

REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: AG-F8-250 CS

Chemical active substance:

Flurochloridone, 250 g/L

Central Zone

Member State: Poland

CORE ASSESSMENT

(authorization)

Sponsor: ADAMA Agan Ltd

Applicant: Country organisation/representative of
ADAMA Agan Ltd. as reported in Part A

Submission date: January 2020

MS Finalisation date: October 2020 (initial Core Assessment)

March 2021 (final Core Assessment)

Version history

When	What
January 2020	dRR submitted by the Applicant
October 2020	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency .
March 2021	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow.

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

The application is submitted for first approval of AG-F8-250 CS, a capsule suspension containing 250 g/L flurochloridone for use in potato, in Central Zone according to article 33 of the Regulation 1107/2009.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

The active substance flurochloridone was included into Annex I of Directive 91/414 (2011/34/EU) with entry into force by 01 June 2011. This inclusion was reported in the EC regulation 540/2011 further the application of the regulation 1107/2009. ADAMA Agan Ltd. was the sole notifier.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Central zone	Poland: Racer 25 CS	-
Southern zone	Spain: Racer 25 CS (18121)	France: Racer ME (8700020) Greece: Racer 25 CS (7851) Portugal: Racer CS (3451) Croatia : Racer 25 CS (UP/I-320-20/05-01/110)

0.1.3 Regulatory history of flurochloridone

Table 0.1-2: Summary of regulatory history of CAS No: 61213-25-0

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2011/34/EU of 08 March 2011 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011
RMS	Spain
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/06/2011
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	-
Date of final Commission (re-registration) deadline (Step 2)	-
Current expiration of approval	31/05/2021
Low risk substance or Candidate for Substitution?	-

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on flurochloridone, and in particular Appendices I and II thereof, as finalized in the Standing Committee on the Food Chain and Animal Health on 04/02/2011 shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

- the risk for non-target plants and aquatic organisms;

- the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions.

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

The SANCO report for Flurochloridone (SANCO/10098/2011 final – 09/03/2011) is considered to provide the relevant review information or a reference to where such information can be found.

Additionally, an EFSA Scientific Report was made available in 2010 (EFSA Journal 2010;8(12):1869) and in 2013 (EFSA Journal 2013;11(3):3116 taking the confirmatory data into account.

Table 0.1-3: Information on minimum purity of flurochloridone

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report
940 g/kg trans flurochloridone: 720-740 g/kg cis flurochloridone: 220-240 g/kg	minimum purity of active substance: 940 g/kg trans flurochloridone: 720-740 g/kg cis flurochloridone: 220-240 g/kg

0.1.4 Regulatory history of the product (if relevant)

The following table provides corresponding information of product codes, product names and authorizations in different EU Member States.

Table 0.1-4: Summary of regulatory history of the product AG-F8-250 CS

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
AG-F8-250 CS	Spain: Racer 25 CS	ES	18121	13/01/2005	31/05/2013
AG-F8-250 CS	Racer ME	FR	8700020	31/12/1987	31/05/2013
AG-F8-250 CS	Racer 25 CS	GR	7851	30/09/2014	31/05/2013
AG-F8-250 CS	Racer CS	PT	3451	05/05/2003	31/05/2013
AG-F8-250 CS	Racer 25 CS	CR	UP/I-320-20/05-01/110	18/09/2017	31/05/2013

0.2 zRMS conclusion

Authorisation of the product AG-F8-250 CS/ Racer 25 CS is recommended to the control weeds in potato.

Uses to be considered safe on the basis of EU methodology:

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses to be considered non-safe on the basis of EU methodology:

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

See column 15 of the GAP table presented in Appendix 1 of this document.

All uses/ GAPs are covered by established MRLs.

Appendix 1 ALL intended uses

PPP (product name/code): AG-F8-250 CS
Active substance 1: flurochloridone
Safener: none
Synergist: none
Applicant: See Part A
Zone(s): Central ^(d)
Verified by MS: yes
Field of use: herbicide

GAP rev. , date: March 2021
Formulation type: CS
Conc. of as 1: 250 g/L
Conc. of safener:
Conc. of synergist:
Professional use: x
Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15*							
Use-No. (e)	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fpn, 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)	Overall conclusions							
					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 as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	PL	Potato Solanum tuberosum/ SOLTU	F	broadleaved and grass weeds; pre-emergence Dicotyledonous weed plants and <i>Echinochloa crus-galli</i>	spray application Spraying	BBCH 00-09; BBCH 00-08; pre-emergence	a) 1 b) 1	n.a.	a) 2 L/ha b) 2 L/ha	a) 500 g/ha b) 500 g/ha	200-300 200-250	n.a.	Water volume in column 12 was adjusted by Efficacy section according to conditions prevailing in trials	A	A	A	A	A	N (algae in D4 and D6 scenarios) R (NTTPs) A (remaining species)	A	A

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 authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

- Remarks** 1 Numeration necessary to allow references
- columns:** 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
- 15 Overall conclusions - explanation for the column 15 is below *

* Explanation for column 15 “Overall conclusions”

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use