REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: AG-F8-250 CS

Chemical active substance:

Flurochloridone, 250 g/L

Central Zone

Zonal Rapporteur 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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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

zRMS comments:
The application is submitted for first approval of AG-F8-250 CS, a capsule suspension containing 250 g/L flurochloridone for use in potato, in Central Zone according to article 33 of the Regulation 1107/2009.
This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

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.

Storage stability
According to the EFSA Journal 2018;16(1):5144:
Storage stability of fortified residues of flurochloridone was investigated in high water (alfalfa, apples, peppers and potatoes), high oil (almonds, soybeans), high acid (oranges) and dry (corn, wheat grain and straw) commodities for an overall period of 3 years (Spain, 2006).The data obtained indicated that flurochloridone was stable in high water, high oil and drycommodities (alfalfa, almonds, apples, corn, peppers, potatoes, soybeans, wheat grain) when keptstored in the dark at -20°C for a minimum of 3 years, while in high acid commodities (oranges) for 12 and in wheat straw for 8 months.
The studies on the magnitude of residues are valid with regard to storage stability.
Enantioconversion of isomers cis/trans (in ratio of 1:3) during storage has not been studied. EFSA suggested to conduct a stability study of the isomers in freezer storage.
No additional data are required at the moment.

Metabolism in plant
The metabolism data was evaluated during the Annex I inclusion of the active substance flurochloridone (Monograph, February 2006 and its Addendum, August 2010) and are sufficient to describe the behaviour of the formulated product.

In EFSA Journal 2018;16(1):5144 it is stated that *Metabolism in plants was investigated in sunflower (oilseeds/pulses group) and potato (root crop group) using a single spray application of ^{14}C-labelled flurochloridone on the pyrrolidone moiety only applied onto the soil surface, just after sowing/planting.*
Identification of metabolites was not possible in sunflower seeds and potato tuber because of the low total radioactive residues (TRRs). The characterisation of residues was only possible in mature sunflower leaves, where flurochloridone accounted for 10–17% TRR (0.15–0.44 mg/kg) and three additional metabolites were identified each representing less than 3% TRR (0.01–0.06 mg/kg).
It is noted that the study was performed with a label on the pyrrolidone moiety only. However, since no cleavage was observed in environmental fate soil studies which used a second label and were assessed during the peer review, additional studies with labelling of the phenyl moiety are not needed (EFSA, 2010).
Based on the results of the metabolism in primary and rotational crops, the residue definition is defined as flurochloridone (sum of cis and trans isomers) by default for both enforcement and risk assessment.
This residue definition is limited to root and tuber crops, pulses and oilseeds following soil treatment.
EFSA emphasises that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of flurochloridone and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

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.

Metabolism in livestock
No animal metabolism studies were submitted during the Annex I inclusion of the active substance flurochloridone.
Information given by the Applicant in point 7.2.25 is sufficient.

Additionally the metabolism study in lactating goats was provided during the Review of the existing MRLs for flurochloridone (Spain, 2017, EFSA Journal 2018;16(1):5144). The metabolism in rat and ruminants is expected to be similar, and the results from the ruminants study may be extrapolated to swine. Based on the available information, it can be concluded that, at the calculated dietary burden, no significant residues are expected in ruminants and swine tissues and in milk. Therefore, the residue definition in these commodities can be defined as flurochloridone (cis and trans isomers) by default for both enforcement and risk assessment.
No further data are required to support the proposed uses.

Definition:
The residue for enforcement and risk assessment in plant commodities
Flurochloridone (sum of cis and trans isomers) by default

Enforcement and risk assessment residue definition for animal commodities:
Flurochloridone (sum of cis and trans isomers) by default

Magnitude of residues in plants
Potatoes

Table 7.1-1: Summary of the critical GAP for the proposed use for AG-F8-250 EC

Crop	Outdoor/ Protected	Growth stage	Maximum Number of Applications	Minimum Application Interval (days)	Maximum		Minimum PHI (days)
					Rate (kg a.s./ha)	Water (L/ha)	
Potato	Outdoor	BBCH 00 - 09	1	n.a.	0.5	300	n.a.

Table 7.1-2: Summary of critical GAPs used for setting the EU MRL

Crop	Outdoor/ Protected	Growth stage	Maximum Number of Applications	Minimum Application Interval (days)	Maximum		Minimum PHI (days)
					Rate (kg a.s./ha)	Water (L/ha)	
Potato	Outdoor	BBCH 00 - 05	1	n.a.	0.75	400	n.r.

n.a.= not applicable
n.r.= not relevant

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.
No additional data are required.

(*) Indicates lower limit of analytical determination

Industrial Processing and/or Household Preparation
No processing studies were submitted during the Annex I inclusion of the active substance flurochloridone.
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.
No additional data are required.

Magnitude of residues in livestock
Flurochloridone is authorised for use on several crops that might be fed to livestock. Livestock dietary burden calculations were performed by EFSA in the framework of Art. 12 evaluation (2018).
Data and explanation presented by Applicant in point 7.2.4 have been accepted and are sufficient to support the

proposed uses. The dossier support only potato where the residue level is below 0.01 mg/kg and according to the median dietary burden calculation where all crops have residues below 0.01 mg/kg, no exceedance above the trigger values of 0.04 mg/kg bw/d was calculated in all animals, so a ruminant and poultry feeding study is not required for the intended use on potato for the product registration AG-F8-250 CS.

Succeeding crops
Crop under evaluation is expected to be grown in rotation.
In EFSA Journal 2018;16(1):5144it is stated that *According to the soil degradation studies evaluated in the framework of the peer review, periods required for DT_{90} values in soil exceeded the trigger value of 100 days and further investigation of residues in rotational crops was required. A confined rotational crop study considered acceptable during the peer review was conducted with ^{14}C-carbonyl-labelled flurochloridone, sprayed uniformly to bare soil (clay loam) at 750 g a.s./ha (corresponding to 1N rate). Following aging of the soil for 33, 131 and 355 days, metabolism was studied in three representative rotational crops (spinach leaf, carrot and wheat).*
In mature crops taken at all PBIs, TRR were very low (max 0.009 mg eq/kg observed in spinach leaves at PBI of 33 days), except in wheat straw and chaff (up to 0.049 mg eq/kg). Due to the low TRR, further metabolite identification was not performed. Residues in rotational crops (cereal grain, leafy vegetables and root crops) are expected to remain below the LOQ of 0.01 mg/kg, provided that flurochloridone is applied according to the GAPs considered in this review. Further information is still considered desirable for wheat straw and chaff in the present review, to verify whether flurochloridone is to be expected in straw from cereals grown in rotation.

Significant residues of flurochloridone in rotational crops are not expected.
Information presented by Applicant 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.

No additional data are required to support the uses of AG-F8-250 CS.

Consumer risk assessment
The TDMI and IESTI calculations presented by Applicant in Appendix 3 are based on the old values of MRLs (Regulation (EC) No 149/2008) and on old version EFSA PRIMo model (EFSA PRIMo rev.3). Therefore new calculations results are presented in point 7.2.8 and in Appendix 3.
The new 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.

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

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation of AG-F8-250 CS are presented in Table 7.1-1. They have been selected from the individual GAPs in the northern zone, Poland, for potato. A list of all intended uses within the Northern zone is given in Part B, Section 0.

Justification for the selection of the critical GAP

The critical GAP use concerns are
- the highest single and yearly application rates (highest single application rate of 2 L prod./ha),
- the maximum number of applications, (1) and

- the application in the pre-emergence crop.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of potato for flurochloridone as laid down in Regulation (EU) 396/2005 is not expected.

The acute and chronic intakes of the active substance are unlikely to present a public health concern.

According to the available data, no specific mitigation measures need to be applied.

Data gaps

Noticed data gaps are:

- none

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
1	Potato (SOLTU)	NEU (PL)	AG-F8-250 CS	F	broadleaved and grass weeds, pre-emergence	CS	250	spray application	BBCH 00-09	1	n.a.	0.167 - 0.250	200 / 300	0.500	n.a.	A

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

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** 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

Explanation for Column 11 “Conclusion”

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation AG-F8-250 CS is composed of active substance flurochloridone.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of flurochloridone

Reference value	Source	Year	Value	Study relied upon	Safety factor
Flurochloridone					
ADI	EFSA 10	2010	0.04 mg/kg bw/day	rat, 2-year study	100
ARfD	EFSA 10	2010	0.04 mg/kg bw	rat, developmental study	500

7.1.2.1 Summary for flurochloridone

Table 7.1-3: Summary for flurochloridone

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Potato	Yes	Yes (8 trials)	Not applicable. The PHI is covered by the time remaining between application and harvest	Yes	Yes	No	No

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

As residues of flurochloridone on potato do not exceed the trigger values defined in Commission Regulation (EU) No 284/2013 respectively No 283/2013, there is no need to investigate the nature of residues and the magnitude in processed commodities.

Residues in succeeding crops have been investigated covering the cGAP uses being considered here. Flurochloridone residue levels in succeeding crops are not expected to exceed 0.01 mg/kg if AG-F8-250 CS is applied in compliance with the GAPs.

Considering dietary burden and based on the intended uses, no significant modification of the intake for livestock is expected. Further investigation of residues in commodities of animal origin is therefore not necessary for authorisation of AG-F8-250 CS.

7.1.2.2 Summary for AG-F8-250 CS

Table 7.1-4: Information on AG-F8-250 CS (KCA 6.8)

Crop	PHI for AG-F8-250 CS proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for AG-F8-250 CS proposed by zRMS	zRMS Comments (if different PHI proposed)
		Flurochloridone		
Potato	Not applicable. The PHI is covered by the time remaining between application and harvest.	Yes	Not applicable. The PHI is covered by the time remaining between application and harvest.	-

NR: not relevant

* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		**Overall waiting period proposed by zRMS for AG-F8-250 CS***
Crop group	**Led by flurochloridone***	
Leafy vegetables	NR	NR
Root vegetables	NR	NR
Cereals	NR	NR

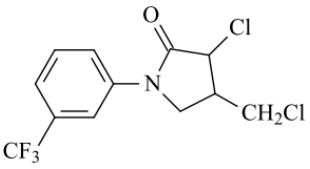
NR: not relevant according to rotationl crop study
* to avoid phytotoxicity a waiting period of at least 1 month should be respected for planting leafy and root succeeding crops. In the case of cereals, a minimum of 3 months have passed since application and the soil is worked before sowing.

Assessment

7.2 Flurochloridone

General data on flurochloridone are summarized in the table below (last updated 2018/06/30)

Table 7.2-1: General information on flurochloridone

Active substance (ISO Common Name)	Flurochloridone
IUPAC	(3RS,4RS;3RS,4SR)-3-chloro-4-chloromethyl-1-(*α,α,α*-trifluoro-m-tolyl)-2-pyrrolidone (isomers in the ratio 3:1)
Chemical structure	
Molecular formula	$C_{12}H_{10}Cl_2F_3NO$
Molar mass	312.12
Chemical group	-
Mode of action (if available)	Flurochloridone is a herbicide that inhibits carotenoid synthesis
Systemic	Yes
Company (ies)	ADAMA Agan Ltd.*
Rapporteur Member State (RMS)	Spain
Approval status	Approved on 01/06/2011 (Commission Directive 2011/34/EU of 08 March 2011 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011)
Restriction (e.g. is restricted to use as "...")	Herbicide only
Review Report	SANCO/10098/2011 Final, 09/03/2011
Current MRL regulation	~~Regulation (EC) No 149/2008~~ Reg. (EU) 2019/973
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes (EFSA, 2010) **; EFSA Journal 2013;11(3):3116
EFSA Journal: conclusion on article 12	Yes (EFSA, 2018) **
Current MRL applications on intended uses	No

* Notifier in the EU process to whom the a.s. belong(s)
** see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data are submitted in the framework of this application.

In the EU evaluation of the active substance flurochloridone the stability of residues during storage of samples has been studied on several crops. ADAMA Agan Ltd. was the sole notifier for Annex I

inclusion. The studies are summarised in table below.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Potato	High starch content	3 years	DAR, 2006[1] EFSA, 2010[2]
Soybeans	High oil content	3 years	
Alfalfa	High water content	3 years	
Almonds	High oil content	3 years	
Apples	High water content	3 years	
Corn	High starch content	3 years	
Peppers	High water content	3 years	
Wheat grain	High starch content	3 years	
Wheat straw	Dry commodity	8 months	
Oranges	High acid content	1 year	

1) Ott, K.W. (1989)
2) Evaluated within EFSA RO 2018 (EFSA 2018)

Conclusion on stability of residues during storage

The storage stability of flurochloridone was investigated during the Annex I inclusion. The data obtained indicated that flurochloridone was stable in high water, high oil, and high starch (potatoes, soybeans, alfalfa, almonds, apples, corn, peppers, wheat grain) when kept stored in the dark at 20°C for a minimum of 3 years, while in high acid commodities (oranges) for 12 and in wheat straw (dry commodity) for 8 months.

The studies summarised above cover the maximum storage period of the field samples according to the residue definition and intended uses. No further data is required to cover the use on potato.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

The stability of residues of flurochloridone in sample extracts was investigated during the development and validation of the analytical methods. In the study of Wolf (2003b), no relevant influence of a 13 day storage period on the recovery was found. Sample extracts were stored at about 4°C.

Conclusion on stability of residues in sample extracts

The stability of residues in sample extracts for the active substance flurochloridone was reviewed during the Annex I inclusion process and no further data is required. The stability of flurochloridone residues in sample extracts obtained from potato tubers was demonstrated for up to 13 days at 4°C. No further data is required for the use on potato.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data are submitted in the framework of this application.

In the EU evaluation of the active substance flurochloridone the plant metabolism has been studied on sunflower and potato. ADAMA Agan Ltd. was the sole notifier for Annex I inclusion. The studies are summarised in table below.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Root and tuber vegetables	Potato	[2-^{14}C] pyrrolidone	Foliar to the soil	0.615	1	68 130	aerial plant parts Root, tuber, aerial plant	DAR, 2006[1] EFSA, 2010[2]
Pulses and oilseeds	Sunflower		Foliar to the soil	0.3 and 0.6	1	30 119	Plant Mature	DAR, 2006[3] EFSA, 2010[2]

1) Van Dijk, A. (1988)
2) Evaluated within EFSA RO 2018 (EFSA 2018)
3) Miaullis, B.J., Parker, D.M., Vispetto, A.R. and Vu , H. (1986)

Summary of plant metabolism studies reported in the EU

The metabolism in plants was investigated in sunflower and potato which covers the category of pulses/oilseeds and root crops respectively. The studies were conducted with the ^{14}C labelling on the pyrrolidone moiety of flurochloridone using a single spray application only applied onto the soil surface, just after sowing/planting. Identification of metabolites was not possible in sunflower seeds and potato tuber because of the low total radioactive residues (TRRs). The characterisation of residues was only possible in mature sunflower leaves, where flurochloridone accounted for 10–17% TRR (0.15–0.44 mg/kg) and three additional metabolites were identified each representing less than 3% TRR (0.01–0.06 mg/kg).
It is noted that the study was performed with a label on the pyrrolidone moiety only. However, since no cleavage was observed in environmental fate soil studies which used a second label and were assessed during the peer review, additional studies with labelling of the phenyl moiety are not needed (EFSA, 2010).

Based on these studies it was proposed to define by default, the residue for monitoring and risk assessment as flurochloridone only (sum of cis and trans isomer pairs) (EFSA, 2010). No information was provided on the respective behaviour of each constituent isomer, but having regard to the supported uses and since no residues are expected in tubers, such information was considered not necessary.

Conclusion on metabolism in primary crops

The intended use on potato (1 × 0.500 kg/ha flurochloridone at BBCH 00-09, foliar application) is covered with the studies summarised above and are sufficiently addressed. Therefore the established residue definitions for enforcement and risk assessment are applicable, as flurochloridone only (sum of cis and trans isomer pairs). No further studies are required to support the intended use on potato for the product AG-F8-250 CS.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data are submitted in the framework of this application.

In the EU evaluation of the active substance flurochloridone the rotational crop metabolism has been studied. One study in residues of succeeding crops was considered as not valid because the application rate was low (0.3 kg a.s./ha), therefore this study is not reported in the summary below. ADAMA Agan Ltd. was the sole notifier for Annex I inclusion. The valid study is summarised in table below.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Spinach	[^{14}C] Flurochloridone carbonyl-label	Bare soil	0.750	33, 131, 355		Emergence Pre-harvest Mature	Addendum to DAR, 2010[1] EFSA, 2010[2]
Root and tuber vegetables	Carrots		Bare soil	0.750	33, 131, 355			
Cereals	Wheat		Bare soil	0.750	33, 131, 355			
New data								
Leafy vegetables	Spinach	[^{14}C] Flurochloridone carbonyl-label	Bare soil	0.750	33, 131, 355		Emergence Pre-harvest Mature	Mamouni A., 2017 Report No. 90020993
Root and tuber vegetables	Carrots		Bare soil	0.750	33, 131, 355			
Cereals	Wheat		Bare soil	0.750	33, 131, 355			

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)
1) Mamouni, A. (2009)
2) Evaluated within EFSA RO 2018 (EFSA 2018)

Summary of plant metabolism studies reported in the EU

The metabolism and distribution of flurochloridone in rotational crops was studied in wheat (cereal), spinach (leafy vegetable) and carrot (root vegetable) in soil treated with carbonyl-label flurochloridone at a rate of 0.75 kg a.s./ha following a plant-back interval of 33 days, 131 days and 355 days. At maturity, the total radioactivity residue was less than 0.01 mg/kg in carrot roots, spinach leaves and cereal grains for all plant back intervals with the exception of residues in straw (ranged from 0.016 to 0.049 mg/kg).

According to the available EU guideline, for the period the experimental part was performed, there was no need for any further analyses due to the very low uptake of radioactive residues. Furthermore, the additional work performed for the analysis of the pre-emergence samples showed that the major part of these residue was non extractable. The extractable part, showed total residues lower than 0.010 mg/kg, where normally no further analyses are triggered. Additionally, the pre-emergence samples represent a very worst case for the residue concentration and are normally not agricultural commodities.

Summary of new plant metabolism studies

This new data is submitted to support the study assessed on the EU evaluation (Mamouni A., 2009). An evaluation of the raw data of the study confined accumulation in rotational crops was done by the same author who made the report (Mamouni A.). The reason of this further evaluation was due to some uncertainties reported by RMS which requires clarification by the Study Director at the time on the

rotational crop study on flurochloridone (Mamouni A., 2009). A comprehensively re-evaluated and a technical response were provided in the document and the outcome on the rotational crops are presented below.

In the spinach only about 40% of the extract could be released from the emergence and pre-harvest samples of interval day 30 and corresponded to less than 0.007 mg/kg. No significant residues could be extracted from the mature samples of interval day 120, showing that most of the radioactivity is physically incorporated into the cell walls. For interval day 365, no significant residues were detected in the harvested commodities (≤ 0.002 mg/kg).

In the carrot, no significant residues were detected in the roots and leaves. Only the samples at emergence showed total residues above 0.01 mg /kg (max. 0.013 mg /kg) for interval day 30, where the maximum uptake is to be expected. The extracted residues were very low and did not exceed 0.006 mg/ kg.
In the mature crop of interval 120 days, the total residues obtained represented 0.022mg/kg, however, no significant residues could be released (extracted), showing that the major part of activity is incorporated in the plant tissues (around 100% as non-extractable residues). No significant residues (≤ 0.003 mg/kg) were detected in the samples harvested from interval day 365.

In the wheat crop, total residues were detected mainly in forage and mature straw representing up to 0.033 mg/kg in the mature straw from interval day 30. However, most of the activity could not be released from the plant material. From the forage and straw of interval day 30 only 17 to 25% of the TRR could be extracted representing less than 0.006 mg/kg. From interval day 120 almost no significant radioactivity could be released from the forage and straw samples. No significant residues (≤ 0.010 mg/kg) were detected in the grain and chaff samples and no significant residues could be extracted.

The observed residues taken up by the plants are well incorporated in the plant cells and could not be released by the all extractions using various solvents with different polarities. The small amounts of released activity showed to be mainly conjugated residues in the dissolved plant tissues.

Since this is an evaluation of a report, a full summary in appendix 2 is not presented in this dossier.

Conclusion on metabolism in rotational crops

The intended application rate on potato (1 × 0.500 kg/ha flurochloridone) is lower than the rate used during the performance of the rotational crop study (0.750 kg/ha). Therefore the established residue definitions for enforcement and risk assessment are applicable.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

No new data are submitted in the framework of this application. According to criteria set out in current regulation (Commission Regulation (EU) No 284/2013 respectively No 283/2013) an investigation of residues in processed potato was not triggered for the applicant since residues on treated crops are below the trigger value of 0.01 mg/kg. Therefore a study is not required on potato.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Root and tuber vegetables (Potatoes) Pulses/oilseeds (Sunflower)
Rotational crops covered	Spinach, carrot and wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not required
Residue pattern in processed commodities similar to pattern in raw commodities?	Not triggered
Plant residue definition for monitoring	Limited to root and tuber crops, pulses and oilseeds following soil treatment: Flurochloridone (sum cis and trans isomers) by default (EFSA 2010, EFSA 2018)
Plant residue definition for risk assessment	Limited to root and tuber crops, pulses and oilseeds following soil treatment: Flurochloridone (sum cis and trans isomers) by default (EFSA 2010, EFSA 2018)
Conversion factor from enforcement to RA	None

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7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application and not required.

In accordance to the OECD guidance document on residues in livestock (OECD ENV/JM/MONO(2013)8), potato (cull, process waste and dried pulp) is regarded as a feedstuff. The residue level of flurochloridone on potato is < 0.01 mg/kg (non-residue situation).

According to the dietary burden calculation, the maximum daily exposure resulting from residues of flurochloridone on potato is below the trigger value of 0.004 mg/kg bw/day, see point 7.2.4. Therefore no study is required for the product registration AG-F8-250 CS.

However, an animal metabolism study was submitted and evaluated on the Review of the existing MRLs for flurochloridone (EFSA, 2018) and it is not summarised in this dossier since it is not trigger for the intended use.

According to the EFSA (2018), the metabolism in rat is similar to the metabolism in ruminant.

No metabolism study on fish is available and this is not required for this PPP authorisation (refer to SANTE/11509/2013-rev. 5.2, Point 4, case 4).

In SANCO/11187/2013 for MRL, rev.3 working document on the nature of pesticide residues in fish, where stays the follow: “They are required when pesticide use may lead to significant residues (> 0.1 mg/kg of the total diet (dry weight basis) in fish feed) and shall be applied to all active substances that are fat soluble, i.e. substances with log Pow ≥ 3”. In accordance to this document, potato is used as a fish feeding stuff but residues of flurochloridone on potato are below the LOQ of 0.01 mg/kg leading to non-significant residues in the total diet (< 0.1 mg/kg). Therefore the study should not be required.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-6: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
Time needed to reach a plateau concentration	3 -4 days
Animal residue definition for monitoring	Flurochloridone (sum cis + trans isomers) by default (EFSA, 2018)
Animal residue definition for risk assessment	Flurochloridone (sum cis + trans isomers) by default (EFSA, 2018)
Conversion factor	Not applicable (EFSA, 2018)
Metabolism in rat and ruminant similar	Yes (EFSA, 2018)
Fat soluble residue	No (EFSA, 2018)

EFSA Journal 2018;16(1):5144

7.2.3 Magnitude of residues in plants (KCA 6.3)

No new data are submitted in the framework of this application.

In the EU evaluation of the active substance flurochloridone the potato field trials were submitted and evaluated. ADAMA Agan Ltd. was the sole notifier for Annex I inclusion. The studies are summarised in table below for the intended use on northern zone, Poland.

Table 7.2-7: Summary of EU reported and new data supporting the intended uses of AG-F8-250 CS and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Potato	DAR, 2006[1] EFSA, 2010	N-EU	GAP on which EU a.s. assessment is based: 1 x 0.75 kg as/ha, pre-emergence, outdoor E = RA: 8 x < 0.01	0.01	0.01	0.01	~~0.1~~ 0.01	Yes

* Source of EU MRL: ~~Regulation (EC) No 149/2008~~ Reg. (EU) 2019/973

1) Balluff, M., (2004)

7.2.3.1 Conclusion on the magnitude of residues in plants

Supervised residue trials on potato have been conducted in Northern Europe with flurochloridone CS formulation during the Annex I inclusion at an application rate ranged 0.680 – 0.77 kg a.s./ha applied once pre-emergence. A total of eight trials in northern zone are available which are considered as valid. The trials were analysed for flurochloridone residues. In all trials, 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.

According to the available data, the intended uses of AG-F8-250 CS on potato are considered acceptable. It is not expected to have residues of flurochloridone above the EU MRL of ~~0.1~~ 0.01* mg/kg when AG-F8-250 CS is applied according to the GAP. No additional field trials are required to support the intended use.

(*) Indicates lower limit of analytical determination

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

In the framework of Art. 12 evaluation, dietary burden calculations were performed by EFSA (2018). The critical GAP use on potato evaluated by EFSA (1×0.750 kg/ha flurochloridone) was performed with an exaggerated application rate in more than 25% the GAP of AG-F8-250 CS (1×0.500 kg/ha flurochloridone). The residue level of field trials is < LOQ of 0.01 mg/kg, in this product registration and in the EFSA (2018). In the EFSA (2018), the dietary burden calculations were done with the following commodities: potato culls, potato process waste, potato dried pulp, carrot culls, sunflower meal, cotton undelinted seed and cotton meal, see Table 7.2-8. The livestock dietary burden calculations were performed according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The results of the EFSA (2018) calculations are reported in Table 7.2-9.

Table 7.2-8: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Flurochloridone				
Potato culls	0.01*	STMR	0.01*	HR
Potato process waste	0.01*	STMR[a]	0.01*	STMR[a]
Potato dried pulp	0.01*	STMR[a]	0.01*	STMR[a]
Carrot culls	0.01*	STMR	0.05	HR
Sunflower meal	0.01*	STMR[a]	0.01*	STMR[a]
Cotton undelinted seed	0.01*	STMR	0.01*	STMR
Cotton meal	0.01*	STMR[a]	0.01*	STMR[a]

STMR: supervised trials median residue; HR: highest residue.
*: Indicates that the input value is proposed at the limit of quantification.
(a): For potatoes and sunflower, cotton meals no default processing factor was applied because flurochloridone is applied early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

Table 7.2-9: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: Flurochloridone					
Beef cattle*	0.0016	0.0036	Carrot culls	0.10	No
Dairy cattle*	0.0016	0.0036	Carrot culls	0.09	No
Ram/ewe	0.0018	0.0045	Carrot culls	0.12	Yes
Lamb	0.0018	0.0041	Carrot culls	0.12	Yes
Swine all diets (Finishing swine*)	0.0010	0.0034	Carrot culls	0.13	No
Poultry all diets	0.0009	0.0033	Carrot culls	0.05	No
Layer poultry only*	0.0009	0.0032	Carrot culls	0.05	No

* These categories correspond to those (formerly) assessed at EU level.

As a result of the EFSA (2018) calculations, the maximum dietary burden on animals was found to exceed the trigger value of 0.04 mg/kg bw/d only on lamb and ram/ewe. The major contributor on all the diets was carrot cull which is not part of the intended uses of AG-F8-250 CS. Since this dossier support only potato where the residue level is below 0.01 mg/kg and according to the median dietary burden calculation where all crops have residues below 0.01 mg/kg, no exceedance above the trigger values of 0.04 mg/kg bw/d was calculated in all animals. Therefore a ruminant and poultry feeding study is not required for the intended use on potato for the product registration AG-F8-250 CS.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

A ruminant and poultry feeding study is not required for the intended use on potato for the product registration AG-F8-250 CS since the dietary burden calculation on animals does not exceed the trigger value of 0.04 mg/kg bw/d.

Available data

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

Conclusion on feeding studies

The requested use on potato is not expected to modify the theoretical maximum daily intake for animals because the expected residues from the critical GAP of AG-F8-250 CS (1×0.500 kg/ha flurochloridone) are within those evaluated on the Review of the existing MRLs for flurochloridone (EFSA, 2018). Therefore, there is no risk for animal MRL to be exceeded. No further studies are required.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

No data available / not required.

The studies are not required since residue of flurochloridone on potato is below the LOQ (0.01 mg/kg) and the contribution of the commodity under consideration to the theoretical maximum daily intake (TMDI) is below 10% of the ADI and the estimated daily intake is below 10% of ARfD for any European consumer group diet.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

It is considered unlikely that significant residues above 0.01 mg/kg of flurochloridone or other compound would be present in rotational crops at any plant back interval for the GAP under consideration (1×0.500 kg/ha flurochloridone). In the study summarised on the nature of residue in rotational crops (see 7.2.2.2), the application rate was 0.750 kg/ha flurochloridone where at maturity total radioactivity residue was less than 0.01 mg/kg in carrot roots, spinach leaves and cereal grains for all plant back intervals with the exception of residues in straw (0.036 mg/kg (33d); 0.016 mg/kg (131d) and 0.049 mg/kg (355d)). However, according to the further evaluation, extractable residues on wheat straw were below 0.01 mg/kg at interval of 30 days and almost no significant radioactivity could be released from the straw samples at interval of 120 days. That means, the observed residues taken up by the plants are well incorporated in the plant cells and could not be released by the all extractions using various solvents with different polarities.

According to the critical GAP of AG-F8-250 CS (1 x 0.500 kg/ha flurochloridone) no residues above the MRL of 0.1 mg/kg set for flurochloridone by the EU are to be expected in the following crops. Residues in mature rotated crops relevant for human consumption are not expected to be presented above the LOQ when AG-F8-250 CS is applied according to the GAP.

Therefore, considering available data dealing with nature of residues, no study dealing with magnitude of residues in succeeding crops is needed.

In addition, phytotoxicity must be taken into account, and therefore, a waiting period of at least 30 days should be respected for planting succeeding crops.

Depending on local conditions, general recommendations are given for 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.

7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of AG-F8-250 CS. Therefore, other special studies are not needed.

According to the data requirements published in the Commission Regulation (EU) No 283/2013 of 1-March-2013 "The objective of the residue level in pollen and bee products study is to determine the residue in products for human consumption resulting from residues taken up by honeybees from crops at blossom." However, no official test guideline exists at the present in the Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances.

In addition according to SANCO/10181/2013 Rev 2.1 (Guidance document for applicants on renewal dossiers) the follow states:

"In some cases, agreed test methods or guidance documents are not yet available for particular data requirements. In these cases, waiving of these particular data requirement points is considered acceptable as long as no test methods or guidance documents are published in form of an update of the Commission Communications 2013/C 95/01 and 2013/C 95/02. Applicants should follow on a routine basis the current developments, e.g. activities of the European Food Safety Authority for guidance documents and in particular publications in the Official Journal."

Consequently, the above data requirements on residue level in pollen and bee products do not need to be addressed at this time.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

According to the EFSA conclusion (2010), the ADI and ARfD of flurochloridone is 0.04 mg/kg bw per day.

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-10: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Flurochloridone				
Potato culls	~~0.1*~~ 0.01 *	EU MRL Reg. (EU) No 2019/973	~~0.1*~~ 0.01 *	EU MRL Reg. (EU) No 2019/973
Other commodities of plant and animal origin	MRL	EU MRL Reg. (EU) No 2019/973	Not allocated	

STMR: supervised trials median residue; HR: highest residue.
(*) Indicates lower limit of analytical determination

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-11: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo ~~rev.3~~ rev.3.1	~~23 %~~ 10% (based on the NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Not required as no concern with TMDI
IESTI (% ARfD) according to EFSA PRIMo ~~rev.3~~ rev.3.1*	Potato: ~~38%~~ 4% (based on children)
NTMDI (% ADI) **	Not provided, not required
NEDI (% ADI)**	Not provided, not required
NESTI (% ARfD) **	Not provided, not required

* include raw and processed commodities if both values are required for PRIMo
** if national model is available

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

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

EFSA (European Food Safety Authority), 2018. Reasoned opinion on the review of the existing maximum residue levels for flurochloridone according to Article 12 of Regulation (EC) No 396/2005. EFSA
Journal 2018;16(1):5144, 33 pp. https://doi.org/10.2903/j.efsa.2018.5144.

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance flurochloridone. EFSA Journal 2010;8(12):1869. [66 pp.]. doi:10.2903/j.efsa.2010.1869. Available online: www.efsa.europa.eu/efsajournal.htm.

EFSA (European Food Safety Authority), 2013. Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance flurochloridone1. EFSA Journal 2013;11(3):3116. [9 pp.].

Spain, 2010. Final Addendum to the Additional Report on flurochloridone, compiled by EFSA, August 2010. Available online: www.efsa.europa.eu.

Spain, 2009. Additional Report to the Draft Assessment Report on the active substance flurochloridone, prepared by the rapporteur Member State Spain in the framework of Commission Regulation (EC) No 33/2008, October 2009. Available online: www.efsa.europa.eu.

Spain, 2006. Draft Assessment Report (DAR) on the active substance flurochloridone prepared by the rapporteur Member State Spain in the framework of Directive 91/414/EEC, February 2006.

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 8.6.1 (KCA 6.6.1)~~	~~Mamouni A.~~	~~2017~~	~~Evaluation of the Raw Data of the study: [^{14}C]-Flurochloridone Confined Accumulation in Rotational Crops Report No. 9000951~~ ~~Exponent International Ltd.~~ ~~Report No. 90020993~~ ~~GLP: no applicable~~ ~~Unpublished~~	~~N~~	~~ADM~~

*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

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
KCA 6.1	Ott, K.W.	1989	Flurochloridone - Storage stability: Crops and soil (WRC-89-239). ICI Americas Inc., Western Research Center, Richmond, California, USA; unpublished report no. RR 89-056B, Agan report no. 90004486 Study dates: February 1984 to August 1987. Non-GLP, unpublished	N	Agan
KCA 6.1	Wolf, S.	2003b	Development and validation of a residue analytical method for flurochloridone in potatoes (tubers) RCC Ltd., report no. 851142 Agan report no. 90006084 GLP, unpublished Part of the analytical methods (see B.5.2)	N	Agan

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
KCA 6.2.1	Miaullis, B.J., Parker, D.M., Vispetto, A.R. and Vu , H.	1986	The nature of the residue of R-40244 in mature sunflowers. Stauffer Chemical Company, Mt. View Research Center, California, USA, unpublished MRC report no. 86-01, Agan report no. 90004469 Study dates: May 1984 to December 1985. Non-GLP, unpublished	N	Agan
KCA 6.2.1	Van Dijk, A.	1988	Uptake and distribution of ^{14}C-Racer in field grown potatoes. RCC Umweltchemie AG, 4452 Itingen, Switzerland, unpublished report no. 089662; Agan report no. 90004468 November 1988. Study dates : May 1987 to February 1988. GLP, unpublished	N	Agan
KCA 6.3	Balluff, M.	2004	Racer 25 CS. Residue behaviour of Flurochloridone in potato 4 sites in Southern Europe 2003, 4 sites in Southern Europe 2004 and 8 sites in Northern Europe 2004. GAB Biotechnologie GmbH, report nº. 20033060/E1-FPPO Agan report 90006647 GLP, unpublished	N	Agan
KCA 6.6.1	Mamouni, A.	2009	^{14}C-Flurochloridone: Confined accumulation in rotational crops.Harlan Laboratories Ltd., unpublished report no. A74553, Agan report no. 9000951 February 16, 2009. GLP, unpublished	N	Agan
KCP 8.6.1 (KCA 6.6.1)	Mamouni A.	2017	Evaluation of the Raw Data of the study: [^{14}C]-Flurochloridone Confined Accumulation in Rotational Crops Report No. 9000951 Exponent International Ltd. Report No. 90020993 GLP: no applicable Unpublished	N	ADM

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

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
-	-	-	-	-	-

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Flurochloridone

A 2.1.1 Stability of residues

No new studies are available and not required.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No new studies are available and not required.

A 2.1.2.1.2 Nature of residue in rotational crops

No new studies are available and not required.

A 2.1.2.1.3 Nature of residues in processed commodities

No new studies are available and not required.

A 2.1.2.2 Nature of residues in livestock

No new studies are available and not required.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Potato

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, 2006)	1	0.75 kg/ha	-	BBCH 00-05	n.a.
cGAP EU (Art. 12, EFSA, 2018)	1	0.75 kg/ha	-	BBCH 00-05	n.a.
Intended cGAP (1*)	**1**	**0.500 kg/ha**	**-**	**BBCH 00-09**	**n.a.**

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
n.a.= not applicable

No new studies are available and not required.

Supervised residue trials on potato have been conducted in Northern Europe with flurochloridone CS formulation during the Annex I inclusion at an application rate 0.680 – 0.77 kg a.s./ha applied once pre-emergence. These trials can be used to support the intended use on potato for the product AG-F8-250 CS.

A 2.1.4 Magnitude of residues in livestock

No new studies are available and not required.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new studies are available and not required.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new studies are available and not required.

A 2.1.7 Other/Special Studies

No new studies are available and not required.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

TMDI calculation presented by Applicant has been deleted. New TDMI calculation is presented below:

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Flurochloridone

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,04	ARfD (mg/kg bw):	0,04
Source of ADI:	EFSA 10	Source of ARfD:	EFSA 10
Year of evaluation:	2010	Year of evaluation:	2010

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	10%	NL toddler	3,83	7%	Milk: Cattle	0,3%	Apples	0,2%	Carrots		
	6%	UK infant	2,38	5%	Milk: Cattle	0,3%	Carrots	0,2%	Eggs: Chicken		
	5%	FR toddler 2 3 yr	1,95	4%	Milk: Cattle	0,2%	Bovine: Muscle/meat	0,1%	Swine: Muscle/meat		
	5%	NL child	1,81	3%	Milk: Cattle	0,2%	Sugar beet roots	0,1%	Apples		
	4%	FR child 3 15 yr	1,72	3%	Milk: Cattle	0,2%	Bovine: Muscle/meat	0,2%	Swine: Muscle/meat		
	4%	DE child	1,62	2%	Milk: Cattle	0,3%	Apples	0,2%	Carrots		
	4%	UK toddler	1,42	3%	Milk: Cattle	0,2%	Bovine: Muscle/meat	0,1%	Eggs: Chicken		
	3%	DK child	1,22	2%	Milk: Cattle	0,3%	Swine: Muscle/meat	0,3%	Carrots		
	3%	SE general	1,15	2%	Milk: Cattle	0,6%	Bovine: Muscle/meat	0,2%	Carrots		
	3%	ES child	1,09	2%	Milk: Cattle	0,2%	Bovine: Muscle/meat	0,2%	Poultry: Muscle/meat		
	3%	FR infant	1,09	2%	Milk: Cattle	0,2%	Carrots	0,0%	Potatoes		
	2%	RO general	0,99	1%	Milk: Cattle	0,1%	Swine: Muscle/meat	0,1%	Wheat		
	2%	DE women 14-50 yr	0,98	2%	Milk: Cattle	0,1%	Sugar beet roots	0,1%	Swine: Muscle/meat		
	2%	DE general	0,97	2%	Milk: Cattle	0,1%	Swine: Muscle/meat	0,1%	Sugar beet roots		
	2%	GEMS/Food G11	0,93	1,0%	Milk: Cattle	0,2%	Swine: Muscle/meat	0,1%	Carrots		
	2%	GEMS/Food G15	0,86	0,9%	Milk: Cattle	0,2%	Swine: Muscle/meat	0,1%	Poultry: Muscle/meat		
	2%	GEMS/Food G07	0,84	0,8%	Milk: Cattle	0,2%	Poultry: Muscle/meat	0,1%	Swine: Muscle/meat		
	2%	GEMS/Food G08	0,79	0,7%	Milk: Cattle	0,2%	Swine: Muscle/meat	0,1%	Poultry: Muscle/meat		
	2%	NL general	0,76	1%	Milk: Cattle	0,1%	Swine: Muscle/meat	0,1%	Bovine: Muscle/meat		
	2%	GEMS/Food G10	0,75	0,7%	Milk: Cattle	0,2%	Poultry: Muscle/meat	0,1%	Bovine: Muscle/meat		
	2%	IE adult	0,64	0,5%	Milk: Cattle	0,1%	Sweet potatoes	0,1%	Carrots		
	1%	GEMS/Food G06	0,55	0,3%	Milk: Cattle	0,2%	Wheat	0,1%	Tomatoes		
	1%	ES adult	0,53	0,6%	Milk: Cattle	0,1%	Bovine: Muscle/meat	0,1%	Swine: Muscle/meat		
	1%	FR adult	0,51	0,6%	Milk: Cattle	0,1%	Swine: Muscle/meat	0,1%	Bovine: Muscle/meat		
	1%	DK adult	0,51	0,7%	Milk: Cattle	0,1%	Swine: Muscle/meat	0,1%	Carrots		
	1%	LT adult	0,41	0,5%	Milk: Cattle	0,1%	Swine: Muscle/meat	0,1%	Potatoes		
	0,9%	FI adult	0,37	0,7%	Coffee beans	0,1%	Carrots	0,0%	Potatoes		
	0,8%	UK adult	0,33	0,4%	Milk: Cattle	0,1%	Bovine: Muscle/meat	0,1%	Poultry: Muscle/meat		
	0,8%	UK vegetarian	0,31	0,4%	Milk: Cattle	0,1%	Wheat	0,0%	Carrots		
	0,7%	IE child	0,26	0,4%	Milk: Cattle	0,0%	Carrots	0,0%	Wheat		
	0,6%	PT general	0,26	0,1%	Potatoes	0,1%	Potatoes	0,1%	Wheat		
	0,6%	FI 3 yr	0,24	0,2%	Carrots	0,1%	Potatoes	0,0%	Bananas		
	0,5%	FI 6 yr	0,19	0,1%	Carrots	0,1%	Potatoes	0,0%	Cocoa beans		
	0,4%	IT toddler	0,18	0,2%	Wheat	0,0%	Other cereals	0,0%	Carrots		
	0,3%	IT adult	0,13	0,1%	Wheat	0,0%	Tomatoes	0,0%	Carrots		
	0,3%	PL general	0,13	0,1%	Potatoes	0,1%	Carrots	0,1%	Apples		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Flurochloridone is unlikely to present a public health concern.

A 3.2 IEDI calculations

Not required as no concern with TMDI

A 3.3 IESTI calculations - Raw commodities

IESTI calculation presented by Applicant has been deleted. New IESTI calculation is presented below:

	Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
	Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations
	The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.		**IESTI new calculations:** The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only. **Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.**	
	Show results for all crops			
Unprocessed commodities	**Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---	**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---	**IESTI new** **Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---	**IESTI new** **Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---
	IESTI	**IESTI**	IESTI new	IESTI new
	Highest % of ARfD/ADI: 4%	Highest % of ARfD/ADI: 0,7%	Highest % of ARfD/ADI: 2%	Highest % of ARfD/ADI: 0,8%
	Commodities: Potatoes	Commodities: Potatoes	Commodities: Potatoes	Commodities: Potatoes
	MRL / input for RA (mg/kg): 0,01 / 0,01	MRL / input for RA (mg/kg): 0,01 / 0,01	MRL / input for RA (mg/kg): 0,01 / 0,01	MRL / input for RA (mg/kg): 0,01 / 0,01
	Exposure (µg/kg bw): 1,5	Exposure (µg/kg bw): 0,30	Exposure (µg/kg bw): 0,66	Exposure (µg/kg bw): 0,31
	Expand/collapse list			
	Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)		**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)**	

A 3.4 IESTI calculations - Processed commodities

IESTI calculation – processed commodities presented by Applicant has been deleted. New IESTI calculation – processed commodities is presented below:

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Potatoes / fried	0,01 / 0,01	0,93	0,2%	Potatoes / chips	0,01 / 0,01	0,08	1%	Potatoes / dried (flakes)	0,01 / 0,05	0,59	0,2%	Potatoes / chips	0,01 / 0,01	0,08
1%	Potatoes / dried (flakes)	0,01 / 0,05	0,59	0,1%	Potatoes / dried (flakes)	0,01 / 0,05	0,06	1%	Potatoes / fried	0,01 / 0,01	0,44	0,1%	Potatoes / dried (flakes)	0,01 / 0,05	0,06
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Expand/collapse list															

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity.

A short term intake of residues of Flurochloridone is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.