

REGISTRATION REPORT

Part A

Risk Management

Product code: MON 74134

Product name(s): ROUNDUP ECLAIR AT

Chemical active substance(s):

Pelargonic acid, 18.3 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Amateur uses

Applicant: EVERGREEN GARDEN CARE FRANCE SAS

Date: 2019/08/05

Table of Contents

1	Details of the application	4
1.1	Application background	4
1.2	Letters of Access	5
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims	5
2	Where protection for data is being claimed for information supporting registration of ROUNDUP ECLAIR AT (MON 74134), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.Details of the authorisation decision	5
2.1	Product identity	5
2.2	Conclusion	6
2.3	Substances of concern for national monitoring	6
2.4	Classification and labelling.....	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011.....	6
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	6
2.5	Risk management.....	6
2.5.1	Restrictions linked to the PPP	7
2.5.2	Specific restrictions linked to the intended uses	8
2.6	Intended uses (only NATIONAL GAP)	9
3	Background of authorisation decision and risk management	11
3.1	Physical and chemical properties (Part B, Section 2)	11
3.2	Efficacy (Part B, Section 3)	11
3.3	Methods of analysis (Part B, Section 5).....	11
3.3.1	Analytical method for the formulation	11
3.3.2	Analytical methods for residues.....	11
3.4	Mammalian toxicology (Part B, Section 6)	12
3.4.1	Acute toxicity.....	12
3.4.2	Operator exposure	12
3.4.3	Worker exposure	13
3.4.4	Bystander and resident exposure	13
3.5	Residues and consumer exposure (Part B, Section 7).....	13
3.6	Environmental fate and behaviour (Part B, Section 8)	15
3.7	Ecotoxicology (Part B, Section 9)	16
3.8	Relevance of metabolites (Part B, Section 10)	17
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	17

5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation.....	17
5.1.1	Post-authorisation monitoring.....	17
5.1.2	Post-authorisation data requirements	17
Appendix 1	Copy of the product authorisation	18
Appendix 2	Copy of the product label	24
Appendix 3	Letter of Access	27

PART A

RISK MANAGEMENT

1 Details of the application

The company Evergreen Garden Care France SAS has requested a marketing authorisation in France for the product ROUNDUP ECLAIR AT (MON 74134), containing 18.3 g/L pelargonic acid as an 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 addendum/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 ROUNDUP ECLAIR AT (MON 74134) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of ROUNDUP ECLAIR AT (MON 74134) 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 ROUNDUP ECLAIR AT (MON 74134).

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.

1.1 Application background

The present registration report concerns the evaluation of Evergreen Garden Care France SAS's application to market ROUNDUP ECLAIR AT (MON 74134) in France as an 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 (2017-3214) 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's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009², 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.

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

ROUNDUP ECLAIR AT (MON 74134)
Part A - National Assessment
FRANCE DEPR version

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011³, 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: any new studies submitted in this application are those necessary for the evaluation of the product ROUNDUP ECLAIR AT (MON 74134) but not previously evaluated during Annex I approval of the active substance.

1.4 Data protection claims

2 Where protection for data is being claimed for information supporting registration of ROUNDUP ECLAIR AT (MON 74134), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.Details of the authorisation decision

2.1 Product identity

Product code	MON 74134
Product name in MS	ROUNDUP ECLAIR AT
Authorisation number	2190514
Low risk (article 47)	No
Function	Herbicide
Applicant	EVERGREEN GARDEN CARE FRANCE SAS
Active substance (incl. content)	Pelargonic acid, 18.3 g/L
Formulation type	Liquid to be applied undiluted (AL)
Packaging	Hand trigger sprayer : 1L, 1.2 L, 3 L (HDPE) Pull'n spray : 5 L (HDPE) Pump'N Go: 2.5L, 5L (HDPE) Refill bottle (Premix): 2.5L, 5L (HDPE) were not acceptable for non-professional user Non professional user
Coformulants of concern for national authorisations	None
Restrictions related to identity	None
Mandatory 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

ROUNDUP ECLAIR AT (MON 74134)
 Part A - National Assessment
 FRANCE DEPR version

Recommended tank mixtures	None
---------------------------	------

2.2 Conclusion

The evaluation of the application for ROUNDUP ECLAIR AT (MON 74134) resulted in the decision to grant the authorisation.

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:	none
Hazard pictograms:	none
Signal word:	none
Hazard statement(s):	none
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
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

	Do not discharge into the sink, gutter or any other water hole the non-used container leftovers.
	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 4 May 2017⁴ 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 2014⁵ provides that:

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “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 extrapolation⁶ is to supply “minor” crops with registered plant protection products.

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

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

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.

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

ROUNDUP ECLAIR AT (MON 74134)

Part A - National Assessment

FRANCE DEPR version

	To protect aquatic organisms do not apply within 5 metres of a surface water body (such as a well, pond, pool, stream or river).
	To protect aquatic organisms, do not apply to sloping gardens or impermeable surfaces near surface water bodies such as asphalt, concrete, cobblestones and slabs.
	Do not apply when bees and beneficial organisms are present.
	Avoid spray drift and runoff to neighbouring plants.
Other specific restrictions	
Re-entry period	Wait until the treated zone or plants have dried.
Storage	The formulation must be protected from frost.

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.

ROUNDUP ECLAIR AT (MON 74134)
 Part A - National Assessment
 FRANCE DEPR version

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.

PPP (product name/code):	ROUNDUP ECLAIR AT / MON 74134	Formulation type:	GAP date: 2019-08-05 AL ^(a, b)
Active substance 1:	Pelargonic acid	Conc. of a.s. 1:	18.3 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):	Pelargonic acid	Non-professional use:	☒
Verified by MS:	Yes		
Field of use:	herbicide		

ROUNDUP ECLAIR AT (MON 74134)

Part A - National Assessment

FRANCE DEPR version

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) RMS conclusion
					Method/Ki nd	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 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	Home and garden uses Cropped and non- cropped Allotments, gardens, around trees, clumps of flowers, along fences	F	Annual and perennial monocotyledonous and dicotyledonous weeds,	Overall spray or spot applicatio n with hand held sprayer	All stages (January- December)	a) 4 – 8	21	a) 100 ml/m²	a) 18.3 kg as/ha	1000	n.a.	Acceptable

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)

ROUNDUP ECLAIR AT (MON 74134) is a liquid to be applied undiluted (AL). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a white, milky homogeneous liquid, with a slight chemical odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self- ignition temperature of 535°C. It has a pH value of 6.97 at 21°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 HDPE. Its technical characteristics are acceptable for a liquid to be applied undiluted (AL) formulation.

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

The formulation must be protected from frost.

3.2 Efficacy (Part B, Section 3)

- ROUNDUP ECLAIR AT (MON 74134) efficacy can be considered as limited but acceptable for the intended use.
- ROUNDUP ECLAIR AT (MON 74134) cannot be considered as a selective product regarding pelargonic acid mode of action. Pelargonic acid is a foliar herbicide. Therefore, it is recommended not to direct green parts of the non-target plants during application.
- The risk of negative impact on succeeding crops are considered as acceptable.
- The risk of resistance appearance or development can be 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.

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, air and biological fluids and tissues.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active Substance: pelargonic acid			
ADI	Not relevant		EU (2009)
ARfD	Not relevant		
AOEL	Not relevant <i>However, an AOEL of 821 mg/kg bw/d has been set in the Draft Assessment Report – Fatty acids (C7-C20) in 2008 according to the UK National Diet & Nutrition Survey based on the average daily intake of fatty acid.</i>		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 18.3 g/L	Spray dilution (used in formulation) 18.3 g/L
	Dermal absorption endpoints %	75	75
Oral absorption	100%		

3.4.1 Acute toxicity

ROUNDUP ECLAIR AT (MON 74134) containing 18.3 g/L pelargonic acid has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G ⁷	Equipment <i>Application method</i>	Maximum application rate kg as /ha	Minimum volume wa- ter (L/ha)
Non cultivated area	F	Manual knapsack, trigger sprayer	18.3kg as/ha	1000

⁷ Open field or glasshouse

ROUNDUP ECLAIR AT (MON 74134)
Part A - National Assessment
FRANCE DEPR version

Considering proposed uses, operator systemic exposure was estimated using the French study from UPJ 2009-2010⁸ dedicated to non-agricultural areas and EFSA model⁹:

Crop	Equipment	PPE and/or working coverall	% AOEL pelargonic acid
Non cultivated area	Manual knapsack, trigger sprayer	-	0,07 (UPJ) 1,87 (EFSA)

According to the model calculations, it can be concluded that the risk for the operator using ROUNDUP ECLAIR AT (MON 74134) is acceptable with a working coverall and gloves during mixing/loading and application.

The proposed packaging has been described in sufficient details, 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 plant protection products by non-professional users is considered to be finalised for packaging described in “2 Details of the authorisation decision”. **Refill bottle (Premix): 2.5L, 5L (HDPE) were not acceptable for non-professional user.**

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

3.4.3 Worker exposure

ROUNDUP ECLAIR AT (MON 74134) 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 of the operator.

Residential exposure was assessed according to EFSA model. Exposure is estimated to 1.19 % and 0.52 % of the AOEL of pelargonic acid for children and adults, respectively. It is concluded that there is no unacceptable risk anticipated for recreational exposure.

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

The critical GAPS with respect to consumer intake and risk assessment for the product ROUNDUP ECLAIR AT (MON 74134) are presented in **Erreur ! Source du renvoi introuvable.** They have been selected from

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

⁹ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

the individual GAPs in the Southern Zone for Home and garden uses, cropped and non-cropped areas. A list of all intended uses within the Southern Zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment.

Fatty acids (including pelargonic acid) are included in Annex IV of Regulation (EC) No 396/2005 containing a list of active substances for which maximum residue levels (MRLs) are not required.

Even if EFSA Journal 2013;11(1):3023 stated that the consumer risk assessment cannot be concluded if fatty acids are not of food grade quality, the consumer will not be exposed linked to the following reasons. Fatty acids are ubiquitous in the environment and form an essential component in the diets of all species. They are also major constituents of all living cells and are an integral part of the ecosystem. They make up the lipo-protein matrix of cell membranes, serve as building blocks for more complex hydrocarbons and serve as a high energy and nutritional food source for most organisms in the form of their triglycerides, i.e. fats and oils.

No residue definition was proposed for the class of compounds known as fatty acids. Fatty acids (including pelargonic acid) are both naturally occurring in the environment and are readily and rapidly metabolised and degraded by all organisms.

At EU level, it was concluded that no residues of toxicological importance is expected during normal metabolism of fatty acids (including pelargonic acid). The setting of an ARfD and an ADI is therefore not considered necessary.

Based on these outcomes, the chronic and the short-term intakes of pelargonic acid residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France, zRMS agrees with the authorization of the intended uses.

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

Data gaps

Noticed data gaps are:

- None

Summary of the evaluation

The product ROUNDUP ECLAIR AT (MON 74134) is composed 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
Glyphosate					
ADI	EFSA	2013	Not allocated	--	--
ARfD	EFSA	2013	Not allocated	--	--

ROUNDUP ECLAIR AT (MON 74134)
Part A - National Assessment
FRANCE DEPR version

Summary for pelargonic acid

Table 2: 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	Home and garden uses Cropped and non-cropped areas	Yes	NR	NR	NR	No MRL required	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

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. Fatty acids (including pelargonic acid) are included in Annex IV of Regulation (EC) No 396/2005 containing a list of active substances for which maximum residue levels (MRLs) are not required. No intakes have been calculated and no consumer risk assessment is required.

Summary for ROUNDUP ECLAIR AT (MON 74134)

Table 3.5-1: Information on ROUNDUP ECLAIR AT (MON 74134)

Crop	PHI for ROUNDUP ECLAIR AT (MON 74134) proposed by applicant	PHI/Withholding period* sufficiently supported for	PHI for ROUNDUP ECLAIR AT (MON 74134) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Pelargonic acid		
Home and garden uses Cropped and non-cropped areas	Not specified	--	Not required	As pelargonic acid is included in annex IV of Regulation 396/2005, the setting of a PHI is considered not necessary

NR: not relevant

* Purpose of withholding period to be specified

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.

ROUNDUP ECLAIR AT (MON 74134)
 Part A - National Assessment
 FRANCE DEPR version

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 PEC_{sw} derived for pelargonic acid are used for the ecotoxicological risk assessment, and mitigation measures are proposed. No PEC_{sw} were provided for impermeable areas, therefore the risk assessment for these uses cannot be finalized.

PEC_{gw} for pelargonic acid do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000¹⁰. 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.

3.7 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.

Different types of packaging are claimed for the formulation of the product ROUNDUP ECLAIR AT (MON 74134).

For the ready to use trigger sprayer packaging (1-3 L), considering the packaging and the application method of the product (ready-to-use product), exposure of soil and surface water compartments to active substance is considered negligible. Consequently, no risk assessment for non-target organisms is deemed necessary, except for bees where an exposure cannot be excluded.

The following safety phrase might be added on the label:

- Do not apply when bees and beneficial organisms are present.

For packaging other than ready to use trigger sprayer (container with hose and pressure sprayer with internal reservoir (2.5-5L) and refill container (2.5-5L)), the risk assessment for birds, aquatic organisms and bees was performed due to a potential increase of the treated areas and spray drift.

The risk to birds is considered acceptable for the intended uses. For aquatic organisms, for the intended uses of ROUNDUP ECLAIR AT (MON 74134) on impermeable surfaces, the risk assessment is not finalized as no PEC_{sw} calculations on hard surfaces were provided in section 8. The following safety phrase might be added on the label:

To protect aquatic organisms, do not apply to sloping gardens or impermeable surfaces such as asphalt, concrete, cobblestones and slabs.

The risk to pelargonic acid following the intended uses of the formulation of the product ROUNDUP ECLAIR AT (MON 74134) on permeable surfaces can be considered as acceptable, with the following mitigation:

- To protect aquatic organisms do not apply within 5 meters of a surface water body (such as a well, pond, stream or river).

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 run-off to neighbouring plants.

¹⁰ Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

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 for 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

No further information is required.

5.1.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 36 months regarding:

- The report of a stability study two years at ambient temperature.

Appendix 1 Copy of the product authorisation



Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et réglementaire,

*Vu la demande d'autorisation de mise sur le marché et les demandes associées du produit phytopharmaceutique **ROUNDUP ECLAIR AT***

*de la société **EVERGREEN GARDEN CARE FRANCE SAS***

*enregistrées sous les **n°2017-3214, 2018-3214 et 2018-3587***

Vu les conclusions de l'évaluation de l'Anses du 22 juillet 2019,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

ROUNDUP ECLAIR AT (MON 74134)
Part A - National Assessment
FRANCE DEPR version



Informations générales sur le produit	
Nom du produit	ROUNDUP ECLAIR AT
Type de produit	Produit de référence
Titulaire	EVERGREEN GARDEN CARE FRANCE SAS 21 chemin de la Sauvegarde 69130 ECULLY FRANCE
Formulation	Autre liquide (AL)
Contenant	18,3 g/L - acide pélargonique
Numéro d'intrant	1162-2017.01
Numéro d'AMM	2190514
Fonction	Herbicide
Gamme d'usage	Amateur / emploi autorisé dans les jardins

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 août 2021.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

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

Attention : à compter du 01/01/2019, la mise sur marché, la délivrance, l'utilisation et la détention des produits de la gamme d'usages « amateur » sont exclusivement réservées aux utilisateurs professionnels, en application de l'article L. 253-7-III du Code rural et de la pêche maritime, à l'exception des produits de la gamme amateurs inscrits sur la liste des produits de biocontrôle, des produits utilisables en agriculture biologique ou des produits à faible risque. Cette interdiction ne s'applique pas aux traitements et mesures nécessaires à la destruction et à la prévention de la propagation des organismes nuisibles mentionnés à l'article L. 251-3, en application de l'article L. 251-8 du même Code.

A Maisons-Alfort le,

05 AOÛT 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)



ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Bouteilles en polyéthylène haute densité avec pulvérisateur à gâchette	1 L ; 1,2 L
Bidons en polyéthylène haute densité avec pulvérisateur à gâchette	3 L
Bidons en polyéthylène haute densité avec pulvérisateur à pression préalable	2,5 L ; 5 L

Classification du produit
La classification retenue est la suivante :
Sans classement.
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									
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	
11015903 Usages non agricoles*Désherbage*All. PJT, Cimet., Voies	100 mL/m ²	8/an	-	Non applicable	5	-	-	-	
Intervalle minimum entre les applications : 21 jours.									



Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
18555901 Jardin d'amateur*Dés herbage	100 mL/m²	8/an	-
Motivation du refus : L'usage est refusé car transitoire et transformé en usage N°11015903 mieux adapté aux revendications.			
00301054 Jardin d'amateur*Dés herbage*All. PJT, Abords non plant.	100 mL/m²	8/an	-
Motivation du refus : L'usage est refusé car transitoire et transformé en usage N°11015903 mieux adapté aux revendications.			



Conditions d'emploi du produit

Stockage et manipulation du produit

- Protéger du gel.

Délai de rentrée :

- Attendre le séchage complet de la zone traitée.

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

Protection de l'eau

- Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidon non utilisés.

Protection de la faune

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

Protection de la flore

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

Exigences complémentaires post-autorisation

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

Détail de la demande post autorisation	Délai (mois)	Réurrence (mois)
Fournir les résultats d'une étude de stabilité au stockage pendant 2 ans, à température ambiante.	36	-

Recommandations relatives à l'étiquette du produit

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

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

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.

TEXT ROUNDUP ECLAIR AT 1.2L

Roundup Eclair AT prêt à l'emploi **détruit rapidement les mauvaises herbes et les mousses.**

Les premiers effets sont visibles 1h après l'application.

Rapidement inactivé dans le sol, il laisse le sol propre.

Polyvalent, il permet de désherber dans les **cours, allées, terrasses, bords de bâtiments ...**

Pour assurer une efficacité maximale, il est recommandé de :

- Traiter dès l'apparition des mauvaises herbes lorsque les feuilles sont jeunes et peu développées.
- Traiter à une température supérieure à 15°C,
- Renouveler l'application après 21 jours pour prolonger la durée du contrôle.

INFORMATIONS REGLEMENTAIRES :

Nom homologué : Roundup Eclair AT - **AMM n°:** XXXXX délivrée le XXXXX

Détenteur de l'autorisation de mise sur le marché : Monsanto France SAS, Eden Park, 1 rue Buster Keaton
 69800 St Priest.

Distributeur : XXXXXX

Substance active: 18,3 g/l (1,8 % p/p) d'acide pélargonique - **Formulation:** prêt à l'emploi

Type et mode d'action du produit: Herbicide de contact

EMPLOI AUTORISE DANS LES JARDINS

Usages et doses homologués: Jardin d'amateur***Désherbage** *All. PJT, abords non plant. 100ml/m²,

DAR: Délai de rentrée: attendre le séchage complet de la zone traitée.

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.

P501 : Éliminer le contenu/récipient dans une déchetterie ou par un organisme agréé.

EUH 401 : Respecter 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.

SPe3 : Pour protéger les organismes aquatiques, respectez une zone non traitée de 5 m par rapport aux points d'eau.

PRÉCAUTIONS D'EMPLOI :

Porter des gants et des chaussures de jardinage.· Eviter toute dérive de pulvérisation (projection) et de ruissellement vers les plantes voisines.·Le produit contient un acide qui peut attaquer certains matériaux riches en calcaire (marbres, dalles, ..).·Se laver les mains après utilisation.·Eloigner les enfants et les animaux domestiques de la zone traitée tant que la pulvérisation n'est pas sèche.·Conserver uniquement dans le récipient d'origine. Ne pas réutiliser l'emballage. Stocker hors gel.·Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau, les fonds de bidon non utilisés.

En cas d'urgence appeler le 15 ou le centre anti-poison, en conservant l'emballage.

*marque déposée de Monsanto Technology LLC

Exemples d'utilisation et conseils

Désherbage des allées et chemins.

Désherbage des terrasses et cours.

Désherbage des bords de bâtiments et clôtures.

Mode d'emploi

Aucune préparation n'est nécessaire : le produit est prêt à l'emploi.

AVANT, conditions à respecter :

Traiter de mars à octobre (pour les ronces, plutôt en automne; pour les chardons, plutôt à la floraison).

Pas de pluie (pendant le traitement et 6h après) pour éviter le lessivage.

Pas de vent pour éviter les projections.

A température modérée (15-25°C) pour optimiser l'efficacité.

Par temps ensoleillé.

Avec le bon équipement : gants imperméables, chaussures de jardinage.

PENDANT l'application

8 applications maximum par an (attendre minimum 21 jours entre chaque application).

Pulvériser à une distance de 20 à 30 cm sur les mauvaises herbes développées ou en croissance.

Speed étant un désherbant non sélectif qui détruit tout végétal traité, éviter les projections sur les plantes à conserver. Couper les feuilles des végétaux à conserver si elles ont reçu une éclaboussure de produit.

Ne jamais traiter à moins de 5 mètres d'un point d'eau (ruisseaux, puits, étang, mare, fossé, grille d'évacuation d'eau, bouche d'égout...) ou sur un terrain en pente pouvant entraîner un ruissellement vers un point d'eau.

Ne pas appliquer sur des surfaces imperméables telles que le bitume, le béton, les pavés, les dalles et dans toute autre situation où les risques de ruissellement sont importants.

Limiter l'exposition des organismes aquatiques pouvant être présents dans des bassins d'ornement.

Eviter toute dérive de pulvérisation et de ruissellement vers les plantes voisines.

APRÈS le traitement

Ne pas entrer dans la zone traitée avant le séchage complet.
Attendre 1 jour avant de replanter.

Pour recevoir le Petit Guide Roundup des Bonnes Pratiques du
Désherbage ou pour toute autre question :
Service Consommateurs Roundup
Scotts France SAS
21 Chemin de la Sauvegarde
69130 Ecully
www.roundup-jardin.com

FDS disponible sur le site www.Quickfds.fr

ROUNDUP ECLAIR AT (MON 74134)
Part A - National Assessment
FRANCE DEPR version

Appendix 3 Letter of Access

Letter(s) of access and, if necessary, an argumentation according to art. 62.4 of Reg (UE) No 1107/2009 have been submitted and are available under request ».