaria media* [STEME]	Knapsack foliar sprayer after dilution in water	Young weeds, optimally smaller than 10 cm April - November	Repeat as necessary a) 4 b) 4	7 - 21	a) 23 L product/ ha b) 92 L product / ha	a)12.99 kg/ha b) 51.96 kg/ha	Min 300 L/ha Max 500 L/ha	n.a.	**Not accaptable** (groundwater)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
4	FR	Permeable surfaces overlaying soil	F	Perennial weeds **Monocotyledon**s e.g. TTTMM including (*Elymus repens [AGRRE])* **and dicotyledon**s e.g. TTTDD including (*Cirsium arvense [CIRAR]; Epilobium angustifolium [CHAAN]; Urtica dioica [URTDI]; Rumex obtusifolius [RUMOB])*	Knapsack foliar sprayer after dilution in water	Young weeds, optimally smaller than 10 cm April - November	Repeat as necessary a) 4 b) 4	7 - 21	a) 23 L product/ ha b) 92 L product / ha	a)12.99 kg/ha b) 51.96 kg/ha	Min 300 L/ha Max 500 L/ha	n.a.	**Not acceptable** (groundwater)
5	FR	Around ornamental shrubs and trees	F	Annual weeds **Monocotyledon**s e.g. TTTMM including but not limited to *Poa annua* [POAAN] **and dicotyledon**s e.g. TTTDD including but not limited to *Sonchus* sp. [SONSS]; *Matricaria* sp. [MATSS]; *Lamium* sp. [LAMSS]; *Veronica persica* [VERPE]; *Stellaria media* [STEME]	Knapsack foliar sprayer after dilution in water	Young weeds, optimally smaller than 10 cm April - November	Repeat as necessary a) 4 b) 4	7 - 21	a) 23 L product/ ha b) 92 L product / ha	a)12.99 kg/ha b) 51.96 kg/ha	Min 300 L/ha Max 500 L/ha	n.a.	**Not acceptable** (groundwater)
6	FR	Around ornamental shrubs and trees	F	Perennial weeds **Monocotyledon**s e.g. TTTMM including but not limited to *Elymus repens [AGRRE]* **and dicotyledon**s e.g. TTTDD including but not limited to *Cirsium arvense [CIRAR]; Epilobium angustifolium*	Knapsack foliar sprayer after dilution in water	Young weeds, optimally smaller than 10 cm April - November	Repeat as necessary a) 4 b) 4	7 - 21	a) 23 L product/ ha b) 92 L product / ha	a)12.99 kg/ha b) 51.96 kg/ha	Min 300 L/ha Max 500 L/ha	n.a.	**Not acceptable** (groundwater)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
				[CHAAN]; Urtica dioica [URTDI]; Rumex obtusifolius [RUMOB]									
7	FR	Hard surfaces	F	Annual weeds **Monocotyledon**s e.g. TTTMM including but not limited to *Poa annua* [POAAN] **and dicotyledon**s e.g. TTTDD including but not limited to *Sonchus* sp. [SONSS]; *Matricaria* sp. [MATSS]; *Lamium* sp. [LAMSS]; *Veronica persica* [VERPE]; *Stellaria media* [STEME]	Knapsack foliar sprayer after dilution in water	Young weeds, optimally smaller than 10 cm April - November	Repeat as necessary a) 4 b) 4	7 - 21	a) 23 L product/ ha b) 92 L product / ha	a)12.99 kg/ha b) 51.96 kg/ha	Min 300 L/ha Max 500 L/ha	n.a.	**Not acceptable** (aquatic organisms)
8	FR	Hard surfaces	F	Perennial weeds **Monocotyledon**s e.g. TTTMM including but not limited to *Elymus repens [AGRRE]* **and dicotyledon**s e.g. TTTDD including but not limited to *Cirsium arvense [CIRAR]; Epilobium angustifolium [CHAAN]; Urtica dioica [URTDI]; Rumex obtusifolius [RUMOB]*	Knapsack foliar sprayer after dilution in water	Young weeds, optimally smaller than 10 cm April - November	Repeat as necessary a) 4 b) 4	7 - 21	a) 23 L product/ ha b) 92 L product / ha	a)12.99 kg/ha b) 51.96 kg/ha	Min 300 L/ha Max 500 L/ha	n.a.	**Not acceptable** (aquatic organisms)

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

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

HERBATAK ULTRA (EC: S19321 R537.001)is an emulsifiable concentrate (EC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a uniform clear yellow mobile liquid with a wax crayon like odour. It is not explosive and has no oxidising properties. The product is not flammable. In aqueous solution (1% dilution), it has a pH value around 3.82 at 22.1°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54 °C; neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in fluorinated HDPE, PET or HDPE containers (extrapolated). Its technical characteristics are acceptable for an emulsifiable concentrate (EC) formulation.

The stability study two years at ambient temperature in progress should be provided in the commercial packaging when available.

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

The product must be protected from frost. The product must be shaken before and during application in accordance with good agricultural practice.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- the efficacy level of HERBATAK ULTRA (EC: S19321 R537.001)applied in post-emergence is considered as limited but acceptable to control moss, dicotylonous and monocotyledonous weeds for all the claimed uses.
- the preparation HERBATAK ULTRA (EC: S19321 R537.001)cannot be considered as a selective preparation regarding perlargonic acid mode of action. Pelargonic acid is a foliar herbicide of contact, not persistant and not systemic acting on foliar cuticule, therefore, it is recommended not to direct green parts of the plants of installed or adjacent crops.
- the risk of negative impact on succeeding crops is considered as acceptable. Nevertheless, specific attention should be paid to susceptible succeeding crops.
- the risk of resistance development or appearance to pelargonic acid is considered as very low.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 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 pelargonic acid does not contain relevant impurity, no analytical method is required.

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.

3.3.2 Analytical methods for residues

The active substance is natural occurring compound and it would be impossible to distinguish between what occurs naturally and what occurs as a result of pesticide usage. So, no analytical methods are required for the determination of residues in plants, food of animal origin, soil, water and air.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

<table>
<tr><td colspan="4">Active Substance: pelargonic acid</td></tr>
<tr><td>ADI</td><td colspan="2">Not relevant</td><td rowspan="3">EU (2009)</td></tr>
<tr><td>ARfD</td><td colspan="2">Not relevant</td></tr>
<tr><td>AOEL</td><td colspan="2">Not relevant
However, an AOEL of 821 mg/kg bw/d has been set in the Draft Assessment Report – Fatty acides (C7-C20) in 2008 according to the UK National Diet & Nutrition Survey based on the average daily intake of fatty acid.</td></tr>
<tr><td rowspan="3">Dermal absorption</td><td colspan="3">Based on default values according to guidance on dermal absorption (Efsa 2012):</td></tr>
<tr><td></td><td>Concentrate
(used in formulation)
565 g/L</td><td>Spray dilution
(used in formulation)
0.03 g/L</td></tr>
<tr><td>Dermal absorption endpoints %</td><td>25</td><td>75</td></tr>
</table>

3.4.1 Acute toxicity

HERBATAK ULTRA (EC: S19321 R537.001)containing 565 g/Lpelargonic acid has a low toxicity in respect to acute oral, inhalation and dermal toxicity is irritating to the rabbit skin and eye and is not a skin sensitizer.

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 only for the following packaging bottle with autodosing chamber and unidose tubes.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop	F/G[7]	Equipment	Application rate kg/L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Non cultivated area	F	Manual hand held knapsack	23 L product/ha 12 995 g as/ha)	300-500	EFSA UPJ

Considering proposed uses, operator systemic exposure was estimated using the French study from UPJ 2009-2010[8] dedicated to non-agricultural areas and EFSA AOEM.:

Crop	Equipment	PPE and/or working coverall	% AOEL Pelargonic acid
Non culti-vated area	Manual hand held knapsack	-	1.2 (EFSA) 2.3 (UPJ)

According to the model calculations, it can be concluded that the risk for the operator using HERBATAK ULTRA (EC: S19321 R537.001) is acceptable without PPE.

3.4.3 Worker exposure

HERBATAK ULTRA (EC: S19321 R537.001)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.

3.4.4 Bystander and resident exposure

In the context of use by non-professionals, it is considered that the assessment for bystanders is covered by that for the operator.
Residential exposure was assessed according to EFSA AOEM. Exposure is estimated to 0.6 and 0.3 % of the AOEL of pelargonic acid for child and adult respectively.
It is concluded that there is no unacceptable risk to the resident exposed to HERBATAK ULTRA (EC: S19321 R537.001).

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

3.5.1 Residues

The data available are considered sufficient for risk assessment.

HERBATAK ULTRA (EC: S19321 R537.001)is proposed for use only on natural surfaces not intended

[7] Open field or glasshouse
[8] Studies and models that can be used to estimate operator exposure during the use of plant protection products in non- agricultural areas. Report from expert group « produits phytosanitaires : substances et préparations chimiques » Working group "évaluation de l'exposition des utilisateurs de produits phytopharmaceutiques en zones non agricoles" - June 2011

to bear vegetation, permeable surfaces overlaying soil, around ornamental shrubs and trees and on hard surfaces to control annual and perennial weeds in home garden situations by non-professional users.

Pelargonic acid is a naturally occurring substance which rapidly degrades in soil (DT_{50} = 3 days; EFSA, 2013) and therefore there is no exposure of consumers to pelargonic acid through succeeding crops.

MRLs are not required for fatty acids C7-C20, i.e. pelargonic acid in either edible or non-edible, no intakes have been calculated and no consumer risk assessment is required.

There are no chronic or short-term dietary intakes of pelargonic acid from the proposed uses, and residues are very unlikely to present a public health concern.

As far as consumer health protection is concerned, France agrees with the authorization of the intended use(s).

According to available data, no specific mitigation measures should apply.

According to available data, no specific mitigation measures should apply.

Data gaps

Noticed data gaps are: /

Data required in post-authorization

- None

Summary of the evaluation

The preparation HERBATAK ULTRA (EC: S19321 R537.001)is composed of iron salt of pelargonic acid.

Table 1: Toxicological reference values for the dietary risk assessment of pelargonic acid

Reference value	Source	Year	Value	Study relied upon	Safety factor
Pelargonic acid					
ADI	No suitable data available (EFSA Journal 2013; 11(1): 3023) Not				
ARfD	No suitable data available (EFSA Journal 2013; 11(1): 3023)				

1.1.1.1 Summary for pelargonic acid

Table 3.5-1: Summary for pelargonic acid

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1, 2, 3, 4, 5, 6, 7, 8	Natural surfaces not intended to bear vegetation. Permeable surfaces overlaying soil. Around ornamental shrubs and trees. Hard surfaces	Yes	Yes	Yes	Yes	Yes	No	No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
NR: not relevant

3.5.1.1 Summary for HERBATAK ULTRA (EC: S19321 R537.001)

Table 3.5-2: Information on HERBATAK ULTRA (EC: S19321 R537.001) (KCA 6.8)

Crop	PHI for HERBATAK ULTRA (EC: S19321 R537.001) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for HERBATAK ULTRA (EC: S19321 R537.001) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Pelargonic acid		
Natural surfaces not intended to bear vegetation. Permeable surfaces overlaying soil. Around ornamental shrubs and	N/A	NR	Not required	As pelargonic acid is included in annex IV of Regulation 396/2005, the setting of a PHI is considered not necessary

Crop	PHI for HERBATAK ULTRA (EC: S19321 R537.001) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for HERBATAK ULTRA (EC: S19321 R537.001) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Pelargonic acid		
trees. Hard surfaces				

NR: not relevant
N/A: Not applicable
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

Not relevant.

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

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

The PEC of pelargonic acid in 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 PECsw derived for the active substance are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw calculations are not deemed necessary for uses on hard surfaces.
However, although PECgw for pelargonic acid are deemed necessary for uses on soft surfaces, none were provided. In addition, PECgw calculations from EFSA Journal (2013) cannot be used to cover the intended uses. Therefore, the risk assessment of groundwater contamination cannot be finalized for uses on soft surfaces.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were

considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

For home and garden uses with a foliar spray, only birds, aquatic and bees assessment is considered relevant for ecotoxicologic assessment. The risk to birds is considered acceptable for the intended uses. For aquatic organisms, the risk to pelargonic acid following the intended uses of the formulation HERBATAK ULTRA (EC: S19321 R537.001) can be considered as acceptable in soft surfaces, with the following mitigation:

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

The risk assessment for aquatic organisms cannot be finalized for uses on hard surfaces.

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

Do not apply when bees and beneficial organisms are present.
Avoid spray drift and runoff to nearby plants.

3.8 Relevance of metabolites (Part B, Section 10)

Not relevant.

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

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

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

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

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

N/A : not registered in France

Appendix 1 Copy of the product authorisation

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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 règlementaire,

Vu la demande d'autorisation de mise sur le marché et la demande associée du produit phytopharmaceutique ***HERBATAK ULTRA***

de la société	*EVERGREEN GARDEN CARE FRANCE SAS*
enregistrées sous les	*n°2017-2965 et 2017-3199*

Vu les conclusions de l'évaluation de l'Anses du 17 mai 2019,

Considérant qu'en l'absence de calculs des concentrations estimées dans les eaux souterraines, un risque de contamination de ces dernières ne peut pas être exclu dans le cas de traitements sur des surfaces perméables,

Considérant qu'en l'absence d'estimation des niveaux d'exposition pour les espèces non cibles aquatiques, un risque d'effet inacceptable pour ces organismes ne peut être exclu dans le cas de traitements sur des surfaces imperméables,

Considérant que les exigences visées à l'article 29 du règlement (CE) n°1107/2009 ne sont donc pas respectées,

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

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Informations générales sur le produit	
Noms du produit	HERBATAK ULTRA SPEED ULTRA
Type de produit	Produit de référence
Titulaire	EVERGREEN GARDEN CARE FRANCE SAS 21, chemin de la Sauvegarde 69130 ECULLY France
Formulation	Concentré émulsionnable (EC)
Contenant	565,5 g/L - acide pélargonique
Numéro d'intrant	1068-2017.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Amateur / emploi autorisé dans les jardins

A Maisons-Alfort le,

08 AOUT 2019

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

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ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
14055905 Arbres et arbustes*Désherbage* Plantat. Pl. terre	23 mL/10 m²	4/an	-
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque inacceptable de contamination des eaux souterraines.		
00501044 Arbre et arbustes*trt ecorces* mousse	23 mL/10 m²	4/an	-
	Motivation du refus : L'usage est refusé puisque inclus dans N°11013901.		
00201024 Cultures fruitières*Désherbage* Cult. Installées	23 mL/10 m²	4/an	-
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque inacceptable de contamination des eaux souterraines.		
12455901 Fruits à coque*Désherbage* Cult. Installées	23 mL/10 m²	4/an	-
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque inacceptable de contamination des eaux souterraines.		
12555902 Fruits à noyau*Désherbage* Cult. Installées	23 mL/10 m²	4/an	-
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque inacceptable de contamination des eaux souterraines.		

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
00301054 Jardin d'amateur*Désherbage* All. PJT, Abords non plant.	23 mL/10 m²	4/an	-
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque inacceptable de contamination des eaux souterraines. L'usage est également refusé car un risque inacceptable pour les organismes aquatiques ne peut être exclu lors d'applications sur des surfaces imperméables.		
12605905 Pommier*Désherbage* Cult. Installées	23 mL/10 m²	4/an	-
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque inacceptable de contamination des eaux souterraines.		
11015924 Traitements généraux*Désherbage* Avt Mise Cult.	23 mL/10 m²	4/an	-
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque inacceptable de contamination des eaux souterraines.		
11015932 Traitements généraux*Désherbage* Cult. Installées	23 mL/10 m²	7/an	-
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque inacceptable de contamination des eaux souterraines.		
11015921 Traitements généraux*Désherbage* Zones Cult. Avt Plantat.	23 mL/10 m²	-/an	-
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque inacceptable de contamination des eaux souterraines.		

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
11015933 Traitements généraux*Désherbage* Zones non cult.	23 mL/10 m²	4/an	-
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque inacceptable de contamination des eaux souterraines. L'usage est également refusé car un risque inacceptable pour les organismes aquatiques ne peut être exclu lors d'applications sur des surfaces imperméables.		
11015908 Traitements généraux* Destruct. Mousses	23 mL/10 m²	4/an	-
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque inacceptable de contamination des eaux souterraines. L'usage est également refusé car un risque inacceptable pour les organismes aquatiques ne peut être exclu lors d'applications sur des surfaces imperméables.		
11013901 Traitements généraux*Trt Ecorces* Mousses, lichens, algues	23 mL/10 m²	4/an	-
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque inacceptable de contamination des eaux souterraines.		
11015903 Usages non agricoles*Désherbage* All. PJT, Cimet., Voies	23 mL/10 m²	4/an	-
	Motivation du refus : L'usage est refusé en raison de l'absence de données permettant d'exclure un risque inacceptable de contamination des eaux souterraines. L'usage est également refusé car un risque inacceptable pour les organismes aquatiques ne peut être exclu lors d'applications sur des surfaces imperméables.		

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 3 Letter of Access

Provided upon request.