# REGISTRATION REPORT Part A

**Risk Management** 

Product code: S19321 R537.001
Product name: HERBATAK ULTRA

Chemical active substance(s): Pelargonic acid, 565.49 g/L

Southern Zone Zonal Rapporteur Member State: France

# NATIONAL ASSESSMENT FRANCE

label extension according to Art. 51

**Applicant: Evergreen Garden Care France SAS Date: 10/03/2022** 

# **Table of Contents**

1	D	DETAILS OF THE APPLICATION						
	1.1	APPLI	CATION BACKGROUND	3				
	1.2	ACTIV	E SUBSTANCE APPROVAL	3				
	1.3		LATORY APPROACH					
	1.4	DATA	PROTECTION CLAIMS	4				
	1.5	LETTE	R(S) OF ACCESS	5				
2	DI	ETAILS	OF THE AUTHORISATION	5				
	2.1	PROD	UCT IDENTITY	-				
	2.2		IFICATION AND LABELLING.					
	2.	2.1	Classification and labelling under Directive 99/45/EC					
		2.2	Classification and labelling in accordance with Regulation (EC) No1272/2008					
	2.	2.3	Other phrases in compliance with Regulation (EU) No 547/2011					
	2.	2.4	Other phrases linked to the preparation					
	2.3	Prod	UCT USES					
3	RI	ISK MA	ANAGEMENT	c				
			ONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES					
		1.1	Physical and chemical properties					
		1.2	Methods of analysis					
	_	1.3	Mammalian Toxicology					
	_	1.4	Residues and Consumer Exposure					
3.		1.5	Environmental fate and behaviour					
		1.6	Ecotoxicology					
		1.7	Efficacy					
			LUSIONS ARISING FROM FRENCH ASSESSMENT					
			WITH THE AUTHORISATION					
ΑI	PPEND	DIX 1 -	COPY OF THE FRENCH DECISION	10				
ΑI	PPEND	DIX 2 -	COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT	14				
ΔΙ	PPFNI	– 2 צור	LETTER(S) OF ACCESS	15				

#### PART A - Risk Management

The company Evergreen Garden Care France SAS (ex Scotts France S.A.S) has requested a label extension in France for the product HERBATAK ULTRA (EC: S19321 R537.001) according to article 51 Regulation (EC) no 1107/2009<sup>1</sup>.

This document describes the specific conditions of use and labelling required for extension of the registration of HERBATAK ULTRA (S19321 R537.001) containing 565.49 g/L pelargonic acid in France.

The conclusions of the risk assessment are based on the already existing registration of the preparation in France. Therefore, the evaluation of the current application is limited to the points not covered by the existing registration.

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

HERBATAK ULTRA (S19321 R537.001) is an Emulsifiable concentrate (EC) product containing 565.49 g/L pelargonic, for use as an herbicide for the control of various weeds. The aim of this registration application is to gain a label extension of use to control moss in lawns.

The complete GAP for the national application in France is provided below, under point 2.3.

#### 1.2 Active substance approval

#### Pelargonic acid

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 2021;19(8):6813

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

## 1.3 Regulatory approach

The present application (n°2020-3897) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses).

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

Since the application is intended for use in France only, the draft Part A was not circulated for comments.

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<sup>2</sup> provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 m;
- unless formally 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, drift buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French order.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A 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)  $N^{\circ}546/2011^{3}$ , and are expressed as "acceptable" or "not acceptable"/"not finalised" in accordance with those criteria.

Finally, the French Order of 12 April 2021<sup>4</sup> 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 extrapolation<sup>5</sup> 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

There is no new data submitted with this application.

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, modifié par l'arrêté du 27 décembre 2019.

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

https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

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

## 1.5 Letter(s) of access

Not relevant for this application.

#### 2 DETAILS OF THE AUTHORISATION

# 2.1 Product identity

Product name (code)	HERBATAK ULTRA (S19321 R537.001)				
Authorisation number	2200526				
Function	herbicide				
Applicant	Evergreen Garden Care France SAS				
Composition	Pelargonic acid; 565.49 g/L				
Formulation type (code)	Emulsifiable concentrate (EC)				
Packaging	Not relevant for extension of authorisation according article 51.				

#### 2.2 Classification and labelling

# 2.2.1 Classification and labelling under Directive 99/45/EC

Not relevant for extension of authorisation according article 51.

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

Not relevant for extension of authorisation according article 51.

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

Refer to the decision of product authorization.

# 2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment<sup>6</sup>: no PPE for a non professional users

Re-entry period<sup>7</sup>: Wait for complet dry in the treated area.

Pre-harvest interval<sup>8</sup>: not relevant

Environmental protection:

- SPe 2: To protect ground water, do not use between September and March on permeable soil
- To protect aquatic organisms, do not use on impermeable soil as bitumen, concrete, cobbles, tiles.
- To protect aquatic organisms, do not apply within 5 metres of a surface water body (such as a well, pond, pool, stream or river).
- Do not apply when pollinating and/or beneficials such as bees, bumble bees, ladybirds, etc. are present.
- Avoid spray drift and run-off to neighbouring plants.

<sup>6</sup> If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

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

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

Other mitigation measures: refer to the decision of product authorisation.

The label must reflect the conditions of authorisation.

#### 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 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as RMS. Those uses are then granted in France.

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

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

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

GAP rev. 1, date: 10/03/22

PPP (product name/code): S19321 R537.001/ HERBATAK ULTRA Formulation type: EC (a, b)

Active substance 1: Pelargonic acid Conc. of a.s. 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
	Member	Crop and/		Pests or Group of pests	Application				1 1			PHI	Remarks:
	state(s)	or situation (crop destination/purpos e of crop)  cording to Articl	Fpn G, Gn, Gpn or I	controlled  (additionally: developmental stages of the pest or pest group)	Method/K ind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	product/ha a) max. rate per appl. b) max. total		L/ha min/ma	(days)	e.g. g safener/synergist per ha (f)
1	FR	Lawns	F	Moss	Watering can	Established Lawns (after BBCH 29) April to November	a) 1 b) 4		a) 18 L/ha b) 72 L/ha	a) 10.17 kg/ha b) 40.68 kg/ha	3600- 10000	n/a	Acceptable

Remarks

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

table heading:

- (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
- use official codes/nomenclatures of EU Member States
  - 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
  - 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.
  - 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.

- 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
- 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 RISK MANAGEMENT

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

# 3.1.1 Physical and chemical properties

Not relevant for extension of authorisation according article 51.

## 3.1.2 Methods of analysis

#### 3.1.2.1 Analytical method for the formulation

Not relevant for extension of authorisation according article 51.

# 3.1.3 Mammalian Toxicology

The preparation is already registered in France. If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

#### 3.1.4 Residues and Consumer Exposure

There is no special risk mitigation necessary regarding consumer exposure.

#### 3.1.5 Environmental fate and behaviour

The intended minor uses for product HERBATAK ULTRA (S19321 R537.001) are covered by uses already authorised. The same conditions of uses apply.

# 3.1.6 Ecotoxicology

According to previous risk assessments performed by Anses, no unacceptable risk for terrestrial and aquatic non-target organisms is expected. Similar mitigation measures as defined for previous risk assessment apply.

# 3.1.7 Efficacy

According to Article 51 of Regulation (EC) No 1107/2009, the efficacy assessment and the absence of any phytotoxicity risk on the crop is not necessary.

#### 3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation  ${\bf can}$  be  ${\bf granted}$  as proposed in Appendix 1 – Copy of the product Decision.

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

No further information is required.

# Appendix 1 - Copy of the French Decision

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# Décision relative à une demande d'extension d'usage 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'extension d'usage mineur du produit phytopharmaceutique HERBATAK ULTRA

de la société EVERGREEN GARDEN CARE France SAS

enregistrée sous le n°2020-3897

Vu les conclusions de l'évaluation de l'Anses du 1er février 2022,

L'autorisation de mise sur le marché du produit référencé ci-après est étendue aux usages décrits dans la présente décision.

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.

HERBATAK ULTRA AMM n°2200526 DocuSign Envelope ID: 2019D01C-5F7B-4448-BBE3-3E7F63367ECC







Informations générales sur le produit						
Noms du produit	HERBATAK ULTRA SPEED ULTRA					
Type de produit	Produit de référence					
Titulaire	EVERGREEN GARDEN CARE France SAS 4 allée des Séquoias 69760 LIMONEST France					
Formulation	Concentré émulsionnable (EC)					
Contenant	565,5 g/L - acide pélargonique					
Numéro d'intrant	9998-2019.01					
Numéro d'AMM	2200526					
Fonction	Herbicide					
Gamme d'usage	Amateur / emploi autorisé dans les jardins					

L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit.

La présente décision peut être retirée ou modifiée si des éléments le justifient.

A Maisons-Alfort, le 10/03/2022

Charlotte Grastilleur

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

HERBATAK ULTRA AMM n°2200526

Page 2 sur 4

DocuSign Envelope ID: 2019D01C-5F7B-4448-BBE3-3E7F63367ECC





# ANNEXE : Modalités d'autorisation du produit

Liste des nouveaux 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	maximum d'application		Délai avant récolte (jours) Zone Non Traitée aquatique (mètres)		Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021) (1)		
18505902	18 mL/10 m²	4/an	-	Non applicable	5	-	-	-		
Gazons de graminées* Trt Part.Aer.*Mousses	Application uniquement entre avril et novembre. Intervalle minimum entre les applications : 7 jours. Usage autorisé dans le cadre de l'article 51 du règlement (CE) n°1107/2009.									

(1): En attente du renouvellement de l'AMM

HERBATAK ULTRA AMM n°2200526

Page 3 sur 4

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Liberté Égalité Fraterni



#### Conditions d'emploi du produit

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

- Attendre le séchage complet de la zone traitée.

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

#### Protection de l'eau

- SPe 2: Pour protéger les eaux souterraines, ne pas appliquer ce produit entre septembre et mars sur surface perméable.

#### Protection de la faune

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

#### Protection de la flore

- Éviter toute dérive de pulvérisation et de ruissellement vers les plantes voisines.

#### Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

Pour les usages mineurs dont l'autorisation a été accordée dans le cadre de l'article 51 du règlement (CE) n°1107/2009, l'attention de l'utilisateur est attirée sur les risques éventuels de phytotoxicité ou de manque d'efficacité.

Avant tout emploi du produit, il est recommandé à l'utilisateur de s'assurer de son efficacité ou de l'absence de risques éventuels de phytotoxicité sur la culture.

Les autres modalités d'autorisation du produit restent inchangées.

HERBATAK ULTRA AMM n\*2200526

Page 4 sur 4

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





# $Appendix \ 3-Letter(s) \ of \ Access$

Not applicable