REGISTRATION REPORT

Part B

Section 1: Identity
Section 2: Physical and chemical properties
Section 4: Further information

Detailed summary of the risk assessment

Product code: AG-F8-250 CS

Chemical active substance:

Flurochloridone, 250 g/L

Central Zone

Member State: Poland

CORE ASSESSMENT

(authorization)

Sponsor: ADAMA Agan Ltd

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

Submission date: January 2020

MS Finalisation date: October 2020 (initial Core Assessment)

March 2021 (final Core Assessment)

Version history

When	What
January 2020	dRR submitted by the Applicant
October 2020	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
March 2021	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow. No comments after the commenting period.

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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance.

Noticed data gaps are:
- None.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Country organisation/representative of ADAMA Agan Ltd. as given in Part A

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance

flurochloridone	min. 940 g/kg trans flurochloridone: 720-740 g/kg cis flurochloridone: 220-240 g/kg

According to Commission Directive (EU) 2011/34 of 08/03/2011 the following relevant impurity have been identified for flurochloridone:

Toluene: max. 8 g/kg

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name:	Please refer to Registration Report Part A for the relevant country
Company code number:	AG-F8-250 CS

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

AG-F8-250 CS was the representative formulation evaluated on EU level for Annex I inclusion.

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
flurochloridone	250 g/L	237.5 – 262.5 g/L	266 g/L	24

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers
** Based on the density of the formulation = 1.1 g/mL

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-2: Information on flurochloridone

Type	Name/Code Number
ISO common name	flurochloridone (isomers in the ratio 3:1)
CAS No.	61213-25-0
EC No.	262-661-3
CIPAC No.	430

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Capsule suspension [Code: CS]

1.6 Function (KCP 1.6)

Herbicide.

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The product is a homogenous brown suspension, with a turpentine like odour. The formulated product is not classified as explosive or as having oxidising properties. The formulation has no flash point and starts boiling at about 102 °C. The self-ignition temperature of 565°C was determined for AG-F8-250 CS and has no other inherently dangerous similar properties.
The pH value of the neat formulation and in aqueous solution (1%) is about 10. The alkalinity of the neat formulation is 0.40 % w/w equivalent sodium hydroxide.
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 intended concentration of use is 0.66 % product to 1 % product.
Recommended cleaning procedure: "Rinse the tank three times with tap water".

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Experimental results on the product AG-F8-250 CS with regard to product classification and labelling:

Studies	Method	Findings	Classification acc. to Regulation (EC) No. 1272/2008
Explosive properties	EEC A.14	Not explosive	None
Oxidising properties	UN Recommendations Screening Procedure	Not oxidizing	None
Flammability	--	Not applicable for CS-formulation	--
Flash point	EEC A.9	> 102°C	None
Auto-flammability	EEC A.15	Self-ignition temperature 565°C	None
pH	CIPAC MT 75.3	pH = 9.97 (neat formulation) pH = 10.05 (1% in distilled water)	None
Viscosity	OECD 114	Kinematic viscosity 1076.9 mm^2/s at 20 °C	None
Surface tension	EEC A.5	47.8 mN/m at 25°C (90% saturated solution in water)	None
Relative density	CIPAC MT 3.3	1.105 g/mL at 20 °C	None

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No precautionary statements according to Regulation (EC) No. 1272/2008 are needed with regard to the physical/chemical data of the product.

Compliance with FAO specifications:

The product AG-F8-250 CS (Racer CS) complies with FAO specifications.

Formulation used for tests

The test item used in the tests has the same composition as the one cited in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	No guideline given _ Visual	Racer CS Batch: GC2802 Purity: 250 g/L a.s.	Colour: brown Physical state: homogenous suspension	Y	**KCP 2.1/01** Gorban I., 2006, Report No. F06-07	Accepted.
Explosive properties (KCP 2.2.1)	92/69/EEC A.14 or Reg. 440/2008	Racer CS Batch: D-08809 Purity: 250 g/L a.s.	Not explosive in BAM fall hammer and Koenen steel tube test	Y	**KCP 2.2.1/01** Atwal S.S. and Woolley S.M., 2008 Report No. 0008/0760	Accepted.
Oxidizing properties (KCP 2.2.2)	UN Recommendations on the Transport of Dangerous Goods "Orange Book" defines a screening procedure	Racer CS	Not oxidising according to screening procedure (Division 5.1). Although the compound contains oxygen, fluorine and chlorine, they are chemically bound only to carbon or hydrogen. Therefore no experimental testing is required.	N	**KCP 2.2.2/01** Weissenfeld M. 2008 Report No. C14472	Accepted.
Flash point (KCP 2.3.1)	92/69/EEC A.9, Setaflash 13740-2 tester	Racer CS Batch: BSNI1502 Purity: 250 g/L a.s.	Racer CS has no flash point at or below its boiling temperature (102°C)	Y	**KCP 2.3.1/01** Lumsden A. M., 2000, Report No. 560/150	Accepted.
Flammability (KCP 2.3.2)	-	-	Not required for liquid formulations	-	-	-
Self-heating (KCP 2.3.3)	IEC 79-4	Racer 25 CS Batch: B3124/90/2 Purity: 250 g/L a.s. (nominal value)	Auto-ignition temperature: 565 ± 5°C	Y	**KCP 2.3.3/01** Harper D.J., 1991 Report No. HT642/90	Accepted.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3 (pH) CIPAC MT 191 (alkalinity)	Racer CS Batch: 61213-25-0	pH at 25°C: 9.97 (neat) Alkalinity: 0.40 % w/w equivalent sodium hydroxide	Y	**KCP 2.4.1/01** O'Connor B.J. and White D.F., 2012, Report No. 41104684	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion	Based on CIPAC MT 75.2 (pH)	Racer CS Batch: GC2802	pH = 10.05 (1% in distilled water)	Y	**KCP 2.1/01** Gorban I., 2006, Report No. F06-07	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.4.2)		Purity: 250 g/L a.s.				
	CIPAC MT 75.3 (pH)	Racer CS Batch: 61213-25-0	pH at 25°C: 9.81 (1% w/w)	Y	**KCP 2.4.1/01** O'Connor B.J. and White D.F., 2012, Report No. 41104684	Accepted.
Viscosity (KCP 2.5.1)	OECD 114, Brookfield LVT viscosimeter (12 rpm)	Racer CS Batch: GC2802 Purity: 250 g/L a.s.	Dynamic viscosity 1840 mPa.s at 40°C	Y	**KCP 2.1/01** Gorban I., 2006, Report No. F06-07	Accepted.
	OECD 114, Brookfield LVDV-II viscosimeter	Racer CS Batch: BSNI1502 Purity: 250 g/L a.s.	Dynamic viscosity 1.19 x 10^3 mPa•s at 20 °C ± 0.5°C 639 mPa•s at 40 °C ± 0.5°C	Y	**KCP 2.5.1/02** Evans A. J. and Mullee D. M., 2001 Report No. 560/151	Accepted.
	Calculated	-	Kinematic viscosity Calculation of kinematic viscosity using density of 1.105 g/ml and viscosity of 1.19 x 10^3 mPa•s at 20 °C 1076.9 mm^2/s at 20 °C	-	-	Accepted.
Surface tension (KCP 2.5.2)	SOP, DuNouy Tensio-meter	Racer CS Batch: GC2802 Purity: 250 g/L a.s.	47.8 mN/m at 25°C (90% saturated solution in water)	Y	**KCP 2.1/01** Gorban I., 2006, Report No. F06-07	Accepted.
Relative density (KCP 2.6.1)	CIPAC MT 3.3	Racer CS Batch: GC2802 Purity: 250 g/L a.s.	Density: 1.105 g/mL at 20 °C	Y	**KCP 2.1/01** Gorban I., 2006, Report No. F06-07	Accepted.
Bulk density (KCP 2.6.2)	-	-	Not required for liquid preparations	-	-	-
Storage Stability after 14 days at 54º C (KCP 2.7.1)	CIPAC MT 75.2, MT 160, MT 185, MT 148, MT 184, and MT 187; Validated GC-	Racer CS Batch: GC2802 Purity: 250 g/L a.s. 1 L HDPE COEX	Appearance and packaging stability: Before storage: Homogenous brown color suspension After storage: Homogenous brown color suspension, no significant change in weight, packaging, no bleeding, claying or sedimentation.	Y	**KCP 2.1/01** Gorban I., 2006, Report No. F06-07	The product showed no significant physical changes after accelerated storage in HDPE container and all performance properties were

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	method	container	Initial content: 243 g/L Content after storage: 237 g/L pH value (1% in water): Before storage: pH 10.05 After storage: 9.64 Spontaneity of dispersion (%): Before Storage: 71 % After storage: 69 % Wet sieve test: (%): Before storage:<0.1% After storage: <0.1% Suspensibilty (%) in water D: Before storage at 0.50%: 72 Before storage at 3.00%: 66 After storage at 0.50%: 69 After storage at 3.00%: 62 Particle size distribution: (%): Before storage: d(0.1) = 1.54 d(0.5) = 8.82 d(0.9) = 17.27 After storage: d(0.1) = 1.40 d(0.5) = 9.07 d(0.9) = 18.56 Before storage: Pourability: 3.93 % Rinsed pourability: 0.20 % After storage: Pourability: 3.92 % Rinsed pourability: 0.19 %			within acceptable limits. The active ingredient content after two weeks of 54ºC storage conditions did not significantly change. No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage, evaluation of this parameter after storage is not necessary. Extrapolation from HDPE to HDPE/EVOH, HDPE/F and HDPE/PA is acceptable. The formulation is expected to be stable for at least 2 years at ambient conditions, based on the accelerated storage study results.
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required as formulation is stable for at least 2 years at ambient conditions.	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Not required as formulation is stable for at least 2 years at ambient conditions.	-	-	-
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 185, MT 184, MT 75.2, MT 148 and MT 160 determination after four cycles of freezing / thawing (from -10°C to 20 °C) Validated GC method	Racer CS Batch: GC2802 Purity: 250 g/L a.s.	Samples were stored in a -10°C bath for at least 18 hours followed by 6 hours storage at 20 ± 2°C. This procedure was repeated four times. Appearance and packaging stability: Before storage: Homogenous brown color suspension After freezing / thawing: Homogenous brown color suspension Initial content: 243 g/L Content after storage: 240 g/L pH value (1% in water): Before storage: pH 10.05 After freezing / thawing: pH 10.02 Spontaneity of dispersion (%): Before Storage: 71 % After freezing / thawing: 71 % Wet sieve test: (%): Before storage: <0.1% After freezing / thawing: <0.1% Suspensibilty (3.0% in water D): Before storage: 66 % After freezing / thawing: 70 % Before storage: Pourability: 3.93 % Rinsed pourability: 0.20 % After freezing / thawing: Pourability: 3.89 % Rinsed pourability: 0.21 %	Y	**KCP 2.1/01** Gorban I., 2006, Report No. F06-07	Accepted.
Ambient temperature shelf life (KCP 2.7.5)	Based on CIPAC MT 190, GC method	Racer CS Batch: 11-12-6049 500 mL HDPE bottle	Results of the analysis of Flurochloridone (total, free and encaplsulated) in CS Formulation before, during and after storage indicated that Racer CS is chemically stable when stored for 2 years at ambient temperature. There was a slight increase in the free flurochloridone con-	Y	**KCP 2.7.5/01** O'Connor B J., ~~2013~~ 2014 Report No. 41104685	Studies accepted. After storage no unacceptable decrease of the content of active substances was

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			tent of the formulation at the 24 month timepoint. However this was concluded to remain insignificant, as the resulting decrease in the calculated encapsulated flurochloridone content remained below 5% of the initial value across the storage period. Please refer to table 2.2 for more details			determined and the product complied with the FAO specifications. The HDPA container showed no indications of physical deterioration that would interfere with the safe handling of the product.
	CIPAC MT 59.3, MT 47.2, MT 75, MT 160, MT 148 GC method, MT 161	Racer CS Batch: BSNI1502 Purity: 250g/L a.s. 5L HDPE container	Appearance and packaging stability: Before storage: light brown opaque liquid, odor similar to turpentine, Packaging: No sign of corrosion or degradation After storage: light brown opaque liquid, odor similar to turpentine, Packaging: No sign of corrosion or degradation. Weight loss: 0.376% Initial content: 22.3 % w/w Content after storage: 22.2 % w/w pH value (1% in water): Before storage: pH = 10.17 After storage: pH = 10.06 pH value neat formulation : Before storage: pH = 10.11 After storage: pH = 9.66 Persistent foaming before storage: Initial: 38 ml foam After 10 sec: 36 foam After 1 min: 13 ml foam After 3 min: a few bubbles remained the periphery Persistent foaming before storage: Initial: 20 ml foam After 10 sec: 10 foam After 1 min: no foam remained Spontaneity of dispersion (%): Before Storage: 90.0 % After storage: 98.4 % Before Storage: Pourability: 94.3 % Residue: 5.68 % Rinsed residue: 0.347%	Y	**KCP 2.5.1/02** Evans A. J. and Mullee D. M., 2001 Report No. 560/151	No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage, evaluation of this parameter after storage is not necessary. Period of validity: 2 years Extrapolation from HDPE to HDPE/EVOH, HDPE/F and HDPE/PA is acceptable.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			After Storage: Pourability: 94.1 % Residue: 5.91 % Rinsed residue: 0.384% Suspensibilty in water D: Concentration: 2.5% Before storage: 90.2 % After storage 77.1%			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not required as formulation is stable for at least 2 years at ambient conditions.	-	-	-
Wettability (KCP 2.8.1)	-	-	Not required for CS formulation	-	-	-
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	Racer CS Batch: BSNI1502 Purity: 250 g/L a.s.	Initial: 38 mL foam 10 sec.: 36 mL foam 1 min.: 13 mL foam 3 min.: few bubbles remained around the periphery Dilution of preparation with CIPAC Standard water C to a conc. of 2.5% v/v.	Y	**KCP 2.5.1/02** Evans A. J. and Mullee D. M., 2001 Report No. 560/151	Accepted.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	Racer CS Batch: BSNI1502 Purity: 250 g/L a.s.	Suspensibilty (%) in water D at 30 °C Before storage at 0.50%: 72 Before storage at 3.00%: 66 After storage at 0.50%: 69 After storage at 3.00%: 62	Y	**KCP 2.1/01** Gorban I., 2006, Report No. F06-07	Accepted.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	Racer CS Batch: GC2802 Purity: 250 g/L a.s.	Spontaneity of dispersion (%): Before Storage: 71 % After storage: 69 %	Y	**KCP 2.1/01** Gorban I., 2006, Report No. F06-07	Accepted.
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for CS formulation	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required for CS formulation	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	Racer CS Batch: GC2802 Purity: 250 g/L a.s.	Particle size distribution: (%): Before storage: d(0.1) = 1.54 d(0.5) = 8.82 d(0.9) = 17.27 After storage: d(0.1) = 1.40 d(0.5) = 9.07 d(0.9) = 18.56	Y	**KCP 2.1/01** Gorban I., 2006, Report No. F06-07	Accepted.
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Racer CS Batch: GC2802 Purity: 250 g/L a.s.	Wet sieve test: (%): Before storage:<0.1% After storage: <0.1%	Y	**KCP 2.1/01** Gorban I., 2006, Report No. F06-07	Accepted.
Dust content (KCP 2.8.5.2.1)	-	-	Not required for CS formulation	-	-	-
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required for CS formulation	-	-	-
Attrition (KCP 2.8.5.3)	-	-	Not required for CS formulation	-	-	-
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for CS formulation	-	-	-
Emulsifiability (KCP 2.8.6.1)	-	-	Not required for CS formulation	-	-	-
Emulsion stability (KCP 2.8.6.2)	-	-	Not required for CS formulation	-	-	-
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not required for CS formulation	-	-	-
Flowability (KCP 2.8.7.1)	-	-	Not required for CS formulation	-	-	-
Pourability (KCP 2.8.7.2)	-	-	Not required for CS formulation	-	-	-
Dustability following accelerated storage	-	-	Not required for CS formulation	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.7.3)						
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not required, formulation will not be used in tank mixtures	-	-	-
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not required, formulation will not be used in tank mixtures	-	-	-
Adhesion to seeds (KCP 2.10.1)	-	-	Not required for CS formulation	-	-	-
Distribution to seed (KCP 2.10.2)	-	-	Not required for CS formulation	-	-	-
Other/special studies (KCP 2.11)	-	-	None	-	-	-

Table 2-2: Test Results of the determination of long-term Storage Stability of Flurochloridone in CS Formulation after Storage at 25 ± 2 ºC

Test Method	Initial	After Storage at 25 ± 2 ºC for 6 months	After Storage at 25 ± 2 ºC for 9 months	After Storage at 25 ± 2 ºC for 12 months	After Storage at 25 ± 2 ºC for 24 months
Active Ingredient Content/Purity*					
Total Flurochloridone (%w/w)	22.4	22.2	22.4	22.3	21.7
Free Flurochloridone (%w/w)	0.764	0.650	0.773	0.581	1.09
Encapsulated Flurochloridone (%w/w)*	21.6	21.5	21.7	21.7	20.6
Appearance					
Test Item	An opaque, brown colored liquid. The color was assessed as 10YR 7/4 (hue, value and chroma respectively) using the Munsell® color system. The test item had a weak odor	An opaque, brown colored liquid, with an oily substance on the surface around the periphery of the vessel. The color was assessed as 10YR 7/4 (hue, value and chroma respectively) using the Munsell® color sys-	An opaque, brown colored liquid, with an oily substance on the surface around the periphery of the vessel. The color was assessed as 10YR 7/4 (hue, value and chroma respectively) using the Munsell® color system. The	An opaque, brown colored liquid, with an oily substance on the surface around the periphery of the vessel. The color was assessed as 10YR 6/4 (hue, value and chroma respectively) using the Munsell® color system. The test item had a	An opaque, brown colored liquid. The color was assessed as 10YR 7/4 (hue, value and chroma respectively) using the Munsell® color system. The test item had a strong odor, characteristic of creosote.

Test Method	Initial	After Storage at 25 ± 2 ºC for 6 months	After Storage at 25 ± 2 ºC for 9 months	After Storage at 25 ± 2 ºC for 12 months	After Storage at 25 ± 2 ºC for 24 months
		tem. The test item had a strong odor, characteristic of creosote.	test item had a strong odor, characteristic of creosote	strong odor, characteristic of creosote.	
Container	An approximately 500 mL capacity, translucent, white colored, PEHD plastic, square profiled bottle. Each bottle has a manufacturer's label present and an opaque white screw-on lid. No signs of corrosion or degradation.	An approximately 500 mL capacity, translucent, white colored, PEHD plastic, square profiled bottle. Each bottle has a manufacturer's label present and an opaque white screw-on lid. No signs of corrosion or degradation.	An approximately 500 mL capacity, translucent, white colored, PEHD plastic, square profiled bottle. Each bottle has a manufacturer's label present and an opaque white screw-on lid. No signs of corrosion or degradation	An approximately 500 mL capacity, translucent, white colored, PEHD plastic, square profiled bottle. Each bottle has a manufacturer's label present and an opaque white screw-on lid. No signs of corrosion or degradation.	An approximately 500 mL capacity, translucent, white colored, PEHD plastic, square profiled bottle. Each bottle has a manufacturer's label present and an opaque white screw-on lid. No signs of corrosion or degradation.
Weight change	-	0.36% (loss)	0.58% (loss)	0.75% (loss)	1.26% (loss)

* Calculated from the difference between total flurochloridone and free flurochloridone.

3 Section 3 is presented as a separate document

Please refer to the separate file "dRR Part B3".

4 Section 4: Further information on the plant protection product

For further information please refer to the MSDS of the product AG-F8-250 CS filed under KCP 4/01.

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

The packaging has been designed in accordance with the criteria and guidelines specified in the FAO "Guideline for the Packaging of Pesticides" and has been approved according to criteria of ADR, IATA, IMDG (IMO) regulations. The formulated product (CS formulation) is intended for containment in 1 L, 5 L, 10 L and 20 L bottles and containers from different suppliers, respectively.

~~The accelerated storage stability of Edelson T. (2014), ref. KCP 2.7.1/01, has been performed with the intended commercial packaging material (1 L HDPE). Tightness of the intended packaging and compatibility of the packaging material with the preparation have been demonstrated in this study.~~

Accelerate storage study (Gorban I., 2006) was performed with a 1L COEX commercial container and the ambient storage studies (Evans A. J. and Mullee D. M. – 5L HDPE, 2001, O'Connor B J., 2014 – 500 mL HDPE) were performed with HDPE container. The HDPE container showed no indications of physical deterioration that would interfere with the safe handling of the product.

Detailed information on the packaging material is summarised below and in ref. KCP 4.4/01-08.

HMWHDPE is a high end grade of HDPE with longer polymer chains. Stability studies results can be extrapolated for this type of material. Extrapolation from HDPE to HDPE/EVOH, HDPE/F and HDPE/PA is also acceptable.

Table 4.1-1: Packaging information for 1 L bottle

Type	**Description (see reference KCP 4.4/01 and 4.4/05)**
Material:	HDPE COEX
Shape/size:	round, 241 mm high, diameter 89.8 mm
Opening:	49.1 mm (includes screw thread)
Closure:	screwed on
Manner of construction	blow molding method
UN/ADR	Compliant

Table 4.1-2: Packaging information for 5 L container

Type	**Description (see reference KCP 4.4/02 and 4.4/06)**
Material:	HDPE/PA COEX
Shape/size:	rectangular, 305 mm (with handle) high, 190 × 140 mm
Opening:	63.4 mm (includes screw thread)
Closure:	screwed on
UN/ADR	Compliant

Table 4.1-3: Packaging information for 10 L container

Type	**Description (see reference KCP 4.4/03 and 4.4/07)**
Material:	HDPE/PA COEX
Shape/size:	rectangular, 384 mm (with handle) high, 226 × 157 mm
Opening:	63.4 mm (includes screw thread)
Closure:	screwed on
UN/ADR	Compliant

Table 4.1-4: Packaging information for 20 L container

Type	**Description (see reference KCP 4.4/04 and 4.4/08)**
Material:	HMWHDPE
Shape/size:	rectangular, 398.5 mm (with handle) high, 297 × 246 mm
Opening:	59.5 mm (includes screw thread)
Closure:	screwed on
Manner of construction	blow molding method
UN/ADR	Compliant

4.2 Recommended methods and precautions (KCP 4.2)

Study Comments: 4.2/01	Recommended cleaning procedure: "Rinse the tank three times with tap water".
Agreed endpoint: 4.2/01	

4.2.1 Procedures for cleaning application equipment and protective clothing (KCP 4.2.1)

Wash all application equipment with water (for cleaning efficiency see chapter 4.2.2 below). Suitable cleaners (commercial detergents) can be used in addition.

Wash protective clothing with washing agents in commercial quality.

4.2.2 Effectiveness of the cleaning procedures (KCP 4.2.2)

At the time of compilation of this dossier, no specific study had been conducted for the product AG-F8-250 CS to investigate the effectiveness of the cleaning procedure described above. Instead, such investigations were replaced by an assessment on a theoretical basis involving a calculation of the predicted residues remaining in the spray tank after cleaning, and subsequently addressing the risk to other crops from these residues applied to the field during another spraying operation.

The efficacy of cleaning the application equipment with regard to impacts on non-target crops was estimated according to the recommendations of the PSD Efficacy Guideline 302 (December, 2001). For the assessment of residues remaining in the spraying equipment after cleaning, a standard sprayer of 2000 litres was considered. Cleaning is performed by a small volume rinse of 200 L of water in the first cleaning step, followed by another two rinses, each with volumes of 400 L corresponding to 20% of the tank volume. A maximum volume of 20 L spray solution was considered to remain in the spray lines and pump after each rinse. Furthermore, the maximum concentration of the product in the initial spray solution was used as a conservative starting point. In summary, the following prerequisites were considered for a worst-case assessment:

Maximum rate per application:	**2 L /ha,** corresponding to 500 g flurochloridone/ha
Spray volumes:	200 – 300 L/ha
Spray volume used for the assessment of effectiveness:	**200 L/ha** (lowest spray volume corresponding to the maximum concentration of the product in diluted spray)
Tank volume:	2000 L
Volume remaining in spray lines and pump after spraying:	**20 L**

Based on these prerequisites and in consideration of 3 rinses each with 200-300 L of water based on good agricultural cleaning procedures described above, residues remaining in the tank after spraying will be diluted to the following levels:

Cleaning step	Water volume [L]	Concentration of residues	
		Product [mL PPP/ L of water]	Active substance [g a.s./L]
			flurochloridone
Tank filling: Residues after spraying:	2000 20	10	2.5
1st step: 1/10 dilution of residual spray volume: Residues after spraying:	200 20	1	0.25
2nd step: 20% of tank volume added: Residues after spraying:	400 20	0.05	0.0125
3rd step: 20% of tank volume added: Residues after spraying:	400 20	0.0025	0.000625
Addition of fresh spray solution: Residues in the tank filling:	2000	0.000025	0.00000625

Based on the calculation above, residues remaining in the spraying equipment after the last of three cleaning steps were estimated at 20 L at a concentration of about 2.5 µL product per L of water, corresponding to a total of about 50 µL of product in the tank. Considering these residues to be completely dissolved in the next tank filling, residues of 0.025 µL of product per litre of water can be expected after refilling the tank with 2000 L of water for another spraying operation. Assuming a range of spray volumes of 200-300 L/ha to be applied to other crops, **residues of 5 – 15 µL/ha will be applied to a non-target crop by re-use of the application equipment**.

Data on the biological activity of the product are available from the two standard test models "seedling emergence" (KCP 10.6.2/01) and "vegetative vigour" (KCP 10.6.2/02), which are considered to be most relevant for the assessment of effects on non-target plants (including non-target crops) after broadcast spraying of the product and tank residues, respectively. The tests were performed according to OECD 208 (2006) and OECD 227 (2006), respectively, and the test substance product was sprayed to the test plants or to the soil after sowing of plants. Each test was performed in 10 representative plant species.

The acceptability of the predicted residue level of the product was assessed by a comparison of the exposure concentration predicted for the re-use of the application equipment with the effect rates (NOER, ER_{50}) in the most sensitive plant species of the “vegetative vigour” and “seedling emergence” test. Effects on shoot height and plant weight were considered as reliable endpoints for toxic effects and the most sensitive of these toxicity figures was used for the following risk assessment:

Maximum predicted exposure of non-target crops with spray residues:

PER = 0.015 mL PRODUCT/ha; i.e. **0.000015 L prod./ha**

Risk from spray residues for seedling emergence of non-target plants:

Toxicity endpoints obtained from reference:
KCP 10.6.2/01: Fiebig (2003a): Terrestrial (non-target) plant test with flurochloridone 250 CS: seedling emergence

Lowest ER_{50} > 340 g a.s./ha, corresponding to > **1.36 L prod./ha**

TER (ER_{50}/PER) **90666**

Risk from spray residues for vegetative vigour of non-target plants:

Toxicity endpoints obtained from reference:

KCP 10.6.2/01: Fiebig., (2003b): Terrestrial (non-target) plant test with flurochloridone 250 CS: Vegetative vigour test of non-target terrestrial plants

Lowest ER_{50} > 59 g a.s./ha, corresponding to > **0.236 L prod./ha**

TER (ER_{50}/PER) **15733**

According to the PSD efficacy guideline 302, a cleaning method can be considered to be acceptable, if the predicted exposure rate of the plant protection product (when the application equipment is re-used after cleaning) is at least an order of magnitude less than the no observable effect level or ED_{10} value for the most sensitive crop species.

Conclusion: The effectiveness of standard cleaning procedures according to Good Agriculture Practice was assessed for the product on a theoretical basis. Residues of the plant protection product remaining in the tank after 3 rinses with water and the predicted exposure of non-target crops after re-use of the application equipment were calculated for worst case conditions. Compared to the effect levels for non-target plants, which are most likely to be affected by herbicide residues, residue levels are far below concentrations that might pose a risk for the terrestrial flora including non-target crops. Thus, any detrimental effect on plants from tank residues can widely be excluded. The cleaning method is therefore considered to be acceptable, and the performance of any small-scale or a large-scale tests is not considered to be required.

Appendix 1 Lists of data considered in support of the evaluation

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**	**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	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	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	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	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	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	ADM
KCP 2.4.2/01	Gorban, I.	2006	See KCP 2.1/01	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**	**Owner***
= KCP 2.1/01					
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	ADM
KCP 2.5.1/01 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	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	ADM
KCP 2.5.2 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	ADM
KCP 2.6.1 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	ADM
KCP 2.7.1 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	ADM
KCP 2.7.4 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	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	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	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	ADM
KCP 2.8.3.1 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	ADM
KCP 2.8.3.2	Gorban, I.	2006	See KCP 2.1/01	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	Owner*
= KCP 2.1/01					
KCP 2.8.5.1.1 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	ADM
KCP 2.8.5.1.2 = KCP 2.1/01	Gorban, I.	2006	See KCP 2.1/01	N	ADM
KCP 4/01	Anonymous	2016	Safety Data Sheet – AG-F8-250 CS ADAMA Agan Ltd., Ashdod, Israel Non-GLP, not published	N	ADM
KCP 4.4/01	Anonymous	2008	1 L COEX packaging information Non-GLP, not published	N	-
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	-
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	-
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	-
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	-
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	-
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	-
KCP 4.4/08	Savaransky, M., Gazit, A.	2005	Test Certification No. 8513234067 The standard Institution of Israel.	N	-

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**	**Owner***
			Report no.: not reported Non-GLP, not published		
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	-

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

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

None.

List of data submitted by the applicant and not 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**	**Owner**
-	-	-	-	-	-

List of data relied on and not submitted by the applicant but necessary for evaluation

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**	**Owner**
-	-	-	-	-	-