

# REGISTRATION REPORT

## **Part A**

### **Risk Management**

Product code: AG-F8-250 CS

Product name(s): Racer 250 CS

Chemical active substance:

Flurochloridone, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## NATIONAL ASSESSMENT - POLAND

Applicant: ADAMA Polska Sp. z o.o.

Sponsor: ADAMA Agan Ltd

Submission date: January 2020

MS Finalisation date: October 2020 (initial National Assessment)

March 2021 (final National Assessment)

November 2021 (re-assessment of the efficacy of 1.5 L/ha dose rate)

### Version history

When	What
January 2020	Initial dRR
October 2020	Initial zRMS assessment  In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and the product label are highlighted in grey, while not agreed use pattern <del>is struck through and shaded</del> .
March 2021	Final report (National Assessment updated following the commenting period)  Additional information/assessments included by the zRMS in the report in response to comments recieved from the Applicant are <b>highlighted in yellow</b> .
November 2021	zRMS reassessment in the scope of the ecotoxicology and efficacy of 1,5 L/ha dose rate, triggered by the negative outcome of the ecotoxicological evaluation at the initially targeted dose rate 2,0 L/ha. The content altered, added or amended in the course of this re-assessment are <b>highlighted in green</b> .

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## **PART A**

# **RISK MANAGEMENT**

This document describes the acceptable use conditions required for the registration of AG-F8-250 CS containing the active substance flurochloridone in Poland. Evaluation for new product is required.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national re-registration by the EU review. It also includes assessment of data and information relating to AG-F8-250 CS where that data has not been considered in the EU review. Otherwise assessments for the safe use of AG-F8-250 CS have been made using endpoints agreed in the EU review of flurochloridone.

This document describes the specific conditions of use and labelling required for Poland for the registration of AG-F8-250 CS.

For a copy of the final product authorisation please refer to Appendix 1.

For a copy of the proposed product label, please refer to Appendix 2

For information on access to protected data, please refer to Appendix 3.

## **1. Details of the application**

### **1.1. Application background**

This application was submitted in January 2020 in Poland.

Applicant details:

ADAMA Polska Sp. z o.o.  
Sienna 39, 00-121 Warsaw  
Poland

Person to contact:

xxx  
xxx  
xxx

The application was for re approval of AG-F8-250 CS, a capsule suspension containing 250 g/L flurochloridone for use in potato.

### **1.2. Justification for submission of tests and studies**

AG-F8-250 CS is a new product not previously registered and hence new studies are submitted in order to comply with the new data requirements as given in Regulation (EC) 284/2013.

### **1.3. Data protection claims**

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company, the Applicant claims data protection for the studies submitted with this application. The list of the studies for which the applicant requests data protection are reported in the Appendix 4 of Part A. The Applicant confirms that no period of data protection has previously been granted in respect of the study or has been granted and not yet expired.

### **1.4. Letters of Access**

No Letters of Access are required as ADAMA Polska Sp. z o.o., a member of the ADAMA Group, notified the inclusion of flurochloridone in Annex I to the Directive 91/414/EEC. The inclusion of flurochloridone into Annex I entered into force on 01 June 2011. All members of the ADAMA Group have unlimited access to these step 1 data.

## 2. Details of the authorisation

### 2.1. Product identity

Product code	AG-F8-250 CS
Product name in MS	Racer 250 CS
Authorization number	n.a.
Function	Herbicide
Applicant	ADAMA Polska Sp. z o.o
Active substance(s) (incl. content)	250 g/L flurochloridone
Formulation type	Capsule suspension (CS)
Packaging	<b>1L bottle</b> Material: HDPE COEX Size: 241 x 89.8 mm Closure: screwed on  <b>5L Jerry can</b> Material: COEX HDPE/PA Size: 305 mm (high) x 190 x 140 mm Closure: screwed on  <b>10L Jerry can</b> Material: COEX HDPE/PA Size: 384 mm (high) x 226 x 157 mm Closure: screwed on  <b>20L Jerry can</b> Material: HMWHDPE Size: 398.5 mm (high) x 297 x 246 mm Closure: screwed on
Coformulants of concern for national authorizations	Not applicable
Restrictions related to identity	Not applicable
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

### 2.2. Conclusion

Performed evaluation demonstrated that the product may be authorised in Poland for pre-emergence uses in potatoes **at application rate of 1.5 L/ha**. Higher application rate of 2.0 L/ha cannot be authorised due to unresolved risk to algae.

~~Performed evaluation demonstrated that the product cannot be authorised in Poland for pre-emergence uses in potatoes due to not resolved risk to algae. Further refinement is deemed necessary for this species.~~

### 2.3. Substances of concern for national monitoring

None.

## 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 Sens. 1 Repr. 1B Aquatic Acute 1 Aquatic Chronic 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:



Signal word: **Danger**

Hazard statements:

**H317: May cause an allergic skin reaction**

**H360Df: May damage the unborn child. Suspected of damaging fertility**

**H400: Very toxic to aquatic life**

**H410: Very toxic to aquatic life with long lasting effects**

EU Specific Hazard Statements:

**EUH401: To avoid risks to human health and the environment, comply with the instructions for use.**

Precautionary statement(s)

P102: Keep out of reach of children

**P201: Obtain special instructions before use.**

**P261 - Avoid breathing spray**

P270: Do not eat, drink or smoke when using this product.

P272: Contaminated work clothing should not be allowed out of the workplace.

**P280: wear protective gloves/protective clothing**

**P302 + P352: IF ON SKIN: wash with plenty of soap and water**

**P308+P313: IF exposed or concerned: Get medical advice/attention.**

**P333+P313: If skin irritation or rash occurs: Get medical advice/attention**

**P391: Collect spillage**

P362: Take off contaminated clothing and wash before reuse.

P501: dispose of content/container in accordance with local regulations

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
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### 2.4.3. Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.



## 2.5. Risk management

### 2.5.1. Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
	OPEX exposure assessment according to the AOEM Model (EFSA calculator) identified safe application of the product and does not indicate the need for the operator to use protective clothing (calculated exposure is below the reference value AOEL 0.04 mg/kg bw/d) however taking into account the classification of the active substance flurochloridone as toxic to reproduction Repr. Cat 1B H360 Df, operators must wear a certified protective garment (protective gloves, protective coverall and waterproof boots) during handling concentrat, mixing and loading spray dilution and during application.
Worker protection:	
	None
Environmental protection	
SPe 3	<p>Aquatic organisms:</p> <p><b>Respect an 10 m vegetated filter strip to surface water bodies</b></p> <p><i>Risk mitigation measures for aquatic organisms will be identified once the risk assessment for algae is completed.</i></p> <p>Non-target plants:</p> <p><i>Respect an 5 m unsprayed buffer zone to non-agricultural land or a standard buffer zone of 1 m in combination with 50 % spray drift reduction nozzles</i></p>
Integrated pest management (IPM)/sustainable use: -	
Environmental protection	
	None
Other specific restrictions: -	

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorization is applied.

### 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):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.

## 2.6. Product uses

GAP rev. 3, date: 2021-11-03

PPP (product name/code) AG-F8-250 CS  
active substance 1 flurochloridone  
active substance 2 -  
safener none  
synergist none  
Applicant: ADAMA Polska  
Zone(s): Central EU

Formulation type: CS  
Conc. of as 1: 250 g/L  
Conc. of as 2: -  
Conc. of safener:  
Conc. of synergist:  
professional use ☒  
non professional use ☐

Central EU															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, Fn, 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, other dose rate expression, dose range (min- max)	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	Solanum tuberosum/ SOLTU	F	Dicotyledonous weed plants and <i>Echinochloa crus-galli</i>	Spraying	BBCH 00- 08; pre- emergence	a) 1 b) 1	n.a.	a) 2,0 L/ha b) 2,0 L/ha	a) 500 b) 500	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 scenario)	A	A			
																			R (NTTPs)					
																			A (remaining species)					
2	PL	Solanum tuberosum/ SOLTU	F	Dicotyledonous weed plants and <i>Echinochloa crus-galli</i>	Spraying	BBCH 00- 08; pre- emergence	a) 1 b) 1	n.a.	a) 1.5 L/ha b) 1.5 L/ha	a) 375 b) 375	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	R (aquatic organisms)	A	A			
																			A (remaining species)					

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

\*\* 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.

\*\*\* Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

### **3. Background of authorisation decision and risk management**

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

##### **3.1.1. Physical and chemical properties (part B, Section 2)**

The product is a homogenous brown suspension, with a turpentine like odour. The formulated product is not classified as explosive or as having oxidizing properties. AG-F8-250 CS is not highly flammable, auto-flammable and has no other inherently dangerous similar properties.

The content of flurochloridone in the formulated product AG-F8-250 CS (Racer CS) did not show any relevant decrease in a 14-day accelerated stability test at 54°C, and was therefore regarded as not heat-sensitive. In a two-year stability study, there was only a negligible decrease of the initial flurochloridone concentration, and the product was therefore considered to be stable over the entire study period. In conclusion, the shelf-life of AG-F8-250 CS at ambient temperature is at least 2 years.

The plant protection product AG-F8-250 CS does not exhibit any technical characteristics that would render it unacceptable and it complies with the FAO specifications.

Recommended cleaning procedure: "Rinse the tank three times with tap water".

**Implications for labelling:** None

**Compliance with FAO specifications:** The product AG-F8-250 CS complies with FAO specifications.

**Compatibility of mixtures:** not applicable

**Nature and characteristics of the packaging:** Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

**Nature and characteristics of the protective clothing and equipment:** Information regarding the required protective clothing and equipment for the safe handling of AG-F8-250 CS has been provided and is considered to be acceptable.

##### **3.1.2. Methods of analysis**

###### **3.1.2.1. Analytical method for the formulation**

The analytical method for total flurochloridone and free flurochloridone determination in AG-F8-250 CS was fully validated according to SANCO/3030/99 rev. 4, 11 July 2000. The results obtained prove that this method is suitable for the detection and quantitation of total flurochloridone and free flurochloridone in the formulation AG-F8-250 CS.

A method was validated for the determination of the active substance flurochloridone in the formulation AG-F8-250 CS. The content of cis- and trans isomers of flurochloridone was analysed in AG-F8-250 CS (Racer 25 CS) by GC with FID detection using an internal standard technique. The identity of the isomers was verified by Mass Spectrometry.

### 3.1.2.2. Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)

In according to the EFSA Journal 2010;8(12):1869 - Conclusion on the peer review of the pesticide risk assessment of the active substance:

*Residues of FLC in plants can be analysed with GC-MS methods. A method of analysis for products of animal origin is not required as no MRL's are proposed. For soil, water and air GC-MS methods are available. The active substance is classified as toxic (T) and therefore a data gap is identified for a method of analysis for body fluids and tissues.*

#### **Soil**

The analytical method of Wolf, S. (2006, A47272) using GC-MS for the determination of flurochloridone residue in soil was provided by the Applicant and validated at EU level (DAR of flurochloridone) with a LOQ=0.01 mg/kg.

#### **Water**

The analytical method of Wolf S. (2005, 85708) using GC-MS for the determination of flurochloridone residue in drinking, ground and surface water was provided by the Applicant and validated at EU level (DAR of flurochloridone) with a LOQ = 0.05 µg/L.

#### **Air**

The analytical method of Wolf, S.(2006, 90009363) using GC-MS for the determination of flurochloridone residue in air was provided by the Applicant and validated at EU level (DAR of flurochloridone) with a LOQ=0.75 µg/m<sup>3</sup>.

#### **Body fluids and tissues**

The active substance is classified as toxic (T) and therefore a data gap is identified for a method of analysis for body fluids and tissues. according to the EFSA Journal 2010;8(12):1869.

As above mentioned methods are not considered highly specific (one ion monitoring), a confirmatory method should be required for the determination of flurochloridone residue in soil, water and air according to SANCO 825/00 rev. 8.1 at the renewal of the active substance.

Therefore the Applicant has already submitted a number of methods for analysis of residues of flurochloridone for the generation of pre-authorization data and methods for post-authorization control and monitoring purposes.

The details of the evaluation of new and additional studies are referred in Appendix 2 and the conclusion is presented below:

- Different analytical methods to determine concentrations of flurochloridone in ecotoxicology media for risk assessment have been developed and validated in accordance with SANCO/3029/99 rev. 4.
- The analytical methods were successfully validated for the determination of flurochloridone in the 4 matrix groups of plant matrices (dry high starch (dried peas), high water (apples), high acid (grapes) and high oil (sunflower seeds) content) and in animal matrices (milk, fat, eggs, muscle and kidney) with a limit of quantification (LOQ) of 0.01 mg/kg, in accordance to SANCO/825/00 rev. 8.1 requirements.
- The analytical method for the determination of flurochloridone (2 isomers: FND-311-Trans and FND-311-Cis) and metabolite R406639 in three different soils was fully validated with a limit of quantification (LOQ) of 0.01 mg/kg for flurochloridone and 0.001 mg/kg for metabolite R406639, in accordance to SANCO/825/00 rev. 8.1 and SANCO/3029/99 rev. 4 requirements.
- The analytical methods for the determination of flurochloridone and metabolites R42819 and R406639 in drinking water and surface water were fully validated with a limit of quantification (LOQ) of 0.05 µg/L in accordance to SANCO/825/00 rev. 8.1 and SANCO/3029/99 rev. 4 requirements.
- The analytical method for the determination of flurochloridone in body fluids (human urine and whole blood) was fully validated with a limit of quantification (LOQ) of 0.01 mg/L in accordance to SANCO/825/00 rev. 8.1 requirements.
- No new method validations will be submitted for the analysis of flurochloridone in air. Studies have been accepted.

## Conclusions

Fully validated analytical methods are available for the enforcement of the proposed residue definition in high water, high acid, high oil content and dry commodities with a LOQ of 0.01 mg/kg, respectively.

### 3.1.3. Mammalian Toxicology

#### 3.1.3.1. Acute Toxicity

AG-F8-250 CS was not the representative formulation in the EU review of the active substance flurochloridone. Acute toxicity studies for AG-F8-250 CS we're not evaluated as part of the EU review of flurochloridone.

The following tests were performed on AG-F8-250 CS: acute oral (rat), acute dermal (rat), skin irritation (rabbit), eye irritation (rabbit) and skin sensitization (guinea pig). The results are summarised in Table IIIA 7.1-1 but no detailed summaries are provided as they have already been assessed and accepted at EU level.

#### Acute toxicological data obtained with AG-F8-250 CS (Racer 250 CS)

Parameter [Reference]	Species	Result mg/kg or mg/m <sup>3</sup> or effect	Classification According to Directive 1999/45/EC
Acute oral LD <sub>50</sub>	Rat	> 5000 mg/ kg bw	Not to be classified
Acute dermal LD <sub>50</sub>	Rat	> 2000 mg/ kg bw	Not to be classified
Skin irritation	Rabbit	Non-irritant	Not to be classified
Eye irritation	Rabbit	Slight irritant	Not to be classified
Skin sensitisation	Guinea pig	sensitising	To be classified

AG-F8-250 CS containing flurochloridone at a nominal concentration of 250 g/L, has a low toxicity in respect to acute oral, acute dermal or acute inhalational route of application. No skin irritation, slight irritancy to the eye and the potential for skin sensitisation was found. According to Regulation 1272/2008/EC, classification as skin sensitising (category 1), H317 (may cause an allergic skin reaction). Repr. 1B H360Df hazard classification of flurochloridone has been agreed by the ECHA/RAC committee. This proposal is available in the RAC Opinion CLH-O-0000001412-86-242/F adopted 30 November 2018 by consensus. This opinion takes into account data submitted in the CLH dossier (DS Spain) and comments provided by MSCAs.

RAC opinion also supports proposal agreed by the EFSA experts to classify flurochloridone as R61 according 67/548/EU see EFSA Journal 2010;8(12):1869 (translation between classification in accordance with Directive 67/548/EEC and current 1272/2008: Repr. Cat 1 R61 = Repr. 1B H360Df).

In cases when RAC opinion has been adopted, reviewer consider this opinion as the latest reliable scientific evidence even if the procedure for formal inclusion of the substance into Annex VI to the CLP Regulation is still on-going.

Thus, RAC opinion for flurochloridone classification should be taken into account when labeling the product.

### 3.1.3.2. Operator Exposure (Part B, Section 3, Point 7.3)

AG-F8-250 CS was not the representative formulation in the EU review of the active substance flurochloridone. Operator exposure to the plant protection product AG-F8-250 CS containing the active substance flurochloridone was not evaluated as part of the EU review of flurochloridone.

According to current GAP, AG-F8-250 CS is intended to be used as pre-emergence (BBCH 00-09) herbicide on potato against broad-leaved and grass weeds. Therefore, all relevant data and risk assessments have been provided and are considered adequate.

#### Summary of critical use patterns (i.e. worst case)

Crop	Application rate (kg as/ha)	Spray dilution (L/ha)	Application equipment	Number applications	Model used
Potato	0.5	100-400	Tractor mounted, boom sprayer	1	AOEM Model (EFSA calculator)

The estimations were compared to the data from the Annex I inclusion of flurochloridone (2011/34/EU) and the SANCO review report for flurochloridone (SANCO/10098/2011 final – 09/03/2011) which are considered to provide the relevant review information or a reference to where such information can be found

**The estimation is reported here for the AOEM model (EFSA calculator)**

#### Exposure models for intended uses

Critical use(s)	Potato (max. 2 L product/ha, 0.5 kg flurochloridone/ha)
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

#### Estimated operator exposure

Estimated operator exposure			
		Flurochloridone	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops			
Application rate		0.5 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0096651	24.2

#### Results:

The potential total systemic exposure of the operator, who is dressed with work wear that covers the body, arms and legs, corresponds to 24% of the AOEL for flurochloridone for potato.

Thus the use with AG-F8-250 CS is at an acceptable risk for the operator, according to the EFSA-OPEX model.

However, OPEX exposure assessment according to the AOEM Model (EFSA calculator) identified safe application of the product and does not indicate the need for the operator to use protective clothing (calculated exposure is below the reference value AOEL 0.04 mg/kg bw/d) taking into account the classification of the active substance flurochloridone as toxic to reproduction Repr. Cat 1B H360 Df ( this

proposal is available in the ECHA/RAC Opinion CLH-O-0000001412-86-242/F adopted 30 November 2018 by consensus) thus, operators must wear a certified protective garment (protective gloves, protective coverall and waterproof boots) during handling concentrate, mixing and loading spray dilution and during application.

As a precautionary measure, the following PPE should be indicated on the label:

### **PPEs recommendation for each phase**

#### Mixing/loading phase:

- Protective gloves (Nitrile)
- Polyester 65% / cotton 35% coverall with a weight of 245 g/m<sup>2</sup> or higher
- Category III / Type PB (3) apron with long sleeves worn over the coverall proposed above

#### Application phase:

- Protective gloves (Nitrile) (when using tractors with operator cabs, use of nitrile gloves during application is only necessary while handling spraying devices)
- Polyester 65% / cotton 35% coverall with a weight of 245 g/m<sup>2</sup> or higher

#### Cleaning phase:

- Protective gloves (Nitrile)
- Polyester 65% / cotton 35% coverall with a weight of 245 g/m<sup>2</sup> or higher
- Category III / Type PB (3) apron with long sleeves worn over the coverall proposed above

### **3.1.3.3. Bystander Exposure (Part B, Section 3, Point 7.4)**

The estimation of resident exposure was performed according to the EFSA guidance on “the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products” (EFSA Journal 2014;12(10):3874). According to this guidance, a bystander risk assessment is required for plant protection products that have significant acute toxicity or the potential to exert toxic effects after a single exposure, based on the 95<sup>th</sup> percentile data values.

However, the guidance does not define how an acute AOEL or the RVAAS shall be appropriately derived. Consequently, it was decided by the EFSA working group to remove the concept from the final version of the guidance.

Therefore the risk assessment for bystanders was performed with the German model (Martin *et al.*, 2008) in order to however provide exposure estimates for bystanders for comparison with the AOEL.

#### **Exposure models for intended uses**

Critical use(s)	Potato (max. 2 L product/ha, 0.5 kg flurochloridone/ha)
Model	<p>For residents the following model was applied: Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015</p> <p>For bystanders the following model was applied: Martin S. <i>et al.</i> (2008) [Guidance for Exposure and Risk Evaluation for Bystanders and Residents Exposed to Plant Protection Products During and After Application; J. Verbr. Lebensm. 3 (2008): 272-281 Birkhäuser Verlag Basel] and Bundesanzeiger (BAnz), 06 January 2012, Issue No. 4, pp. 75-76.</p>



### Estimated resident exposure

		Flurochloridone	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 (m) Drift reduction technology: no DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.5 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0067585	16.9
	Vapour (75 <sup>th</sup> perc.)	0.0010700	2.68
	Deposits (75 <sup>th</sup> perc.)	0.0011340	2.84
	Re-entry (75 <sup>th</sup> perc.)	0.0084375	21.1
	<b>Sum (mean)</b>	<b>0.0123603</b>	<b>30.9</b>
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0016100	4.03
	Vapour (75 <sup>th</sup> perc.)	0.0002300	0.58
	Deposits (75 <sup>th</sup> perc.)	0.0003407	0.85
	Re-entry (75 <sup>th</sup> perc.)	0.0046875	11.7
	<b>Sum (mean)</b>	<b>0.0049832</b>	<b>12.5</b>

### Estimated bystander exposure

		Flurochloridone	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Buffer zone: 1 (m) Drift reduction technology: no DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha			
Application rate		0.5 kg a.s./ha	
Bystander child Drift rate: 2.77 % (1 m) Body weight: 16.15 kg		0.0018059	4.51
Bystander adult Drift rate: 2.77 % (1 m) Body weight: 60 kg		0.0023106	5.78

The calculated total systemic exposure values are below the AOEL. Therefore, it is concluded that there is no undue risk to any bystander after accidental short-term exposure to AG-F8-250 SC. There is also no undue risk to residents. This has no labelling implications.

The risk assessment complies with the Uniform Principles.

#### 3.1.3.4. Worker Exposure (Part B, Section 3, Point 7.5)

The product is used in pre-emergence of both crops and weeds. Thus, workers are not exposed to flurochloridone via foliage contaminated with the product. No inspection or maintenance is routinely performed and moreover, harvest is done fully automatically. Concluding, there should be no re-entry with direct contact to the foliage for workers and consequently no exposure.

Therefore, an estimation of the worker exposure is not considered necessary. It was performed nevertheless to demonstrate the acceptable risk for the worker.

### Exposure models for intended uses

Critical use(s)	Potato (max. 2 L product/ha, 0.5 kg flurochloridone/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

### Estimated worker exposure

		Flurochloridone	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Inspection, irrigation - Outdoor Work rate: 2 hours/day, DT50: 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.5 kg a.s./ha	
Body weight: 60 kg	Potential exposure TC: 12500 cm <sup>2</sup> /person/h	0.0625000	156.3
	Work wear (arms, body and legs covered) TC: 1400 cm <sup>2</sup> /person/h	0.0070000	17.5
	Work wear (arms, body and legs covered) and gloves TC: not available	NA	NA

### Results:

The potential total systemic exposure of the worker, who is dressed with work wear that covers the body, arms and legs, corresponds to 18% of the AOEL for flurochloridone for potato.

Thus the use with AG-F8-250 CS is at an acceptable risk for the worker, according to the EFSA-OPEX model.

## 3.1.4. Residues and Consumer Exposure

### 3.1.4.1. Residues

Potatoes are the major crops in northern Europe (EU guideline Document SANCO 7525/VI/95-rev.10.3 of 13 June 2017). A minimum of eight trials representative of the proposed growing area for outdoor over two seasons are required.

No new data were submitted in the framework of this application by the Applicant.

The metabolism of flurochloridone in plants is sufficiently addressed and no additional metabolism studies are necessary to support the proposed uses of the product AG-F8-250 CS.

Residue trials were conducted in potato during the Annex I inclusion of the active substance flurochloridone (Monograph, February 2006).

Eight residue trials on potatoes conducted in Northern Europe have been presented by Applicant. The trials were carried out with a single application of flurochloridone CS formulation at an application rate ranged 0.68 – 0.77 kg a.s./ha applied pre-emergence. All trials the flurochloridone residues in potato were below the limit of quantification (LOQ=0.01 mg/kg).

The trials were performed at an exaggerated application rate, however since no residues were found above 0.01 mg/kg (LOQ), the trials can be used to support the product AG-F8-250 CS.

The studies on the magnitude of residues are valid with regard to storage stability.

Available results show that the in force MRL on potatoes of 0.01\* mg/kg (Reg. (EU) 2019/973) will not be exceeded.

The processing studies are not required for potatoes since residue levels are below 0.1 mg/kg and TMDI is below 10% of the ADI for this commodity.

Crop under evaluation is expected to be grown in rotation.

Significant residues of flurochloridone in rotational crops are not expected.

Information presented by Applicant in Part B, Section 7, in point 7.2.6 has been accepted and conclusions are presented below:

- taking into account the phytotoxicity a waiting period of at least 30 days should be respected for planting succeeding crops;
- in case of crop failure to avoid phytotoxicity effects a waiting period of at least 1 month should be respected for planting leafy and root succeeding crops. In the case of cereals, a minimum of 3 months have passed since application and the soil is worked before sowing.

There are sufficient data to support the uses of AG-F8-250 CS on potatoes at the intended GAP.

(\*) Indicates lower limit of analytical determination

### **3.1.4.2. Consumer exposure**

The calculation of the TMDI using EFSA model, version 3.1 and all MRLs according to Regulation (EU) No 2019/973 led to a utilisation of the ADI of 10% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is Milk: Cattle with 7% of the ADI. Therefore the intended uses will not result in a consumer chronic exposure exceeding the ADI.

For the acute exposure only the intended use was considered. EFSA PRIMo Rev. 3.1 calculates a maximum utilisation of the ARfD of 4% in case of potatoes for children and 0.7% for adults.

The proposed uses of flurochloridone in the product AG-F8-250 CS do not represent unacceptable chronic and acute risks for the consumer.

No further studies are required to support the proposed uses.

### **3.1.5. Environmental fate and behaviour**

Besides new data on the flurochloridone metabolite R42819, all data were reviewed in the EU review (flurochloridone). Appropriate endpoints from the EU review were used to calculate PECs for AG-F8-250 CS, flurochloridone and its metabolites R406639 and R42819 in soil, surface water and groundwater for the intended use patterns.

Based on new data on the flurochloridone metabolite R42819 provided in this submission, appropriate endpoints were used for tier 2 calculations of PECs for R42819 in groundwater for the intended use patterns.

#### **3.1.5.1.1. Predicted Environmental Concentration in Soil (PEC<sub>soil</sub>) (Part B, Section 5, Points 9.4 and 9.5)**

The PEC<sub>soil</sub> of AG-F8-250 CS and the active substance flurochloridone were calculated using equations proposed in the FOCUS soil persistence. The decline of flurochloridone concentrations in soil was estimated as established in the EU review, based on the FOMC model.

The  $PEC_{soil}$  values for metabolites were calculated based on pseudo-application rates derived using parent application rate corrected for molar ratio and maximum occurrence. For calculation of accumulation potential EU agreed degradation data were considered.

The results for  $PEC_{soil}$  for the active substance were used for the eco-toxicological risk assessment.

### **3.1.5.2. Predicted Environmental Concentration in Ground Water ( $PEC_{GW}$ ) (Part B, Section 5, Point 9.6)**

Predicted concentrations of flurochloridone and its relevant soil metabolites after pre-emergence application to potatoes were calculated using FOCUS-PELMO 5.5.3, FOCUS-PEARL 4.4.4 and FOCUS MACRO 5.5.4 with consideration of the EU agreed input parameters. For the parent and metabolite R406639  $PEC_{gw}$  values were clearly below the threshold concentration of 0.1 µg/L at Tier 1. For metabolite R42819 unacceptable leaching was concluded at Tier 1 and further evaluation was performed based on Tier 2 EU input parameters agreed in the course of evaluation of confirmatory data. The Tier 2  $PEC_{gw}$  values for this compound were below the threshold concentration of 0.1 µg/L.

Overall, based on the results of the performed groundwater modelling, no unacceptable leaching of flurochloridone and its metabolites is expected when AG-F8-250 CS is used according to the Polish GAP.

### **3.1.5.3. Predicted Environmental Concentration in Surface Water ( $PEC_{SW}$ ) (Part B, Section 5, Points 9.7 and 9.8)**

Predicted concentrations in surface water for flurochloridone were determined using FOCUS Surface Water calculations at Steps 1-4. Calculations for the metabolite were available up to Step 2. The versions of the models used for the Step 3 and 4 calculations were FOCUS SWASH 5.3, FOCUS SPIN 2.2, FOCUS PRZM 4.3.1, FOCUS MACRO 5.5.4, FOCUS TOXWA 5.5.3, EVA 3, rev 2e.

The EU agreed input parameters were considered in the performed simulations with exception of some slight deviations which had no impact on the obtained surface water exposure.

The results for  $PEC_{SW}$  for the active substance and its metabolites were used for the eco-toxicological risk assessment.

### **3.1.5.4. Predicted Environmental Concentration in Air ( $PEC_{Air}$ ) (Part B, Section 5, Point 9.9)**

Not calculated – due to low volatility and rapid photochemical oxidative degradation of flurochloridone in air.

**Implications for labelling resulting from environmental fate assessment:** none.

## **3.1.6. Ecotoxicology**

### **3.1.6.1. Effects on Terrestrial Vertebrates**

#### **Birds**

Acute and long-term reproductive Screening Step assessments with resulting TERs above the relevant trigger values indicate a low and acceptable dietary risk for birds exposed to the active substance flurochloridone.

A secondary poisoning assessment indicates a low risk for earthworm- and fish-eating birds. The exposure of birds to drinking water from pools in leaf whorls is not relevant for the proposed uses of AG-F8-250 CS. Detailed risk assessments for birds exposed via drinking water from puddles formed on the field are not triggered.

Thus, treatment with AG-F8-250 CS in accordance with the proposed use patterns in potato poses low risk to birds.

### Terrestrial vertebrates other than birds

The acute Screening Step assessment results in TERs above the relevant trigger values, indicating a low and acceptable dietary risk for mammals exposed to the active substance flurochloridone.

A secondary poisoning assessment indicates a low risk for earthworm- and fish-eating mammals. Detailed risk assessments for mammals exposed via drinking water from puddles formed on the field are not triggered.

Thus, treatment with AG-F8-250 CS in accordance with the proposed use patterns in potato poses a low risk to terrestrial vertebrates other than birds.

### 3.1.6.2. Effects on Aquatic Species

The risk assessment for aquatic organisms was carried out according to the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013;11(7):3290).

Based on the performed evaluation acceptable acute and chronic risk following application of AG-F8-250 CS at 500 g a.s./ha could be concluded for fish, *Daphnia magna*, sediment-dwellers and aquatic macrophytes with no need for risk mitigation measures in all scenarios relevant for Poland. Available data were sufficient to demonstrate acceptable risk to algae in R1 scenario provided that 10 m vegetated filter strip is respected. In scenario D3 10 meters unsprayed buffer zone to surface water bodies is required.

However, available data were not sufficient to demonstrate acceptable risk to algae in D4 scenario from application of higher rate of 500 g a.s./ha, which remains thus unresolved. Additional modelling performed with consideration of wider buffer zones would not address the risk in D scenarios, where the exposure is driven by drainage and currently there are no efficient mitigation measures enabling reduction of the exposure.

Additional evaluation performed for lower application rate of AG-F8-250 CS at 375 g a.s./ha demonstrated acceptable risk to aquatic organisms in all scenarios relevant for Poland, provided that 10 m vegetated filter strip from surface water bodies is respected.

Based on the performed evaluation acceptable acute and chronic risk following application of AG-F8-250 CS could be concluded for fish, *Daphnia magna*, sediment dwellers and aquatic macrophytes with no need for risk mitigation measures, with exception of aquatic macrophytes in R3 scenario, where 10 m vegetated filter strip was required in order to demonstrate acceptable risk.

Available data were sufficient to demonstrate acceptable risk to algae in R1 scenario provided that 10 m vegetated filter strip is respected. In scenario D3 10 meters unsprayed buffer zone to surface water bodies is required.

However, available data were not sufficient to demonstrate acceptable risk to algae in D4 scenario, which remains thus unresolved.

Additional modelling performed with consideration of wider buffer zones would not address the risk in D scenarios, where the exposure is driven by drainage and currently there are no efficient mitigation measures enabling reduction of the exposure. The only option would be reduction of the application rate.

which potentially may not be possible from the efficacy point of view.

Potentially, the risk in R scenarios could be further refined with STEP 4 PEC<sub>sw</sub> values calculated using VFSmod, which is currently acceptable in Poland. However, this would not address the risk in D scenarios, where the exposure is driven by drainage and currently there are no efficient mitigation measures enabling reduction of the exposure. The only option would be reduction of the application rate, which potentially may not be possible from the efficacy point of view.

### **3.1.6.3. Effects on Bees and Other Arthropod Species**

#### **Bees**

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

Risk assessments with Hazard Quotients for both, acute oral and contact toxicity are below the trigger indicating a low and acceptable risk for bees from exposure to AG-F8-250 CS in accordance with the worst-case use pattern.

#### **Other non-target arthropods**

The risk assessment was conducted according to the ESCORT 2 Guidance Document (2000) and the Guidance Document on Terrestrial Ecotoxicology (2002).

An acceptable in-field risk is indicated based on data for AG-F8-250 CS for the standard test species *Aphidius rhopalosiphi* and *Typhlodromus pyri*.

The off-field risk is indicated to be acceptable based on the available data without the necessity to account for risk mitigation measures.

### **3.1.6.4. Effects on Earthworms and Other Soil Macro-organisms**

The risk assessment was conducted according to the Guidance Document on Terrestrial Ecotoxicology (2002).

With TERs for chronic risk exceeding the relevant trigger values, the intended uses of AG-F8-250 CS do not pose an unacceptable risk to earthworms as well as soil meso- and macrofauna other than earthworms.

### **3.1.6.5. Effects on organic matter breakdown**

Evaluation of effects on soil organic matter is not performed anymore. The risk to soil organisms is addressed in evaluation to soil macro- and meso-fauna as well as soil micro-organisms.

### **3.1.6.6. Effects on Soil Non-target Micro-organisms**

The risk assessment was conducted according to the Guidance Document on Terrestrial Ecotoxicology (2002).

An acceptable risk for soil microbial functions is indicated for the intended worst-case uses of AG-F8-250 CS by Predicted Environmental Concentrations lower than the No Observed Adverse Effect Concentrations (i.e. concentrations causing less than 25% effect on nitrogen transformation or carbon respiration after  $\leq 100$  days).

### 3.1.6.7. Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna)

#### Non-Target Plants

The risk assessment was conducted according to the Guidance Document on Terrestrial Ecotoxicology (2002).

From the worst case application rate of 500 g a.s./ha (2.0 L product/ha) an acceptable off-field risk is indicated for terrestrial non-target plants exposed towards AG-F8-250 CS in accordance with the intended worst-case use patterns in pre-emergence crops based on the data for vegetative vigour as well as seedling emergence and growth with the necessity to account for risk mitigation requirements as 5 m buffer distance or 50% drift reducing nozzles.

Acceptable risk with no need for risk mitigation measures could be concluded for lower intended application rate of 375 g a.s./ha (1.5 L product/ha).

#### Other non-target species (Flora and Fauna)

Tests on other non-target species are not required.

#### Implications for labelling resulting from ecotoxicological assessment:

Labelling under Regulation 1272/2008:

Signal Word: Danger

Hazard Class- and Category: Aquatic Acute 1, Aquatic Chronic 1

Hazard Statements: H400, H410

Precautionary Statements: P391, P501

### 3.1.7. Efficacy

AG-F8-250 CS is intended to control broad-leaved weeds and *Echinochloa crus-galli* in potato crops. AG-F8-250 CS is to be applied pre-emergence of the crop.

#### Minimum effective dose tests

With two exceptions only, wherever the efficacy exceeded 95% it was achieved by the target dose rate alone. Therefore the dose rate 2,0 L/ha of the test item AG-F8-250 CS may be considered as the proper minimum effective dose rate against majority of the weed species for which the label claim is made.

However, the negative ecotoxicological evaluation of the 2,0 L/ha dose rate had triggered reassessment of the product efficacy at 1,5L/ha. Although resulting in some shifts in weed susceptibility classification (see below), this reassessment demonstrated that, when used at the dose rate of 1,5 L/ha, the test item AG-F8-250CS (Racer 250 CS) still represents a decent tool for the control of broadleaved weeds in potato crop.

#### Efficacy tests

A total of 11 efficacy tests were carried out for the present submission. Their results allow for the following listing and classification of the target weed species in the product label, according to weed susceptibility to the 2.0 L/ha dose rate:

Highly susceptible:	BRSNW, CAPBP, GASPA, MATIN, STEME and THLAR,
Susceptible:	CHEAL, GALAP, GERPU, POLCO and SOLNI,
Moderately susceptible:	ECHCG and VIOAR.

On the other hand, the reassessment of the efficacy at 1,5 L/ha resulted in the following classification:

Highly susceptible:	EROCI*, GASPA and MATIN,
Susceptible:	BRSNW, CAPBP, CHEAL, GERPU, STEME and THLAR,

Moderately susceptible: GALAP, POLCO, SOLNI and VIOAR,

Moderately tolerant: ECHCG,

\*EROCI have appeared in the present classification even though it had been not included in the evaluation of the 2,0 L/ha dose rate because, contrary to the 2,0 L/ha treatment, the weed was present in the plots treated with 1,5 L/ha dose rate.

### Effects on the processing procedure

Lack of additional tests in this range. Active substances comprising in this product has been applied for many years, not only in Poland but also in the other countries of Europe. Detailed information had been submitted at first registration of flurochloridone product Racer 250 EC.

### Effects on the yield of treated plants and plant products

No significant negative effect on yield and its parameters should be expected after the application of the test item, compared to the former formulation used as standard reference: Racer 250 EC. See the paragraph below as well.

### Phytotoxicity to host crop

Phytotoxicity was monitored in 11 efficacy trials and tested in 8 selectivity trials, of which six tested yield, five of them tested harvestable yield and three tested starch content in tubers. Phytotoxicity symptoms were infrequent, and none of them affected yield quantity or quality. It may be concluded that no significant negative effect on yield and its parameters should be expected after application of the test item, compared to the former formulation used as standard reference: Racer 250 EC.

### Possible development of resistance or cross-resistance

Considering the mode of action of flurochloridone, it is likely that some weeds develop resistance to flurochloridone as it could be on diflufenican. Even taken the absence of resistance reported to flurochloridone, standard resistance management strategy must be incorporated in the product label. The active of the test item is not the only herbicide in the market belonging to the MoA group no 12, therefore the limited number of applications per growth season alone do not warrant the limited exposure of weeds to this mode of action. The respective resistance management phrases have been proposed to be placed in the product label.

## 3.2. Conclusions

Performed evaluation demonstrated that the product **cannot be authorised** in Poland for pre-emergence uses in potatoes **at 2.0 L/ha due to not resolved risk to algae in scenario D4**. Further refinement for algae is deemed necessary for this **application rate** species.

**For lower application rate of 1.5 L/ha acceptable risk to all groups of non-target species (including algae) could be concluded provided that 10 m vegetated filter strip to surface water bodies is respected and this application rate may be authorised in Poland.**

The recommended PPEs for the intended use of AG-F8-250 CS are the following:

#### Mixing/loading phase:

- Nitrile gloves
- Polyester 65% / cotton 35% coverall with a weight of 245 g/m<sup>2</sup> or higher
- Category III / Type PB (3) apron with long sleeves worn over the coverall proposed above

#### Application phase:

- Nitrile gloves (when using tractors with operator cabs, use of nitrile gloves during application is only necessary while handling spraying devices)
- Polyester 65% / cotton 35% coverall with a weight of 245 g/m<sup>2</sup> or higher



Cleaning phase:

- Nitrile gloves
- Polyester 65% / cotton 35% coverall with a weight of 245 g/m<sup>2</sup> or higher
- Category III / Type PB (3) apron with long sleeves worn over the coverall proposed above

### **3.3. Substances of concern for national monitoring**

No national monitoring is in place on flurochloridone.

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

Not relevant since the product does not contain substances classified as candidate for substitution.

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

Further data to address the risk to algae **from the higher application rate of 2.0 L product/ha** are necessary.

Additional modelling performed with consideration of wider buffer zones would not address the risk in D scenarios, where the exposure is driven by drainage and currently there are no efficient mitigation measures enabling reduction of the exposure. The only option would be reduction of the application rate, which potentially may not be possible from the efficacy point of view.

~~Potentially, the risk in R scenarios could be further refined with STEP 4 PEC<sub>sw</sub> values calculated using VFSmod, which is currently acceptable in Poland. However, this would not address the risk in D scenarios, where the exposure is driven by drainage and currently there are no efficient mitigation measures enabling reduction of the exposure. The only option would be reduction of the application rate, which potentially may not be possible from the efficacy point of view.~~

## **Appendix 1 – Copy of the product authorisation**

## Appendix 2 – Copy of the product label

### **Komentarz oceniających:**

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, pozostałości, toksykologii i istotności toksykologicznej metabolitów, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich **szarym kolorem**.

Zakres zmian jest następujący:

### **Sekcja właściwości fizykochemiczne:**

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodnie z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008r. nie jest wymagane.
2. Okres ważności: 2 lata w opakowaniach wykonanych z HDPE na podstawie wyników 2-letnich badań stabilności. Zgodnie z zapisami aktualnie obowiązującej wytycznej w sprawie zasad zatwierdzania opakowań środków ochrony roślin z dnia 17/10/2019 możliwa jest ekstrapolacja wyników badań stabilności z opakowań wykonanych z HDPE na HDPE/PA, HDPE/EVOH, HDPE/F. W związku z powyższym, wszystkie opakowania wymienione, w punkcie 4.1 Sekcji 1 można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin.
3. Brak uwag do punktów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin i opakowania oraz sporządzania cieczy użytkowej.
4. Brak uwag do zapisu nazwy grupy chemicznej, do której przyporządkowano substancje czynną. Dodano zawartość substancji czynnej wyrażoną w procentach (zawartość została obliczona w oparciu o gęstość produktu 1,105 g/ml zgodnie z punktem 2.6.1 Sekcji 1).

### **Sekcja skuteczność:**

1. Poprawiono nazwany we wstępie do etykiety zakres zwalczanych chwastów, usuwając zapis o chwastach jednoliściennych jako grupie, który jest nieuprawniony w świetle przedłożonych badań skuteczności.
2. Poprawiono nazwę grupy mechanizmów działania, zgodnie ze współczesną klasyfikacją HRAC.
3. Skorygowano zakres zwalczanych chwastów. **Ponownie skorygowano tabelę wrażliwości chwastów, w wyniku powtórnej oceny skuteczności dawki 1,5 L/ha.**
4. Skorygowano fazę rozwojową rośliny uprawnej w chwili aplikacji, tak aby była zgodna z warunkami badań przedłożonych z niniejszym wnioskiem.
5. Skorygowano rozdział dotyczący strategii antyodpornościowej, między innymi usuwając zagadnienia, które nie odnoszą się specyficznie do wnioskowanego środka ale zmniejszają efektywny odbiór kluczowych treści przez końcowego użytkownika.
6. Poprawiono nieprecyzyjne słownictwo odnoszące się do elementów budowy opryskiwacza.
7. **Skorygowano maksymalną/zalecaną dawkę dla jednorazowego zastosowania środka w ziemiaku z 2,0 l/ha na 1,5 l/ha.**

### **Sekcja metody analityczne:**

1. Brak uwag.

### **Sekcja toksykologia i istotność toksykologiczna metabolitów:**

1. W części dotyczącej klasyfikacji zagrożeń dodano zwrot **H360Df** zgodnie z opinią ECHA/RAC CLH-O-0000001412-86-242/F z dnia 30 Listopad 2018,
2. Zmodyfikowano zwroty P280, P261 oraz dodano zwrot P308-313.
3. W części dotyczącej zasad bezpieczeństwa dla osób stosujących środek, zapis zmodyfikowano tak aby stanowił wypadkową szacowania narażenia oraz klasyfikacji zagrożeń. **Oceniający zwraca uwagę na fakt że s.c.z. flurochloridon, zawarta we wnioskowanym środku ochrony roślin została zaklasyfikowana przez ECHA/RAC jak toksyczna dla reprodukcji kategorii 1 (Repr. 1B H360Df) i po formalnym przyjęciu zharmonizowanej klasyfikacji przez KE nie powinna być stosowana w środkach ochrony roślin (Rozp.1107/2009WE art. 4 pkt 7).**

**Zgodnie z ustaleniami Harmonizacyjnymi z dnia 21.12.2018 r. przyjętymi przez Ministerstwo Rolnictwa i Rozwoju Wsi oraz Jednostki Upoważnione do opracowywania ocen lub uwag., w brzmieniu następującym:**

**Klasyfikacja substancji, które komitet RAC sklasyfikował (a nie wprowadzono tej klasyfikacji jeszcze do rozporządzenia CLP) jako rakotwórcze kat. 1A lub 1B lub działające szkodliwie na rozrodczość kat. 1A lub 1B, będzie miała swoje odzwierciedlenie w klasyfikacji środka ochrony roślin zawierającego tak**

sklasyfikowaną substancję. Klasyfikacja taka powoduje, że narażenie na środek powinno być minimalne. W związku z tym, podmiot upoważniony będzie w takich przypadkach proponował adekwatne środki ograniczające ryzyko minimalizujące narażenie (takie jak np. zamknięta kabina pojazdu w trakcie oprysku, strefy buforowe, oznakowanie pola itp.).

**Mając na względzie ww. stanowisko zaakceptowane przez Min. Rol. i RW oraz ekspertów z Jednostek upoważnionych, proponujemy następujące zalecenia:**

- operatorzy - Stosować rękawice ochronne oraz odzież ochronną zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu, zalecana kabina w ciągniku,
- pracownicy polowi (inspekcja uprawy, podlewanie zgodnie z EFSA Journal 2014;12(10):3874) – strój roboczy (kombinezon) oraz rękawice ochronne,
- osoby postronne i rezydenci – strefa buforowa co najmniej 2m od krawędzi pola, technika ograniczenia znosu, oznakowanie pola.

#### **Sekcja pozostałości:**

1. Wprowadzono do etykiety brakujący zapis dotyczący okresu karencji:  
„Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):  
Ziemniaki – nie wymagany”
2. Dodano zapis dotyczący okresu od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:  
„Ze względu na fitotoksyczność okres ten powinien wynosić co najmniej 30 dni.”
3. W punkcie dotyczącym następstwa roślin wprowadzono zaproponowany przez Wnioskodawcę i zaakceptowany przez oceniającego w części B7 następujący zapis:  
„Biorąc pod uwagę fitotoksyczność, należy przestrzegać 30-dniowego okresu od ostatniego zastosowania środka na rośliny chronione do dnia, w którym można siać lub sadzić rośliny uprawiane następnie.  
W przypadku wcześniejszej likwidacji plantacji można sadzić lub siać rośliny liściowe oraz korzeniowe co najmniej 30 dni od ostatniego zastosowania środka Racer 250 CS oraz minimum 3 miesiące w przypadku siania zbóż.”

#### **Sekcja los i zachowanie w środowisku:**

1. Brak uwag.

#### **Sekcja ekotoksykologia:**

1. Dodano zwrot P501.
2. Poprawiono zwroty dotyczące zarządzania ryzykiem dla organizmów wodnych i roślin lądowych niebędących celem działania środka.
3. Projekt etykiety nie został sprawdzony pod kątem ekotoksykologii, gdyż dostępne dane były wystarczające do zakończenia oceny ryzyka dla organizmów wodnych (głonów) ze scenariusza D4. Etykieta zostanie sprawdzona po dostarczeniu dodatkowych danych umożliwiających wyjaśnienie ryzyka dla głonów i ich ocenie. Do tego czasu środek nie może zostać zarejestrowany w Polsce.

#### **Posiadacz zezwolenia:**

ADAMA Polska Sp. z o.o., ul. Sienna 39, 00 - 121 Warszawa, tel. +48 22 395 66 60, infolinia:  
+48 22 395 66 66, e - mail: [biuro@adama.com](mailto:biuro@adama.com), [www.adama.com](http://www.adama.com)

#### **Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie:**

.....


## **RACER 250 CS**

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

flurochloridon (związek z grupy pochodnych pyrolidonu) - 250 g/l (22,7%) w 1 litrze środka.

2. Zezwolenie MRiRW nr ..... z dnia .....  
3.

	
<b>UWAGA Niebezpieczeństwo</b>	
H317	Może powodować reakcję alergiczną skóry
H361d H360Df	Podjeżdżewa się, że działa szkodliwie na dziecko w łonie matki. Możliwość przeniesienia szkodliwych substancji na płód.
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i dla środowiska, należy postępować zgodnie z instrukcją użycia.
P261	Unikać wdychania mgły/par rozpylonej cieczy.
P272	Zanieczyszczonej odzieży ochronnej nie wyciągać poza miejsce pracy
P280	Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy.
P308+P313	W przypadku narażenia lub styczności: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P302+P352	W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody/mydłem
P333+P313	W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P362+P364	Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.
P391	Zebrać wyciek.
P501	Zawartość/pojemnik usuwać do recyklingu bądź składowania na składowiskach odpowiednich dla pestycydów lub spalania w odpowiednich instalacjach

## OPIS DZIAŁANIA

HERBICYD selektywny w formie mikro kapsułek w cieczy do rozcieńczania wodą, stosowany dogłębowo. Produkt przeznaczony do zwalczania chwastów jedno- i dwuliściennych chwastów dwuliściennych i chwastnicy jednostronnej w uprawie ziemniaka.

Zgodnie z klasyfikacją HRAC substancja czynna flurochloridon, zaliczana jest do grupy F+ 12 według klasyfikacji HRAC (2020).

## DZIAŁANIE NA CHWASTY

Środek zawiera substancję flurochloridon, która należy do grupy chemicznej pochodnych pyrolidonu.

Środek wnika do rośliny poprzez korzenie oraz liście i wpływa na zahamowanie biosyntezy karotenoidów. Środek działa na chwasty w okresie ich kiełkowania, w małym stopniu działa na chwasty po wschodach. Szybkość działania zależy od fazy rozwojowej zwalczanych chwastów, panujących warunków atmosferycznych – temperatury, wilgotności powietrza oraz tempa wzrostu chwastów.

<b>Chwasty wrażliwe</b>	samosiewy rzepaku, iglica pospolita, maruna bezwonna, tobołki polne, żółtlica drobnokwiatowa, powój polny, psianka czarna, komosa biała, rdestówka powojowata, bodziszek drobny, gwiazdnica pospolita, przytulia czeplna, tasznik pospolity, fiołek trójbarwny
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<b>Chwasty średnio-wrażliwe</b>	chwastnica jednostronna, przetacznik perski, fiołek polny
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<b>Chwasty wrażliwe</b>	samosiewy rzepaku, tasznik pospolity, komosa biała, iglica pospolita, przytulia czepna, żółtlica drobnokwiatowa, bodziszek drobny, maruna bezwonna, rdestówka powojowata, psianka czarna, gwiazdnica pospolita, tobołki polne
<b>Chwasty średnio wrażliwe</b>	chwastnica jednostronna, przytulia czepna, rdestówka powojowata, psianka czarna, rdest plamisty, fiołek polny,
<b>Chwasty średnio odporne</b>	chwastnica jednostronna
<b>Chwasty odporne</b>	-

## STOSOWANIE ŚRODKA

Środek przeznaczony do opryskiwania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

### Ziemniaki

Maksymalna/zalecana dawka dla jednorazowego zastosowania: ~~2,0~~ 1,5 l/ha

Termin stosowania:

Zabieg należy wykonać maksymalnie 7-10 dni (BBCH 00-09) przed wschodami roślin, po uprzednim obredleniu i zbronowaniu pola.

W przypadku odmian wczesnych i bardzo wczesnych, zabieg należy wykonać na wilgotną glebę do 5 dni po posadzeniu podkiełkowanych sadzeniaków i po ostatnim obredleniu.

Zalecana ilość objętość wody: ~~200-300~~ 200-250 l/ha.

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

## ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Ziemniaki – nie wymagany.

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:

Ze względu na fitotoksyczność okres ten powinien wynosić co najmniej 30 dni.

Należy uwzględnić NASTĘPSTWO ROŚLIN.

### 1. Strategia zarządzania odpornością

Środek RACER 250 CS zawiera flurochloridon, substancję czynną zaliczaną do grupy mechanizmów działania nr 12 wg klasyfikacji HRAC (2020). Aby zminimalizować ryzyko wystąpienia i rozwoju odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:

- postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin
- stosować środek w zalecanej dawce, w zalecany terminie zapewniającym optymalne zwalczanie chwastów,
- oprysk wykonać na wilgotną glebę,
- stosować RACER 25 CS jeden raz w sezonie wegetacyjnym



- stosować RACER 25 CS w rotacji z herbicydami działające na inne procesy życiowe chwastów (o mechanizmie działania różnym od mechanizmu grupy 12 w klasyfikacji HRAC),
- ~~dostosować dobór środka chwastobójczego oraz decyzji o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości;~~
- ~~stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania;~~
- ~~stosować mieszanke herbicydów (substancji czynnych) o różnym mechanizmie działania;~~
- ~~stosować herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej;~~
- ~~dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów;~~
- używać różnych metod kontroli zachwaszczenia, w tym zmianowania upraw,
- czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
- ~~używać kwalifikowanego materiału nasadzeniowego;~~
- informować posiadacza zezwolenia o nie satysfakcjonującym zwalczaniu chwastów,
- W celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.

2. Środka nie stosować:

- w czasie wschodów i po wschodach roślin uprawnych
- w temperaturze powyżej 25°C
- podczas wiatru stwarzającego możliwość zwiewania cieczy użytkowej,
- środek może powodować przejściowe objawy fitotoksyczności rośliny uprawnej, jednak bez ujemnego wpływu na plon.

3. Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych i tereny sąsiadujące,
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

4. Regularnie sprawdzać aparaturę do opryskiwania. Przed użyciem sprawdzić pojemność cieczy w urządzeniu i ~~wyrazu~~ wydatek cieczy z dysz. Podczas jazdy i podczas opryskiwania ciecz użytkową utrzymywać w ruchu za pomocą włączonego mieszadła.

## NASTĘPSTWO ROŚLIN

Po zbiorze ziemniaków traktowanych środkiem Racer 250 CS lub w przypadku zaorania plantacji tych roślin, na tym samym polu po bronowaniu, można uprawiać pszenicę ozimą, pszenżyto ozime, żyto, ziemniaki, słonecznik, czosnek, marchew, pasternak, pietruszkę i seler, a po wykonaniu orki również kukurydzę.

Nie uprawiać w tym samym roku buraków, gorczycy, rzepaku ozimego, kapusty i innych roślin krzyżowych.

Biorąc pod uwagę fitotoksyczność, należy przestrzegać 30-dniowego okresu od ostatniego zastosowania środka na rośliny chronione do dnia, w którym można siać lub sadzić rośliny uprawiane następnie. W przypadku wcześniejszej likwidacji plantacji można sadzić lub siać rośliny liściowe oraz korzeniowe co najmniej 30 dni od ostatniego zastosowania środka Racer 250 CS oraz minimum 3 miesiące w przypadku siania zbóż.

## SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość.

Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości ciągle dokładnie mieszając. Zabieg wykonywać z włączonym mieszadłem.

Po wlewniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne ciecz w zbiorniku mechanicznie wymieszać.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy, dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

## **POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY**

Resztki cieczy użytkowej należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Bezpośrednio po pracy aparaturę dokładnie wymyć oraz przepłukać co najmniej trzykrotnie wodą. ~~Końcówki~~ **Dysze** opryskiwacza oraz filtry myć osobno.

Sposób mycia opryskiwacza:

1. Dokładnie wymyć wodą wszystkie wewnętrzne powierzchnie opryskiwacza (łącznie z pokrywą) używając do tego wody w ilości co najmniej 10% pojemności opryskiwacza. Usunąć widoczny osad. Oplukać pompę, filtry oraz belkę po zdjęciu końcówek dysz (te elementy wymyć oddzielnie).
2. Procedurę mycia powtórzyć.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

W przypadku mycia aparatury przy użyciu środków przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować zgodnie z instrukcją dołączoną do środka myjącego.

### Uwaga:

Ze względu na bardzo dużą wrażliwość niektórych roślin uprawnych nawet na znikome ilości środka, bardzo ważne jest dokładne wymycie opryskiwacza po zabiegu, zwłaszcza przed użyciem w innych roślinach niż zalecane.

Nieutralizowane odpowiednio resztki środka pozostawione w opryskiwaczu mogą być powodem silnych uszkodzeń roślin uprawnych wrażliwych na ten środek.

## **ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy roboczej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

~~Stosować rękawice ochronne, ochronę oczu, ochronę twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.~~

Stosować rękawice ochronne oraz odzież ochronną zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu

Unikać zanieczyszczania skóry.

Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

Nie wdychać rozpylonej cieczy użytkowej.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

### **ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO:**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie **zadarnionej strefy ochronnej o szerokości 10 m od zbiorników i cieków wodnych**. ~~strefy ochronnej o szerokości 20 m od zbiorników i cieków wodnych.~~

W celu ochrony roślin niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości **1 m od terenów nieużytkowanym rolniczo**.

~~— 5 m od terenów nieużytkowanych rolniczo lub;~~

~~— 1m od terenów nieużytkowanym rolniczo z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%.~~

### **WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0°C-30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnianego do odbierania odpadów niebezpiecznych.

Opróżnione opakowanie po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

### **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

Okres ważności - 2 lata

Data produkcji - .....

Zawartość netto - .....  
Nr partii - .....

### **Appendix 3 – Letter of Access**

Not required.

## Appendix 4 List of data considered for national authorization

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Owner*
KCP 2.1/01	Gorban, I.	2006	RACER 25 CS (Flurochloridone 250 g/L CS) Determination of Storage Stability and Shelf Life Specification Data of RACER 25 CS Stored at 54°C for 14 Days Report No. F06-07, Sponsor Reference No. 90009450 ADAMA Agan, Ashdod, Israel GLP / Unpublished	N	Y	ADM
KCP 2.2.1/01	Atwal, S.S. and Woolley, S.M.	2008	Racer 25 CS (250 g/L flurochloridone) Determination of Explosive Properties Report No. 0008/0760 SafePharm Laboratories Ltd., UK GLP / Unpublished	N	Y	ADM
KCP 2.2.2/01	Weissenfeld, M.	2008	Expert statement Flurochloridone CS Formulation Determination of the Oxidising Properties Report No. C14472, Sponsor Reference No. 90011557 RCC Ltd., Switzerland Non-GLP / Unpublished	N	N	ADM
KCP 2.3.1/01	Lumsden, A. M.	2000	Racer CS: Determination of Accelerated Storage Stability and Physico-Chemical Characteristics Report No. 560/150, Sponsor Reference No. 90004612 SafePharm Laboratories Ltd., UK GLP / Unpublished	N	Y	ADM
KCP 2.3.3/01	Harper, D.J.	1991	Report on the Auto-flammability characteristics of Racer 25 CS Report No. HT642/90, Sponsor Reference No. 90004608 ICI FCMO, UK GLP / Unpublished	N	Y	ADM
KCP 2.4.1/01	O'Connor, B.J. and White, D.F.	2012	CS Formulation Flurochloridone: Determination of pH value and alkalinity Report No. 41104684 Harlan Laboratories Ltd., UK GLP / Unpublished	N	Y	ADM

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Owner*</b>
KCP 2.4.2/01 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	Y	ADM
KCP 2.4.2/02 = KCP 2.4.1/01	O'Connor, B.J. and White, D.F.	2012	See KCP 2.4.1/01	N	Y	ADM
KCP 2.5.1/01 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	Y	ADM
KCP 2.5.1/02	Evans, A. J. and Mullee, D. M.	2001	Racer CS: Determination of Long-term Storage Stability and Physico-Chemical Characteristics Report No. 560/151, Sponsor Reference No. 90005202 SafePharm Laboratories Ltd., UK GLP / Unpublished	N	Y	ADM
KCP 2.5.2 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	Y	ADM
KCP 2.6.1 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	Y	ADM
KCP 2.7.1 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	Y	ADM
KCP 2.7.4 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	Y	ADM
KCP 2.7.5/01	O'Connor, B J.	2013	CS Formulation Flurochloridone: Determination of Long-Term Storage Stability Report No. 41104685 Harlan Laboratories Ltd., UK GLP / Unpublished	N	Y	ADM
KCP 2.7.5/02 = KCP 2.5.1/02	Evans, A. J. and Mullee, D. M.	2001	See KCP 2.5.1/02	N	Y	ADM
KCP 2.8.2 = KCP 2.5.1/02	Evans, A. J. and Mullee, D. M.	2001	See KCP 2.5.1/02	N	Y	ADM
KCP 2.8.3.1 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	Y	ADM

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Owner*</b>
KCP 2.8.3.2 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	Y	ADM
KCP 2.8.5.1.1 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	Y	ADM
KCP 2.8.5.1.2 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	Y	ADM
KCP 4/01	Anonymous	2016	Safety Data Sheet – AG-F8-250 CS ADAMA Agan Ltd., Ashdod, Israel Non-GLP, not published	N	N	ADM
KCP 4.4/01	Anonymous	2008	1 L COEX packaging information Non-GLP, not published	N	N	ADM
KCP 4.4/02	Anonymous	2009	5/0.27 Lit. Plastic Jerrycan – Agro PE/PA CO-EX Metal, Plastik and Fiber Industries ELN-Hachoresh, No. 9700502612 Non-GLP, not published	N	N	ADM
KCP 4.4/03	Anonymous	2004	10 Lit. Plastic Jerrycan – Agrogan PE/PA CO-EX Metal, Plastik and Fiber Industries ELN-Hachoresh/Lehavot-Havlva, No. 9701004612 Non-GLP, not published	N	N	ADM
KCP 4.4/04	Anonymous	2009	B-20/1.30 Lts. White. Plastic Jerrycan with UN Approval Metal, Plastik and Fiber Industries ELN-Hachoresh, No.9702012501 Non-GLP, not published	N	N	ADM
KCP 4.4/05	Passy, N., Besser, I.	2007	Technion R&D Foundation Certification No. 210 Technion Research and Development Foundation Ltd., No. AMRAZ119H Non-GLP, not published	N	N	ADM
KCP 4.4/06	Miltz, J., Passy, N.	2010	Technion R&D Foundation Certification No. 237 Technion Research and Development Foundation Ltd., No. PLASTIV30H 19 10 2 Non-GLP, not published	N	N	ADM
KCP 4.4/07	Savaransky, M., Gazit, A.	2007	Test Certification No. 8733205541 The standard Institution of Israel. Report no.: not reported Non-GLP, not published	N	N	ADM

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Owner*
KCP 4.4/08	Savaransky, M., Gazit, A.	2005	Test Certification No. 8513234067 The standard Institution of Israel. Report no.: not reported Non-GLP, not published	N	N	ADM
KCP 4.4/01	Anonymous	2012	Safety Data Sheet – EU Regulation No. 1907/2006, Annex II - Flurochloridone 25 ME Agan Chemical Manufacturers Ltd. No. H-01620-16534-RAII, Non-GLP, Not published	N	N	ADM
KCP 6	Daniel Słomka	2018	Określenie skuteczności działania preparatu Racer 25 CS (AG-F8-250 CS; flurochloridon 250 g/l) zastosowanego przedwschodowo w zwalczaniu chwastów dwuliściennych w uprawie ziemniaka. Polska, 2018. Efficacy evaluation of a pre-emergence application of Racer 25 CS (AG-F8-250 CS; flurochloridon 250 g/l) against broad-leaved weeds in potato. Poland, 2018. GEP Not Published Trial sponsor code: PL18HESOLTU070A Final report nr: S18-02668-01	N	Y	ADAMA Polska
KCP 6	Monika Brodała-Jabłońska	2018	Określenie skuteczności działania preparatu Racer 25 CS (AG-F8-250 CS; flurochloridon 250 g/l) zastosowanego przedwschodowo w zwalczaniu chwastów dwuliściennych w uprawie ziemniaka. Polska, 2018. Efficacy evaluation of a pre-emergence application of Racer 25 CS (AG-F8-250 CS; flurochloridon 250 g/l) against broad-leaved weeds in potato. Poland, 2018. GEP Not published Trial sponsor code: PL18HESOLTU070B Final report no S18-02668-02	N	Y	ADAMA Polska
KCP 6	dr inż. Agnieszka Kukuła, PhD	2018	Ocena skuteczności preparatu AG-F8-250 CS w zwalczaniu chwastów w uprawie ziemniaka (The evaluation of efficacy of AG-F8-250 CS for the control of weeds on potato) GEP Not published sponsor's code: PL18HESOLTU070D final report nr: 18ADA0409-2	N	Y	ADAMA Polska



<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Owner*</b>
KCP 6	dr inż. Agnieszka Kukuła, PhD	2019	Ocena skuteczności i selektywności preparatu AG-F8-250 CS w zwalczaniu chwastów w uprawie ziemniaka (The evaluation of efficacy and selectivity of AG-F8-250 CS for the control of weeds on potato) “Efficacy and selectivity of AG-F8-250 CS in potato in Poland in 2019” GEP Not published Sponsor’s code: PL19HESOLTU031A Final report nr: 19ADA0581-1	N	Y	ADAMA Polska
KCP 6	Mgr inż. Adam Szemendera	2019	Skuteczność preparatu AG-F8-250 CS w zwalczaniu chwastów w uprawie ziemniaka. Polska 2019 Efficacy of AG-F8-250 CS in control of weeds in potato, Poland 2019 GEP Not published Sponsor’s code: PL19HESOLTU031B Final report nr: 212_01_F19_362	N	Y	ADAMA Polska
KCP 6	Mgr inż. Adam Szemendera	2019	Skuteczność preparatu AG-F8-250 CS w zwalczaniu chwastów w uprawie ziemniaka, Polska 2019 Efficacy of AG-F8-250 CS in control of weeds in potato, Poland 2019 GEP Not published Sponsor’s code: PL19HESOLTU031C Final report nr: 1_01_F19_01	N	Y	ADAMA Polska
KCP 6	Mgr inż. Adam Szemendera	2019	Skuteczność preparatu AG-F8-250 CS w zwalczaniu chwastów w uprawie ziemniaka, Polska 2019 Efficacy of AG-F8-250 CS in control of weeds in potato, Poland 2019 GEP Not published Sponsor’s code: PL19HESOLTU031D Final report nr: 1_02_F19_02	N	Y	ADAMA Polska
KCP 6	Adam Pawlak	2019	Skuteczność i selektywność AG-F8-250 CS stosowanego przeciwko chwastom w ziemniakach, Polska 2019 Efficacy and selectivity of AG-F8-250 CS in potato in Poland 2019. GEP Not published Sponsor’s code: PL19HESOLTU031E Finl report nr: APK-19-39012-PL01	N	Y	ADAMA Polska

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Owner*
KCP 6	Adam Pawlak	2019	Skuteczność i selektywność AG-F8-250 CS stosowanego przeciwko chwastom w ziemniakach, Polska 2019 Efficacy and selectivity of AG-F8-250 CS in potato in Poland 2019. GEP Not published Sponsor' code: PL19HESOLTU031F Final report nr: APK-19-39012-PL02	N	Y	ADAMA Polska
KCP 6	Beata Szymańska	2019	Badanie skuteczności produktu AG-F8-250 CS w zwalczaniu chwastów w uprawie ziemniaka Efficacy of product AG-F8-250 CS against herbs in potatoes cultivation. GEP Not published Sponsor's code: PL19HESOLTU031G Trial code: AF/19/Z/13/Gr/031G	N	Y	ADAMA Polska
KCP 6	Beata Szymańska	2019	Badanie skuteczności produktu AG-F8-250 CS w zwalczaniu chwastów w uprawie ziemniaka Efficacy of product AG-F8-250 CS against herbs in potatoes GEP Not published Sponsor's code: PL19HESOLTU031H Trial code: AF/19/Z/13/ZŁ/031H	N	Y	ADAMA Polska
KCP 6.4	Mgr Krzysztof Rusek	2018	Selektywność preparatu AG-F8-250 CS stosowanego w terminie zwalczania chwastów w uprawie ziemniaka, Polska 2018 Selectivity of AG-F8-250 CS in control of weeds in potato, Poland 2018 GEP Not published Sponsor' code: PL18HSSOLTU071A Final report nr: 123_01_F18_256	N	Y	ADAMA Polska
KCP 6.4	Mgr Krzysztof Rusek	2018	Selektywność preparatu AG-F8-250 CS stosowanego w terminie zwalczania chwastów w uprawie ziemniaka, Polska 2018 Selectivity of AG-F8-250 CS in control of weeds in potato, Poland 2018 GEP Not published Sponsor' code: PL18HSSOLTU071B Final report nr: 123_02_F18_257	N	Y	ADAMA Polska

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Owner*</b>
KCP 6.4	Mgr Krzysztof Rusek	2018	Selektywność preparatu AG-F8-250 CS stosowanego w terminie zwalczania chwastów w uprawie ziemniaka, Polska 2018 Selectivity of AG-F8-250 CS in control of weeds in potato, Poland 2018 GEP Not published Sponsor' code: PL18HSSOLTU071C Final report nr: 123_03_F18_258	N	Y	ADAMA Polska
KCP 6.4	Mgr Krzysztof Rusek	2018	Selektywność preparatu AG-F8-250 CS stosowanego w terminie zwalczania chwastów w uprawie ziemniaka, Polska 2018 Selectivity of AG-F8-250 CS in control of weeds in potato, Poland 2018 GEP Not published Sponsor' code: PL18HSSOLTU071D Final report nr: 123_03_F18_259	N	Y	ADAMA Polska
KCP 6.4	dr inż. Agnieszka Kukuła, PhD	2019	Ocena selektywności preparatu AG-F8-250 CS w uprawie ziemniaka (The evaluation of selectivity of AG-F8-250 CS on potato) "Selectivity of AG-F8-250 CS on potato in Poland in 2019" GEP Not published Sponsor' code: PL19HSSOLTU032A Final report nr: 19ADA0580-1	N	Y	ADAMA Polska
KCP 6.4	dr inż. Agnieszka Kukuła, PhD	2019	Ocena selektywności preparatu AG-F8-250 CS w uprawie ziemniaka (The evaluation of selectivity of AG-F8-250 CS on potato) "Selectivity of AG-F8-250 CS on potato in Poland in 2019" GEP Not published Sponsor' code: PL19HSSOLTU032B Final report nr: 19ADA0580-2	N	Y	ADAMA Polska
KCP 6.4	Mgr inż. Adam Szemendera	2019	Selektywność preparatu AG-F8-250 CS stosowanego w zwalczaniu chwastów w uprawie ziemniaka, Polska 2019 Selectivity of AG-F8-250 CS in control of weeds in potato, Poland 2019 GEP Not published Sponsor' code: PL19HSSOLTU032C Final report nr: 2_01_F19_03	N	Y	ADAMA Polska

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Owner*</b>
KCP 6.4	Mgr inż. Adam Szemendera	2019	Selektywność preparatu AG-F8-250 CS stosowanego w zwalczaniu chwastów w uprawie ziemniaka, Polska 2019 Selectivity of AG-F8-250 CS in control of weeds in potato, Poland 2019 GEP Not published Sponsor' code: PL19HSSOLTU032D Final report nr: 2_02_F19_04	N	Y	ADAMA Polska
KCP 5.1.1/01	Gorban, I.	2006	RACER 25 CS (Flurochloridone 250 g/L CS) Determination of Storage Stability and Shelf Life Specification Data of RACER 25 CS Stored at 54°C for 14 Days Report No. F06-07, Sponsor Reference No. 90009450 ADAMA Agan, Ashdod, Israel GLP Unpublished	N	Y	ADM
KCP 5.1.1/02	Ricau, H.	2018	Validation of the analytical methods for the determination of total flurochloridone and free flurochloridone in AG-F8-250 CS Report No. 17-901066-005, Sponsor Reference No. 90021272 ANADIAG Group DEFITRACES, Brindas, France GLP Unpublished	N	Y	ADM
KCP 5.1.2/03	Liedtke, A.	2013a	Flurochloridone technical: Toxicity to Chlamydomonas reinhardtii in a 72-Hour Algal Growth Inhibition Test Supplemented with Testing for Recovery of Growth Report No. D65727, Sponsor Reference No. 90015442 Harlan Laboratories Ltd., Switzerland GLP Unpublished	N	Y	ADM
KCP 5.1.2/04	Liedtke, A.	2013b	Flurochloridone technical: Toxicity to Chlorella vulgaris in a 72-Hour Algal Growth Inhibition Test Report No. D65738, Sponsor Reference No. 90015443 Harlan Laboratories Ltd., Switzerland GLP Unpublished	N	Y	ADM

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Owner*</b>
KCP 5.1.2/05	Liedtke, A.	2013c	Flurochloridone technical: Toxicity to Navicula pelliculosa in a 72-Hour Algal Growth Inhibition Test Supplemented with Testing for Recovery of Growth Report No. D65740, Sponsor Reference No. 90015444 Harlan Laboratories Ltd., Switzerland GLP Unpublished	N	Y	ADM
KCP 5.1.2/08	Scheerbaum, D.	2013a	Flurochloridone technical: Alga, Growth Inhibition Test with Pseudokirchneriella subcapitata, 72 hours Report No. SPO15371, Sponsor Reference No. 90015448 Dr.U.Noack-Laboratorien, Germany GLP Unpublished	N	Y	ADM
KCP 5.1.2/09	Scheerbaum, D.	2013b	Flurochloridone technical: Alga, Growth Inhibition Test with Nitzschia communis, 72 hours Report No. SNC15371, Sponsor Reference No. 90015449 Dr.U.Noack-Laboratorien, Germany GLP Unpublished	N	Y	ADM
KCP 5.1.2/10	Scheerbaum, D.	2013c	Flurochloridone technical: Alga, Growth Inhibition Test with Synechococcus leopoliensis, 72 hours Report No. SSL15371, Sponsor Reference No. 90015450 Dr.U.Noack-Laboratorien, Germany GLP Unpublished	N	Y	ADM
KCP 5.1.2/11	Scheerbaum, D.	2013d	Flurochloridone technical: Alga, Growth Inhibition Test with Chromulina nebulosa, 72 hours Report No. SCN15371, Sponsor Reference No. 90016462 Dr.U.Noack-Laboratorien, Germany GLP Unpublished	N	Y	ADM
KCP 5.1.2/12	Scheerbaum, D.	2013e	Flurochloridone technical: Alga, Growth Inhibition Test with Ankistrodesmus falcatus, 72 hours Report No. SAF15371, Sponsor Reference No. 90016463 Dr.U.Noack-Laboratorien, Germany GLP Unpublished	N	Y	ADM

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Owner*</b>
KCP 5.1.2/13	Wenzel, A.	2015a	Freshwater Alga, Growth Inhibition Test Flurochloridone (technical): Desmodesmus subspicatus Toxicity Test - Testing for Recovery of Growth Report No. ADM-003/4-10/B, Sponsor Reference No. 90016481 Fraunhofer Institute for Molecular Biology and Applied Ecology IME, Germany GLP Unpublished	N	Y	ADM
KCP 5.1.2/17	Molitor, A.M.	2017	AG-F8-250 EC (Flurochloridone 250 EC) - Assessment of Effects on the Adult Honey Bee, Apis mellifera L., in a 10 Day Chronic Feeding Test under Laboratory Conditions Report No. S17-00282, Sponsor Reference No. 90020495 Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH GLP Unpublished	N	Y	ADM
KCP 5.1.2/18	Molitor, A.M.	2018	AG-F8-250 EC (Flurochloridone 250 EC) - Honey Bee (Apis mellifera L.) 22 Day Larval Toxicity Test (Repeated Exposure) Report No. S17-00318, Sponsor Reference No. 90020496 Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH GLP Unpublished	N	Y	ADM
KCP 5.2/01	Garrigue, P.	2017a	Validation of Residue Analytical Method for Determination of Flurochloridone in Plant Matrices Report No.: BPL17-0001, Sponsor Reference No. 90020483 SGS Multilab, Laboratory of Rouen , France GLP Unpublished	N	Y	ADM
KCP 5.2/02	Hauler, C.	2018a	Independent Laboratory Validation of an Analytical Method for the Determination of Flurochloridone in Different Matrices of Plant Origin Report No.: S17-08035; Sponsor Reference No. 90021292 Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Germany GLP Unpublished	N	Y	ADM
KCP 5.2/03	Garrigue, P.	2017b	Validation of Residue Analytical Method for Determination of Flurochloridone in Animal Matrices Report No.: BPL17-0002, Sponsor Reference No. 90020484 SGS Multilab, Laboratory of Rouen , France GLP Unpublished	N	Y	ADM

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Owner*</b>
KCP 5.2/04	Hauler, C.	2018b	Independent Laboratory Validation of an Analytical Method for the Determination of Flurochloridone in Different Matrices of Animal Origin Report No.: S17-08036 and amendment 1; Sponsor Reference No. 90021293 Eurofins Agrosience Services EcoChem GmbH / Eurofins Agrosience Services Ecotox GmbH, Germany GLP Unpublished	N	Y	ADM
KCP 5.2/05	Brown, D.	2018	Flurochloridone (2 isomers) and Metabolite, R406639: Non-radiolabelled Environmental Fate Method Validation in Three Soils Report No.: 39322 and amendment 1, Sponsor Reference No. 90020530 Charles River Laboratories Edinburgh Ltd, UK GLP Unpublished	N	Y	ADM
KCP 5.2/06	Garrigue, P.	2017c	Validation of Residue Analytical Method for Determination of Flurochloridone in Water Report No.: BPL17-0004 and amendment 1, Sponsor Reference No. 90020486 SGS Multilab, Laboratory of Rouen , France GLP Unpublished	N	Y	ADM
KCP 5.2/07	Hauler, C.	2018c	Independent Laboratory Validation of an Analytical Method for the Determination of Flurochloridone in Water Report No.: S17-08037; Sponsor Reference No. 90021294 Eurofins Agrosience Services EcoChem GmbH / Eurofins Agrosience Services Ecotox GmbH, Germany GLP Unpublished	N	Y	ADM
KCP 5.2/08	Garrigue, P.	2017d	Validation of Residue Analytical Method for Determination of Flurochloridone Metabolites R42819 and R406639 in Water Report No.: BPL17-0005 and amendment 1, Sponsor Reference No. 90020487 SGS Multilab, Laboratory of Rouen , France GLP Unpublished	N	Y	ADM

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Owner*</b>
KCP 5.2/09	Garrigue, P.	2017e	Validation of Residue Analytical Method for Determination of Flurochloridone in Body Fluid Matrices Report No.: BPL17-0003, Sponsor Reference No. 90020485 SGS Multilab, Laboratory of Rouen , France GLP Unpublished	N	Y	ADM
KCP 7.1.1/01	XXX	1986a	Single oral toxicity study in the rat – Racer ME Agan Report no. 818607 GLP Unpublished	Y	Y	ADM
KCP 7.1.2/01	XXX	1986b	Acute dermal toxicity study in the rat – Racer ME Agan Report no. 828607 GLP Unpublished	Y	Y	ADM
KCP 7.1.4/01	XXX	1986a	Acute dermal irritation/corrosion – Racer ME Agan Report no. 808607 GLP Unpublished	Y	Y	ADM
KCP 7.1.5/01	XXX	1986b	Acute eye irritation/corrosion study – Racer ME Agan Report no. 798607 GLP Unpublished	Y	Y	ADM
KCP 7.1.6/01	XXX	2006	Racer 25 CS: Contact hypersensitivity in albino Guinea pigs, maximisation test Agan Report no. A46607 GLP Unpublished	Y	Y	ADM
KCP 7.3/03	Kane T. J	2007	Flurochloridone, in vitro Dermal Penetration Study Using Human Skin Huntington Life Sciences Ltd., Report No. AGM0265 Agan Report No. 90009461 GLP Unpublished	N	Y	ADM



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KCP 8.6.1 (KCA 6.6.1)	Mamouni A.	2017	Evaluation of the Raw Data of the study: [14C] Flurochloridone Confined Accumulation in Rotational Crops Report No. 9000951 Exponent International Ltd. Report No. 90020993 GLP: no applicable Unpublished	N	Y	ADM
KCP 10.2.3/01	Liedtke, A.	2013a	Flurochloridone technical: Toxicity to Chlamydomonas reinhardtii in a 72-Hour Algal Growth Inhibition Test Supplemented with Testing for Recovery of Growth Report No. D65727 (test facility report number); 90015442 (sponsor report number) Harlan Laboratories Ltd., Itingen, Switzerland GLP Unpublished	N	Y	ADM
KCP 10.2.3/02	Liedtke, A.	2013b	Flurochloridone technical: Toxicity to Chlorella vulgaris in a 72-Hour Algal Growth Inhibition Test Report No. D65738 (test facility report number); 90015443 (sponsor report number) Harlan Laboratories Ltd., Itingen, Switzerland GLP Unpublished	N	Y	ADM
KCP 10.2.3/03	Liedtke, A.	2013c	Flurochloridone technical: Toxicity to Navicula pelliculosa in a 72-Hour Algal Growth Inhibition Test Supplemented with Testing for Recovery of Growth Report No. D65740 (test facility report number); 90015444 (sponsor report number) Harlan Laboratories Ltd., Itingen, Switzerland GLP Unpublished	N	Y	ADM
KCP 10.2.3/04	Scheerbaum, D.	2013a	Flurochloridone Technical – Alga, Growth Inhibition Test with Pseudokirchneriella subcapitata, 72 hours Report No. SPO15371 (test facility report number); 90015448 (sponsor report number) Dr. U. Noack-Laboratorien, Sarstedt, Germany GLP Unpublished	N	Y	ADM
KCP 10.2.3/05	Scheerbaum, D.	2013b	Flurochloridone Technical – Alga, Growth Inhibition Test with Nitzschia communis, 72 hours Report No. SNC15371 (test facility report number); 90015449 (sponsor report number) Dr. U. Noack-Laboratorien, Sarstedt, Germany GLP Unpublished	N	Y	ADM

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Owner*</b>
KCP 10.2.3/06	Scheerbaum, D.	2013c	Flurochloridone Technical – Alga, Growth Inhibition Test with <i>Synechococcus leopoliensis</i> , 72 hours Report No. SSL15371 (test facility report number); 90015450 (sponsor report number) Dr. U. Noack-Laboratorien, Sarstedt, Germany GLP Unpublished	N	Y	ADM
KCP 10.2.3/07	Scheerbaum, D.	2013d	Flurochloridone Technical – Alga, Growth Inhibition Test with <i>Chromulina nebulosa</i> , 72 hours Report No. SCN15371 (test facility report number); 90016462 (sponsor report number) Dr. U. Noack-Laboratorien, Sarstedt, Germany GLP Unpublished	N	Y	ADM
KCP 10.2.3/08	Scheerbaum, D.	2013e	Flurochloridone Technical – Alga, Growth Inhibition Test with <i>Ankistrodesmus falcatus</i> , 72 hours Report No. SAF15371 (test facility report number); 90016463 (sponsor report number) Dr. U. Noack-Laboratorien, Sarstedt, Germany GLP Unpublished	N	Y	ADM
KCP 10.2.3/9	Wenzel, A.	2015a	Freshwater Alga, Growth Inhibition Test Flurochloridone (technical): <i>Desmodesmus subspicatus</i> Toxicity Test - Testing for Recovery of Growth Report No. ADM-003/4-10/B (test facility report number); 90016481 (sponsor report number) Fraunhofer IME, Schmallenberg, Germany GLP Unpublished	N	Y	ADM
10.3.1.2/01	Molitor, A.M.	2017	AG-F8-250 EC (Flurochloridone 250 EC) - Assessment of Effects on the Adult Honey Bee, <i>Apis mellifera</i> L., in a 10 Day Chronic Feeding Test under Laboratory Conditions Report No. S17-00282 (test facility report number); 90020495 (sponsor report number) Eurofins Agrosience Services EcoChem GmbH / Eurofins Agrosience Services Ecotox GmbH, Niefern-Öschelbronn, Germany GLP Unpublished	N	Y	ADM

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Owner*</b>
10.3.1.3/01	Molitor, A.M.	2018	AG-F8-250 EC (Flurochloridone 250 EC) - Honey Bee ( <i>Apis mellifera</i> L.) 22 Day Larval Toxicity Test (Repeated Exposure) Report No. S17-00318 (test facility report number); 90020496 (sponsor report number) Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Niefern-Öschelbronn, Germany GLP Unpublished	N	Y	ADM
10.4.2.1/01	Geary, N.	2017a	AG-F8-250 EC (Flurochloridone 250 EC) – A laboratory test to determine the effects of fresh residues on the springtail <i>Folsomia candida</i> (Collembola, Isotomidae) in an artificial soil substrate Report No. AGAN-17-26 (test facility report number); 90020545 (sponsor report number) Mambo-Tox Ltd., Southampton, UK GLP Unpublished	N	Y	ADM
10.4.2.1/02	Geary, N.	2017b	AG-F8-250 CS (Flurochloridone 250 CS) – A laboratory test to determine the effects of fresh residues on the predatory soil mite <i>Hypoaspis aculeifer</i> (Acari, Laelapidae) Report No. AGAN-17-29 (test facility report number); 90020988 (sponsor report number) Mambo-Tox Ltd., Southampton, UK GLP Unpublished	N	Y	ADM

\*The sponsor company (ADM, ADAMA Agan Ltd., ADAMA Polska ) is a member of ADAMA Agricultural Solutions.