

FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 126000 B

Product name(s): CLARA

Chemical active substances:

Chlormequat chloride, 720 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Sharda Cropchem Ltd.

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Version history

When	What
December 2022	Applicant update
May 2023	ZRMs evaluated dRR submitted by Applicant.
October 2023	ZRMs corrected RR according to commenting period.

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

The evaluator's comments and corrections are marked with a grey background colour.

Chlormequat chloride

Stability of Residues

The storage stability of chlormequat chloride in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2009). Residues of chlormequat chloride in wheat grain and straw are stable at least 24 months. In processed fractions (bran, whole grain bread, malt and beer) chlormequat chloride is stable up to a period of 13 months.

Residues of chlormequat chloride in animals products (cow meat, mild and hen eggs) are stable for at least 12 months.

Metabolism in plants and animals

The metabolism of chlormequat in primary crops belonging to the group of cereals/grass has been investigated in the framework of the EU pesticides peer review under Directive 91/414/EEC (EFSA, 2009).

Plant residue definition for monitoring Sum of chlormequat and its salts, expressed as chlormequat chloride (Reg. (EU) 2022/1290)

Plant residue definition for risk assessment Sum of chlormequat and its salts, expressed as chlormequat chloride ((only for cereals, pears and cultivated fungi) (EFSA Journal 2016;14(3):4422)

The intended uses are covered by the established residue definitions.

No additional studies are required.

The residue definition for animal products for monitoring and risk assessment is set as sum of Chlormequat and its salts expressed as Chlormequat chloride.

Magnitude of residues in plants

Proposed uses:

1 application, BBCH 29-32, 0.936-1.51 kg a.s./ha

Applicant refers to new trials and to EU unprotected data.

Trials GAP: 1.512 kg a.s./ha, BBCH 29-31 (new studies)

1.5 kg as/ha, BBCH 34-37 (trials evaluated in the DAR)

Sufficient trials on wheat are available to support the proposed use.

The residues arising from the proposed uses will not exceed the MRLs established for wheat.

Use is accepted.

Magnitude of residues in livestock

The dietary burden was updated by zRMS based on trials data and European data, which was reported by EFSA in Reasoned Opinion (EFSA, 2020).

No exceedance of the current EU-MRL is expected.

Magnitude of residues in processed commodities

Available EU data are sufficient to cover the proposed use.

Magnitude of residues in representative succeeding crops

EFSA Journal 2020;18(1):5982:

The available rotational crop metabolism studies demonstrated that no significant residues (residues below 0.01 mg/kg) are expected in succeeding crops (lettuces, radishes and wheat) planted in soil treated at 2 kg a.s./ha.

Field rotational crop studies are not required.

Restrictions for succeeding crops are not required.

EFSA Journal 2020;18(1):5982:

Considering that high residue levels are expected in cereals straw, residues in mushrooms may occur via the uptake of chlormequat from growth substrate composed of cereal straws that have been previously treated with chlormequat (EFSA, 2019b). A restriction should be considered to avoid the use of cereals straw treated with chlormequat as horticultural growth medium or as mulch.

Proposed label restriction: do not use straw from wheat treated with chlormequat as horticultural growth medium in cultivation of fungi.

Other / special studies

Wheat have not melliferous capacity. Studies are not required.

Estimation of exposure through diet and other means

Calculation based on trials data (input: STMR from field trials – wheat) and MRLs for animal commodities was made by zRMS.

The proposed uses of Chlormequat chloride in the formulation SHA 126000 B do not represent unacceptable acute and chronic risks for the consumer.

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 SHA 126000 B are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central Europe for winter wheat. A list of all intended uses within the Central Europe is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for chlormequat chloride as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of chlormequat chloride residues are unlikely to present a public

health concern.

As far as consumer health protection is concerned, Poland agrees with the authorization of the intended use(s).

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

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

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	Winter wheat	CEU	SHA 126000 B	F	Regulation of growth, prevention of lodging	SL	720 g/L	Foliar spray	BBCH 29-32	1	-	0.312-0.755	200-300	0.936-1.51	-	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 SHA 126000 B is composed of chlormequat chloride.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Chlormequat chloride					
ADI	EFSA	2008	0.04 mg/kg bw/d	1-year dog study	100
ARfD	EFSA	2008	0.09 mg/kg bw	4-week dog studies	100

7.1.2.1 Summary for chlormequat chloride

Table 7.1-3: Summary for chlormequat chloride

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	Winter wheat	Yes	Yes	Yes	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

7.1.2.2 Summary for SHA 126000 B

Table 7.1-4: Information on SHA 126000 B (KCA 6.8)

Crop	PHI for SHA 126000 B proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for SHA 126000 B proposed by zRMS	zRMS Comments (if different PHI proposed)
		Chlormequat chloride				
Winter wheat	NR	NR	NR	NR		

NR: not relevant

* Purpose of withholding period to be specified

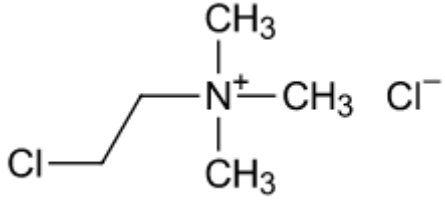
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Assessment

7.2 Chlormequat chloride

General data on chlormequat chloride are summarized in the table below (last updated 2022/02/18)

Table 7.2-1: General information on chlormequat chloride

Active substance (ISO Common Name)	Chlormequat chloride
IUPAC	2-chloroethyltrimethylammonium chloride
Chemical structure	
Molecular formula	C ₅ H ₁₃ Cl ₂ N
Molar mass	158.1 g/mol
Chemical group	Quarternary ammonium compound
Mode of action (if available)	Inhibits cell elongation
Systemic	Yes
Company (ies)	CCC Task Force
Rapporteur Member State (RMS)	Austria
Approval status	Approved Date of (01/12/2009) and reference to decision (COMMISSION DIRECTIVE 2010/2/EU - REGULATION (EU) No 540/2011)
Restriction	Plant growth regulator
Review Report	SANCO/175/08 final rev 2 29/05/2015
Current MRL regulation	Reg. (EU) 2020/1565 Reg. (EU) 2022/1290
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 Scientific Report (2008) 179, 1-77)
EFSA Journal: conclusion on article 12	Yes (EFSA Journal 2016;14(3):4422)
Current MRL applications on intended uses	EFSA-Q-2010-00181 All Commodities Status: Reasoned opinion available (EFSA Journal 2016;14(3):4422)/SANCO/175/08 final rev 2

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 submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat grain and straw	High starch content	24 months	Zietz E., 2004, Report No.: IF- 101/23411-00, DAR, UK, Part B7, 2007 EFSA, 2008
Wheat and barley (bran, whole grain bread, malt and beer)	Processed fractions	13 months	
Animal Products			
Ruminant	Cow meat, milk	12 months	Zenide D., 2002, Report No.: A-51-01-01 DAR, UK, Part B7, 2007 EFSA, 2008
Poultry	Eggs	12 months	

Conclusion on stability of residues during storage

Residues of chlormequat chloride in animals products (cow meat, mild and hen eggs) are stable for at least 12 months. In processed fractions (bran, whole grain bread, malt and beer) chlormequat chloride is stable up to a period of 13 months and in wheat grain and straw for a period of 24 months.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Not relevant.

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 submitted in the framework of this application.

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								
Cereals	Wheat	2-chloroethyl-[1,2- ¹⁴ C]-triethylammonium chloride	Foliar, F	1.4	1	Forage: 0, 28, 84 Grain and straw: 118	-	Keller E., 1990, Report No.: BASF 90/0299, DAR, UK, Part B7, 2007, EFSA 2016

Summary of plant metabolism studies reported in the EU

The nature of the residues in plants following the use of chlormequat chloride was studied in wheat. After a single application of 2-chloroethyl-[1,2-¹⁴C]-triethylammonium chloride at a rate slightly below the critical GAP (0.9N) at GS71 (intended uses: GS 30-49 for different commodities and regions) samples were collected 0, 28 and 84 days after treatment and at maturity. Total radioactive residues (TRR) in forage samples decreased from 49.24 mg/kg at day 0 to 14.35 mg/kg at day 84 after application. TRR in straw and grain was 45.8 mg/kg and 1.3 mg/kg respectively. Whereas the radioactive residues in forage and straw samples were mostly extractable (85-90% TRR and 89% TRR respectively), only 52% TRR was extracted from grain samples. The unextracted residues in straw and grain samples were further investigated. In grain 0.2%, 35.6%, 1.2% and 15.8% TRR were found in the protein, lignin, cellulose and starch fraction respectively. In straw 5.1% and 0.1% TRR were found in the lignin and the cellulose fraction respectively. In extracts of forage sampled at day 0, 28 and 84 respectively, 40-42 mg/kg, 32-33 mg/kg and 9.7-10.5 mg/kg chlormequat were found. Concentrations of 36-37 mg/kg (78-81% of TRR) and 0.37-0.41 mg/kg (28-30% of TRR) chlormequat were detected in straw and grain. Betain was the only other radioactive component identified (0.04-0.05 mg/kg or 3-5% of TRR in grain and at 0.06 mg/kg or 0.1% of TRR in straw).

Conclusion on metabolism in primary crops

Plant residue definition for monitoring and risk assessment is set as sum of chlormequat and its salts, expressed as chlormequat chloride.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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	Lettuce	2-chloroethyl-[1- ¹⁴ C]-triethylammonium chloride	Soil treatment	2	30, 120, 365	At maturity	-	Veit P., 2003, Report No.: BASF 2003/1004686, DAR, UK, Part B7, 2007, EFSA, 2016
		2-chloroethyl-[1,2- ¹⁴ C]-triethylammonium chloride	Soil treatment	1.5	30	At maturity	-	Hofmann M., 1992, Report No.: 92/10223, DAR, UK, Part B7, 2007, EFSA, 2016
Root and tuber vegetables	White radish	2-chloroethyl-[1- ¹⁴ C]-triethylammonium chloride	Soil treatment	2	30, 120, 365	At maturity	-	Veit P., 2003, Report No.: BASF 2003/1004686

								DAR, UK, Part B7, 2007, EFSA, 2016
	Carrot	2-chloroethyl- [1,2- ¹⁴ C]- triethylammonium chloride	Soil treatment	1.5	30	At maturity	-	Hofmann M., 1992, Report No.: 92/10223, DAR, UK, Part B7, 2007, EFSA, 2016
Pulses and oilseeds	Green beans	2-chloroethyl- [1,2- ¹⁴ C]- triethylammonium chloride	Soil treatment	1.5	30	At maturity	-	Hofmann M., 1992, Report No.: 92/10223, DAR, UK, Part B7, 2007, EFSA, 2016
Cereals	Spring wheat	2-chloroethyl-[1- ¹⁴ C]- triethylammonium chloride	Soil treatment	2	30, 120, 365	At maturity	-	Veit P., 2003, Report No.: BASF 2003/1004686, DAR, UK, Part B7, 2007, EFSA, 2016
		2-chloroethyl- [1,2- ¹⁴ C]- triethylammonium chloride	Soil treatment	1.5	30	At maturity	-	Hofmann M., 1992, Report No.: 92/10223, DAR, UK, Part B7, 2007, EFSA, 2016

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

The metabolism and distribution in rotational crops was investigated in two studies. In the first study, soil was treated with 2-chloroethyl-[1-¹⁴C]-triethylammonium chloride at a rate of 2 kg a.s./ha (1.3N). Lettuce, white radish and spring wheat were planted after 30, 120 and 365 days of aging. TRR was relatively low in lettuce and radish for all three plant-back intervals (max. 0.021 mg/kg, 0.046 mg/kg and 0.037 mg/kg in lettuce, radish leaves and radish roots respectively). Considerable concentrations of radioactive residues were found in wheat (max. 0.153 mg/kg, 0.336 mg/kg, 0.229 mg/kg and 0.197 mg/kg in forage, straw, chaff and grain respectively). Extractability of the TRR by methanol and water ranged from 46-68% in radish root to 12-20% in wheat grain. Further residues could be released by treatment with ammonia or enzymes. Extracts were analysed by HPLC. Besides chlormequat, further polar compounds were found but could not be identified. Radioactive residues in soil were 19.9-24.0 mg/kg, 0.29-0.51 mg/kg, 0.31 mg/kg and 0.26 mg/kg after 0, 30, 120 and 365 days of ageing respectively. In a second rotational crop study, soil was treated with 2-chloroethyl-[1,2-¹⁴C]-triethylammonium chloride at a rate equivalent to 1.5 kg a.s./ha (1N). After ageing of the soil for 30 days, spring wheat, carrot, lettuce and green beans were planted. Low concentrations of TRR were found in beans, carrot and lettuce (max. 0.01 mg/kg in crop parts for human consumption; TRR of 0.052 mg/kg, 0.041 and 0.066 mg/kg were found in wheat grain, forage and straw respectively).

Conclusion on metabolism in rotational crops

Residue definition for rotational crops is the same as for primary crops i.e. sum of chlormequat and its salts, expressed as chlormequat chloride.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	pH = 4 (to simulate beer brewing) – parent compound – 86.1% pH = 5 (to simulate bread making) – parent compound – 85.8 %	Adam D., 2004, Report No.: 854870, DAR, UK, Part B7, 2007, EFSA, 2016

Conclusion on nature of residues in processed commodities

The parent compound – chlormequat – is stable under processing conditions of baking and brewing.

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

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

Endpoints	
Plant groups covered	Cereals (Wheat)
Rotational crops covered	Leafy vegetables (lettuce) Root and tuber vegetables (white radish, carrot) Pulses and oilseeds (green bean) Cereals (wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	a.s. is stable
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes (only for the investigated processes: bread making and beer brewing)
Plant residue definition for monitoring	Sum of chlormequat and its salts, expressed as chlormequat chloride Reg. (EU) 2020/1565 Reg. (EU) 2022/1290
Plant residue definition for risk assessment	Sum of chlormequat and its salts, expressed as chlormequat chloride EFSA, 2016
Conversion factor from enforcement to RA	Not relevant

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.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label posi- tion	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	¹⁴ C- chlormequat chloride	2	28.9 mg/kg diet	7	Milk	twice daily	Phillips M., McCombe W.S., Gedik L., 2003a, Report No.: 20589; 2004, Report No.: 200554, DAR, UK, Part B7, 2007, EFSA, 2016
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	¹⁴ C- chlormequat chloride	10	3.0 mg a.s.	14	Eggs	daily	Phillips M., McCombe W.S., Gedik L., 2003b, Report No.: 20357, DAR, UK, Part B7, 2007, EFSA, 2016
						Excreta	daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

In lactating goats dosed at 62.5 mg (28.9 mg/kg diet as received) for 7 consecutive days, the majority of the applied radioactivity was found in excreta (49% in urine, 30% in faeces and 0.6% in milk). Additional 8% were recovered in cage wash and 1.6% in the gastro-intestinal contents. Tissues accounted only for 0.13% of the applied dose (0.36 mg/kg TRR in liver, 1.45 mg/kg TRR in kidney, 0.23 mg/kg TRR in muscle and 0.030 mg/kg TRR in fat). Organic extraction recovered 67% of TRR in fat and 77-92% of TRR in other tissues, but only 17-20% of TRR in milk. Chlormequat accounted for 42%, 83%, 76% and 4% of TRR in the organic extracts of liver, kidney, muscle and milk respectively. No further metabolites were identified. Unextractable residues were further characterised using acid and enzyme treatment.

For laying hens dosed at 3.0 mg a.s. for 14 consecutive days the majority of the radioactivity was recovered in excreta (92.6%). Egg white and egg yolk contained 0.05% and 0.34% of the administered radioactivity, tissues only approximately 0.04%. In kidney, liver, muscle and abdominal fat TRR of 0.352 mg/kg, 0.36 mg/kg, 0.12 mg/kg and 0.06 mg/kg were found. Organic extraction recovered 65% of TRR in liver and kidney, 75% in muscle and 62-69% in egg yolk, but only 6% in egg white and 15% in fat. Unextractable residues were further characterised by various treatments. Only in one of the egg yolk samples a substantial amount of the radioactive residues (0.210 mg/kg, 21.6%) remained unextracted. Chlormequat was the only identified component of the residue. It was present at levels of 6.5% TRR (0.023 mg/kg) in kidney, 1.8% (0.007 mg/kg) TRR in liver and 48% TRR (0.47 mg/kg) in one egg yolk sample.

Conclusion on metabolism in livestock

Residue definition for animal products for monitoring and risk assessment is sum of chlormequat and its salts expressed as chlormequat chloride.

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

Table 7.2-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	4 days in milk
	5 days in eggs
Animal residue definition for monitoring	Sum of chlormequat and its salts, expressed as chlormequat chloride Reg. (EU) 2020/1565 Reg. (EU) 2022/1290
Animal residue definition for risk assessment	Sum of chlormequat and its salts, expressed as chlormequat chloride EFSA, 2016
Conversion factor	Not relevant
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

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

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of SHA 126000 B 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
Wheat grain	New trials	N-EU	Trials GAP: 1x1512 g a.s/ha, BBCH 29-31, PHI 63-122d, outdoor Grain: 0.0064 (<LOQ), 0.0463, 0.0759, 0.2389, 0.2976, 0.3020, 0.3258, 0.3582 <0.01, 0.05, 0.08, 0.24, 2x 0.30, 0.33, 0.36	N/A				
	Addendum to the DAR, 2008	N-EU	GAP on which EU a.s. assessment is based: 1 x 1.5 kg as/ha, BBCH 34-37, PHI 57-94d, outdoor Grain: 0.26, 0.45, 0.74, 0.80					
	Overall supporting data for cGAP	N-EU	Grain: 0.0064 (<LOQ), 0.0463, 0.0759, 0.2389, 0.26, 0.2976, 0.3020, 0.3258, 0.3582, 0.45, 0.74, 0.80 Grain: <0.01, 0.05, 0.08, 0.24, 0.26, 2x 0.30, 0.33, 0.36 , 0.45, 0.74, 0.80,	0.300	0.80	1.311	7.0	Yes
Wheat straw	New trials	N-EU	Trials GAP: 1x1512 g a.s/ha, BBCH 29-31, PHI 63-122d, outdoor Straw: 0.3434, 0.7995, 1.2510, 1.6438, 1.8011, 4.4560, 4.8074, 5.0014 0.34, 0.80, 1.25, 1.64, 1.80, 4.46, 4.81, 5.0	N/A				

	Addendum to the DAR, 2008	N-EU	GAP on which EU a.s. assessment is based: 1 x 1.5 kg as/ha, BBCH 34-37, PHI 57-94d, outdoor Straw: 4.06, 16.73, 18.8, 31.3					
	Overall supporting data for cGAP	N-EU	Straw: 0.3434, 0.7995, 1.2510, 1.6438, 1.8011, 4.06, 4.4560, 4.8074, 5.0014, 16.73, 18.8, 31.3 0.34, 0.80, 1.25, 1.64, 1.80, 4.06, 4.46, 4.81, 5.0, 16.73, 18.8, 31.3	4.258 4.26	31.3	46.021	-	-

* Source of EU MRL: ~~Reg. (EU) 2020/1565~~ Reg. (EU) 2022/1290

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on winter wheat are considered acceptable, for outdoor uses.

The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-10: 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: sum of chlormequat and its salts, expressed as chlormequat-chloride				
Barley straw	6.90	STMR (EFSA, 2016)	39.0	HR (EFSA, 2016)
Oat straw	4.40	STMR (EFSA, 2016)	11	HR (EFSA, 2016)
Rye straw	4.80	STMR (EFSA, 2016)	7.80	HR (EFSA, 2016)
Wheat straw	13.40	STMR (EFSA, 2016)	28.70	HR (EFSA, 2016)
Barley grain	0.68	STMR (EFSA, 2016)	0.68	STMR (EFSA, 2016)
Oat grain	3.10	STMR (EFSA, 2016)	3.10	STMR (EFSA, 2016)
Rye grain	1.10	STMR (EFSA, 2016)	1.10	STMR (EFSA, 2016)
Wheat grain	0.96	STMR (EFSA, 2016)	0.96	STMR (EFSA, 2016)
Brewer's grain dried	2.24	STMR (0.68) * PF (3.3)	2.24	STMR (0.68) * PF (3.3)
Distiller's grain dried	3.17	STMR (0.96) * PF (3.3)	3.17	STMR (0.96) * PF (3.3)
Wheat gluten meal	1.73	STMR (0.96) * PF (1.8)	1.73	STMR (0.96) * PF (1.8)
Wheat milled by-pdts	6.72	STMR (0.96) * PF (7)	6.72	STMR (0.96) * PF (7)

Table 7.2-11: Results of the dietary burden calculation

Calculations were made using Animal Model 2017.

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: sum of chlormequat and its salts, expressed as chlormequat-chloride					
Cattle (all diets)	0.259	0.647	Barley straw	16.83	Y
Cattle (dairy only)	0.259	0.647	Barley straw	16.83	Y
Sheep (all diets)	0.436	1.247	Barley straw	29.35	Y
Sheep (ewe only)	0.328	0.978	Barley straw	29.35	Y
Swine (all diets)	0.167	0.167	Wheat milled bypds	5.56	Y
Poultry (all diets)	0.376	0.494	Wheat straw	7.23	Y
Poultry (layer only)	0.376	0.494	Wheat straw	7.23	Y

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

zRMS:

The dietary burden was updated based on trials data and European data, which was reported by EFSA in Reasoned Opinion (EFSA, 2020).

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment (EFSA, 2020)	Input value (mg/kg)	Comment (EFSA, 2020)
Risk assessment residue definition: Sum of Chlormequat and its salts, expressed as Chlormequat-chloride				
Barley straw	18.0	(EFSA, 2020)	55.0	(EFSA, 2020)
Oat straw	4.40	(EFSA, 2020)	11.00	(EFSA, 2020)
Rye straw	5.42	(EFSA, 2020)	11.48	(EFSA, 2020)
Triticale straw	15.48	(EFSA, 2020)	65.79	(EFSA, 2020)
Wheat straw	4.26	Residue trials	31.30	Residue trials
Barley grain	1.24	(EFSA, 2020)	1.24	(EFSA, 2020)
Oat grain	3.10	(EFSA, 2020)	3.10	(EFSA, 2020)
Rye grain	1.42	(EFSA, 2020)	1.42	(EFSA, 2020)
Triticale grain	1.19	(EFSA, 2020)	1.19	(EFSA, 2020)
Wheat grain	0.30	Residue trials	0.30	Residue trials

The data available within this application are less critical and therefore covered by the calculations done in the framework of EFSA Reasoned Opinion (EFSA, 2020). No new data is required.

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)	Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM				0.004
	Median	Maximum	Median	Maximum			mg/kg bw

Cattle (all diets)	0,314	0,794	8,18	20,65	Dairy cattle	Barley	straw	Yes
Cattle (dairy only)	0,314	0,794	8,18	20,65	Dairy cattle	Barley	straw	Yes
Sheep (all diets)	0,575	1,635	13,53	38,76	Lamb	Barley	straw	Yes
Sheep (ewe only)	0,451	1,292	13,53	38,76	Ram/Ewe	Barley	straw	Yes
Swine (all diets)	0,095	0,095	3,15	3,15	Swine (finishing)	Oat	grain	Yes
Poultry (all diets)	0,269	0,443	3,93	6,47	Poultry layer	Wheat	straw	Yes
Poultry (layer only)	0,269	0,443	3,93	6,47	Poultry layer	Wheat	straw	Yes

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

Table 7.2-12: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) ^(b)	Highest residue (mg/kg) ^(c)	Calculated MRL (mg/kg)	CF for RA ^(d)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforce-ment		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (EFSA, 2016)												
Enforcement residue definition: Sum of Chlormequat and its salts, expressed as Chlormequat-chloride												
Pig meat	0.167	0.167	0.38 (3.3 N)		< 0.05	< 0.05	< 0.05	< 0.05	0.04	< 0.05	0.02	1
			1 N		0.02	0.02	0.02	0.02				
Pig fat			0.38 (3.3 N)		< 0.05	< 0.05	< 0.05	< 0.05	0.04	< 0.05	0.02	1
			1 N		0.02	0.02	0.02	0.02				
Pig liver			0.38 (3.3 N)		0.08	0.10	0.08	0.10	0.07	0.10	0.05*	1
			1 N		0.05	0.05	0.05	0.05				
Pig kidney			0.38 (3.3 N)		0.14	0.30	0.14	0.30	0.12	0.30	0.1	1
			1 N		0.05	0.09	0.05	0.09				
Ruminant meat	0.259	0.647	1.09		0.07	0.11	0.07	0.11	0.09	0.11	0.15	1
			1 N		0.05	0.11	0.05	0.11				
Ruminant fat			1.09		0.05	0.05	0.05	0.05	0.05	0.05	0.06	1
			1 N		0.05	0.05	0.05	0.05				
Ruminant liver			1.09		0.06	0.09	0.06	0.09	0.09	0.09	0.1	1
			1 N		0.08	0.09	0.08	0.09				
Ruminant kidney			1.09		0.40	0.46	0.40	0.46	0.43	0.46	0.5	1
			1 N		0.17	0.45	0.17	0.45				

Poultry meat	0.376	0.494	0.38 (2.4 N)		< 0.05	< 0.05	< 0.05	< 0.05	0.04	< 0.05	0.03	1
			1 N		0.02	0.02	0.02	0.02				
Poultry fat			0.38 (2.4 N)		< 0.05	< 0.05	< 0.05	< 0.05	0.04	< 0.05	0.03	1
			1 N		0.02	0.02	0.02	0.02				
Poultry liver			0.38 (2.4 N)		0.06	0.09	0.06	0.09	0.06	0.09	0.05*	1
			1 N		0.05	0.05	0.05	0.05				
Milk	0.259	0.647	0.38		0.03	N/A	0.03	N/A	0.03	0.03	0.03	1
			1 N		0.01	0.03	0.01	0.03				
Eggs	0.376	0.494	0.38 (2.4 N)		< 0.05	< 0.05	< 0.05	< 0.05	0.04	< 0.05	0.03	1
			1 N		0.02	0.02	0.02	0.02				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.

n.r.: Not reported

(*): Indicates that the MRL is set at the limit of analytical quantification.

(F): MRL is expressed as mg/kg of fat contained in the whole product.

(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

(d): The median conversion factor for enforcement to risk assessment.

(e): Mean residue level from day X until day XX (X cows, Y sampling days).

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

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

7.2.5.1 Available data for all crops under consideration

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

Table 7.2-13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Enforcement residue definition: Sum of Chlormequat and its salts, expressed as Chlormequat-chloride					
Wheat, whole-meal flour	4	1	-		Zietz E., Klimmek S., 2004a, Report No.: IF-101/11753-00 DAR, UK, Part B7, 2007, EFSA, 2016
Wheat, whole-meal bread	4	0.5	-	-	
Wheat, white flour	4	0.3	-	-	
Wheat, bran	4	3.1	-		

* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

** The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

7.2.5.2 Conclusion on processing studies

Chlormequat chloride decreased or was unchanged over processing, except for the bran fractions where a mean processing factor of 3.1 was obtained.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

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 SHA 126000 B. Therefore, other special studies are not needed.

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).

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-14: 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: Sum of Chlormequat and its salts, expressed as Chlormequat-chloride				
Pears	0.05*	Mean of monitoring data (EFSA, 2016)	0.07	MRL derived from monitoring data (EFSA, 2016)
Cultivated fungi	0.22	Mean of monitoring data (EFSA, 2016)	3	MRL derived from monitoring data (EFSA, 2016)
Barley grain	0.68	STMR (EFSA, 2016)	1.4	HR (EFSA, 2016)
Oats grain	3.1	STMR (EFSA, 2016)	7.4	HR (EFSA, 2016)
Rye grain	1.1	STMR (EFSA, 2016)	2.6	HR (EFSA, 2016)
Wheat grain	0.96	STMR (EFSA, 2016)	2.1	HR (EFSA, 2016)
Swine meat	0.02	STMR muscle (EFSA, 2016)	0.02	HR muscle (EFSA, 2016)
Swine fat	0.02	STMR (EFSA, 2016)	0.02	HR (EFSA, 2016)
Swine liver	0.05*	STMR (EFSA, 2016)	0.05*	HR (EFSA, 2016)
Swine kidney	0.05	STMR (EFSA, 2016)	0.09	HR (EFSA, 2016)
Ruminant meat	0.05	STMR muscle (EFSA, 2016)	0.11	HR muscle (EFSA, 2016)
Ruminant fat	0.05	STMR (EFSA, 2016)	0.05	HR (EFSA, 2016)
Ruminant liver	0.08	STMR (EFSA, 2016)	0.09	HR (EFSA, 2016)
Ruminant kidney	0.17	STMR (EFSA, 2016)	0.45	HR (EFSA, 2016)
Poultry meat	0.02	STMR muscle (EFSA, 2016)	0.02	HR (EFSA, 2016)
Poultry fat	0.02	STMR (EFSA, 2016)	0.02	HR (EFSA, 2016)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Poultry liver	0.05*	STMR (EFSA, 2016)	0.05*	HR (EFSA, 2016)
Milk	0.01	STMR (EFSA, 2016)	0.03	HR (EFSA, 2016)
Eggs	0.02	STMR (EFSA, 2016)	0.02	HR (EFSA, 2016)

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-15: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	With MRL values from Reg. (EU) No 2020/1565: Reg. (EU) 2022/1290: 222% based on DK child
IEDI (% ADI) according to EFSA PRIMo	With MRL from Reg. (EU) No. 2020/1565 Reg. (EU) 2022/1290 and input value from EFSA 2016 (without consideration of the existing CXLs – rye grain, wheat grain, milk): 34% based on NL toddler 45% based on DK child
UESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities: <u>Results for children:</u> Wheat: 15% <u>Results for adults:</u> Wheat: 9% Processed commodities: <u>Results for children:</u> Wheat/ milling (flour): 13% Wheat/ milling (wholemeal)-baking: 6% <u>Results for adults:</u> Wheat/ bread/ pizza: 5% Wheat/ pasta: 4% Wheat/ bread (wholemeal): 4%
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

* include raw and processed commodities if both values are required for PRIMo

** if national model is available

The proposed uses of Chlormequat chloride in the formulation Chlormequat chloride 72 % SL do not represent unacceptable acute and chronic risks for the consumer.


zRMS:

Calculation based on trials data (input: STMR from field trials – wheat) and MRLs for animal commodi-

ties:

IEDI (% ADI) according to EFSA PRIMo rev.3.1	80% NL toodler (highest contributor: milk cattle)
IENTI (% ARfD) according to EFSA PRIMo rev.3.1	<p>Unprocessed commodities: <u>Results for children:</u> Wheat: 5%</p> <p><u>Results for adults:</u> Wheat: 3%</p> <p>Processed commodities: <u>Results for children:</u> Wheat/ milling (flour): 4% Wheat/ milling (wholemeal)-baking: 4%</p> <p><u>Results for adults:</u> Wheat/ bread/ pizza: 1% Wheat/ pasta: 1% Wheat/ bread (wholemeal): 1%</p>

The proposed uses of Chlormequat chloride in the formulation Chlormequat chloride 72 % SL do not represent unacceptable acute and chronic risks for the consumer.

 European Food Safety Authority EFSA PRIMo revision 3.1; 2021/01/06		Chlormequat chloride				Input values					
		LOQs (mg/kg) range from: _____ to: _____									
		Toxicological reference values				<div>Details - chronic risk assessment</div> <div>Supplementary results - chronic risk assessment</div> <div>Details - acute risk assessment/children</div> <div>Details - acute risk assessment/adults</div>					
		ADI (mg/kg bw/day): 0,04		ARfD (mg/kg bw): 0,09							
		Source of ADI: EFSA		Source of ARfD: EFSA							
Year of evaluation: 2008		Year of evaluation: 2008									
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IED/TMDI)											
				No of diets exceeding the ADI : _____				Exposure resulting from			
TMDI/NED/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
	80%	NL toddler	32,20	75%	Milk: Cattle	3%	Wheat	0,8%	Bovine: Muscle/meat		
	53%	UK infant	21,15	48%	Milk: Cattle	2%	Wheat	0,9%	Bovine: Muscle/meat		
	42%	FR toddler 2 3 yr	16,71	37%	Milk: Cattle	2%	Wheat	0,9%	Bovine: Muscle/meat		
	36%	NL child	14,45	31%	Milk: Cattle	3%	Wheat	0,8%	Swine: Muscle/meat		
	35%	FR child 3 15 yr	14,19	29%	Milk: Cattle	3%	Wheat	1%	Bovine: Muscle/meat		
	30%	UK toddler	12,17	26%	Milk: Cattle	3%	Wheat	1,0%	Bovine: Muscle/meat		
	29%	DE child	11,64	25%	Milk: Cattle	3%	Wheat	0,4%	Swine: Muscle/meat		
	23%	DK child	9,09	16%	Milk: Cattle	3%	Wheat	2%	Swine: Muscle/meat		
	22%	FR infant	8,94	21%	Milk: Cattle	0,6%	Wheat	0,3%	Swine: Muscle/meat		
	22%	ES child	8,82	16%	Milk: Cattle	3%	Wheat	1%	Bovine: Muscle/meat		
	22%	SE general	8,60	15%	Milk: Cattle	3%	Bovine: Muscle/meat	2%	Wheat		
	20%	RO general	7,93	15%	Milk: Cattle	4%	Wheat	0,9%	Swine: Muscle/meat		
	19%	DE women 14-50 yr	7,41	15%	Milk: Cattle	2%	Wheat	0,7%	Swine: Muscle/meat		
	18%	DE general	7,37	15%	Milk: Cattle	1%	Wheat	0,8%	Swine: Muscle/meat		
	15%	GEMS/Food G15	5,95	9%	Milk: Cattle	3%	Wheat	1%	Swine: Muscle/meat		
	14%	GEMS/Food G11	5,77	10%	Milk: Cattle	3%	Wheat	0,9%	Swine: Muscle/meat		
	14%	GEMS/Food G07	5,69	8%	Milk: Cattle	3%	Wheat	0,9%	Swine: Muscle/meat		
	14%	NL general	5,49	11%	Milk: Cattle	1%	Wheat	0,7%	Swine: Muscle/meat		
	12%	GEMS/Food G08	4,99	7%	Milk: Cattle	3%	Wheat	1%	Swine: Muscle/meat		
	12%	GEMS/Food G10	4,76	7%	Milk: Cattle	3%	Wheat	0,7%	Bovine: Muscle/meat		
	10%	GEMS/Food G06	3,90	5%	Wheat	3%	Milk: Cattle	0,2%	Milk: Sheep		
	10%	IE adult	3,89	5%	Milk: Cattle	2%	Wheat	0,8%	Sheep: Liver		
	10%	ES adult	3,88	6%	Milk: Cattle	2%	Wheat	0,6%	Bovine: Muscle/meat		
	9%	DK adult	3,61	7%	Milk: Cattle	0,8%	Wheat	0,7%	Swine: Muscle/meat		
	9%	FR adult	3,60	6%	Milk: Cattle	2%	Wheat	0,5%	Swine: Muscle/meat		
	7%	LT adult	2,80	5%	Milk: Cattle	0,8%	Wheat	0,7%	Swine: Muscle/meat		
	6%	UK vegetarian	2,31	4%	Milk: Cattle	2%	Wheat	0,1%	Eggs: Chicken		
	6%	UK adult	2,30	4%	Milk: Cattle	1%	Wheat	0,5%	Bovine: Muscle/meat		
	6%	IE child	2,27	4%	Milk: Cattle	0,9%	Wheat	0,1%	Swine: Muscle/meat		
	5%	IT toddler	1,99	5%	Wheat		FRUIT AND TREE NUTS				
	3%	IT adult	1,24	3%	Wheat		FRUIT AND TREE NUTS				
	3%	PT general	1,18	3%	Wheat		FRUIT AND TREE NUTS				
	0,9%	FI 3 yr	0,36	0,9%	Wheat	0,0%	Honey and other apiculture products				
0,7%	FI 6 yr	0,29	0,7%	Wheat	0,0%	Honey and other apiculture products					
0,2%	FI adult	0,10	0,2%	Wheat		FRUIT AND TREE NUTS					
	Column7					FRUIT AND TREE NUTS					
Conclusion: The estimated long-term dietary intake (TMDI/NED/IEDI) was below the ADI. The long-term intake of residues of Chlormequat chloride is unlikely to present a public health concern. DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.											

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 ARID. **DISCLAIMER:** Dietary data from the UK were included in PRIMO when the UK was a member of the EU.

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children

No. of commodities for which ARID/ADI is exceeded (ESTI):

Results for adults

No. of commodities for which ARID/ADI is exceeded (ESTI):

ESTI

Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
60%	Milk: Cattle	0.5 / 0.5	62
13%	Bovine: Liver	1.5 / 1.5	12
13%	Milk: Goat	0.5 / 0.5	12
12%	Bovine: Edible offals	1.5 / 1.5	11
6%	Bovine: Kidney	1.5 / 1.5	5.6
5%	Swine: Edible offals	1.5 / 1.5	4.5
5%	Wheat	0.3 / 0.3	4.3
4%	Swine: Muscle/meat	0.3 / 0.3	3.6
2%	Sheep: Muscle/meat	0.4 / 0.4	2.2
2%	Bovine: Muscle/meat	0.3 / 0.3	2.2
2%	Other farmed animals:	0.3 / 0.3	2.1
2%	Swine: Kidney	1.5 / 1.5	1.9
2%	Eggs: Chicken	0.15 / 0.15	1.9
2%	Swine: Liver	1.5 / 1.5	1.8
2%	Equine: Muscle/meat	0.3 / 0.3	1.8

Expand/collapse list

Results for children

No. of commodities for which ARID/ADI is exceeded (ESTI):

Results for adults

No. of commodities for which ARID/ADI is exceeded (ESTI):

ESTI

Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
21%	Milk: Cattle	0.5 / 0.5	19
10%	Milk: Goat	0.5 / 0.5	9.2
8%	Milk: Sheep	0.5 / 0.5	7.6
7%	Bovine: Liver	1.5 / 1.5	6.0
6%	Bovine: Edible offals (other	1.5 / 1.5	5.0
5%	Sheep: Liver	1.5 / 1.5	4.2
4%	Swine: Edible offals (other	1.5 / 1.5	3.9
4%	Swine: Kidney	1.5 / 1.5	3.3
4%	Bovine: Kidney	1.5 / 1.5	3.2
3%	Wheat	0.3 / 0.3	2.5
2%	Swine: Liver	1.5 / 1.5	2.1
2%	Sheep: Muscle/meat	0.4 / 0.4	1.9
2%	Bovine: Muscle	0.3 / 0.3	1.7
2%	Other farmed animals:	0.3 / 0.3	1.7
2%	Swine: Muscle/meat	0.3 / 0.3	1.5

Expand/collapse list

Total number of commodities exceeding the ARID/ADI in children and adult diets (ESTI calculation)

ESTI new

Results for children

No. of commodities for which ARID/ADI is exceeded (ESTI new):

ESTI new

Results for adults

No. of commodities for which ARID/ADI is exceeded (ESTI new):

ESTI new

Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
69%	Milk: Cattle	0.5 / 0.5	62
13%	Bovine: Liver	1.5 / 1.5	12
13%	Milk: Goat	0.5 / 0.5	12
12%	Bovine: Edible offals	1.5 / 1.5	11
6%	Bovine: Kidney	1.5 / 1.5	5.6
5%	Swine: Edible offals	1.5 / 1.5	4.5
5%	Wheat	0.3 / 0.3	4.3
4%	Swine: Muscle/meat	0.3 / 0.3	3.6
2%	Sheep: Muscle/meat	0.4 / 0.4	2.2
2%	Bovine: Muscle/meat	0.3 / 0.3	2.2
2%	Swine: Kidney	1.5 / 1.5	1.9
2%	Eggs: Chicken	0.15 / 0.15	1.9
2%	Swine: Liver	1.5 / 1.5	1.8
2%	Equine: Muscle/meat	0.3 / 0.3	1.8
2%	Milk: Sheep	0.5 / 0.5	1.8

Expand/collapse list

ESTI new

Results for children

No. of commodities for which ARID/ADI is exceeded (ESTI new):

ESTI new

Results for adults

No. of commodities for which ARID/ADI is exceeded (ESTI new):

ESTI new

Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
21%	Milk: Cattle	0.5 / 0.5	19
10%	Milk: Goat	0.5 / 0.5	9.2
8%	Milk: Sheep	0.5 / 0.5	7.6
7%	Bovine: Liver	1.5 / 1.5	6.0
6%	Bovine: Edible offals (other	1.5 / 1.5	5.0
5%	Sheep: Liver	1.5 / 1.5	4.2
4%	Swine: Edible offals (other	1.5 / 1.5	3.9
4%	Swine: Kidney	1.5 / 1.5	3.3
4%	Bovine: Kidney	1.5 / 1.5	3.2
3%	Wheat	0.3 / 0.3	2.5
2%	Swine: Liver	1.5 / 1.5	2.1
2%	Sheep: Muscle/meat	0.4 / 0.4	1.9
2%	Bovine: Muscle	0.3 / 0.3	1.7
2%	Swine: Muscle/meat	0.3 / 0.3	1.5
2%	Equine: Muscle/meat	0.3 / 0.3	1.4

Expand/collapse list

Total number of commodities found exceeding the ARID/ADI in children and adult diets (ESTI new calculation)

Processed commodities

Results for children

No. of processed commodities for which ARID/ADI is exceeded (ESTI):

Results for adults

No. of processed commodities for which ARID/ADI is exceeded (ESTI):

ESTI

Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Wheat /milling (flour)	0.3 / 0.3	3.6
2%	Wheat /milling (wholemeal)	0.3 / 0.3	1.7

Expand/collapse list

Results for children

No. of processed commodities for which ARID/ADI is exceeded (ESTI):

Results for adults

No. of processed commodities for which ARID/ADI is exceeded (ESTI):

ESTI

Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat /bread/pizza	0.3 / 0.3	1.3
1%	Wheat /pasta	0.3 / 0.3	1.1
1%	Wheat /bread	0.3 / 0.3	1.0

Expand/collapse list

Results for children

No. of processed commodities for which ARID/ADI is exceeded (ESTI new):

Results for adults

No. of processed commodities for which ARID/ADI is exceeded (ESTI new):

ESTI new

Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Wheat /milling (flour)	0.3 / 0.3	3.6
2%	Wheat /milling	0.3 / 0.3	1.7

Expand/collapse list

ESTI new

Results for children

No. of processed commodities for which ARID/ADI is exceeded (ESTI new):

ESTI new

Results for adults

No. of processed commodities for which ARID/ADI is exceeded (ESTI new):

ESTI new

Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat /bread/pizza	0.3 / 0.3	1.3
1%	Wheat /pasta	0.3 / 0.3	1.1
1%	Wheat /bread (wholemeal)	0.3 / 0.3	1.0

Expand/collapse list

Total number of commodities found exceeding the ARID/ADI in children and adult diets (ESTI new calculation)

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity. Ashort term intake of residues of Chloromequat chloride is unlikely to present a public health risk. For processed commodities, no exceedance of the ARID/ADI was identified.

7.3 References

EFSA (European Food Safety Authority), 2008. Conclusion regarding the peer review of the pesticide risk assessment of the active substance Chlormequat (considered variant Chlormequat chloride). 29 September 2008 (EFSA Scientific Report (2008) 179, 1-77).

EFSA (European Food Safety Authority), 2016. Review of the existing maximum residues levels for Chlormequat according to Article 12 of Regulation (EC) No. 396/2005. 7 March 2016 (EFSA Journal 2016;14(3):4422)

United Kingdom, 2007. Draft Assessment Report (DAR), Chlormequat, Volume 3, Annex B, part 3, B.7, November 2007

United Kingdom, 2008. Final addendum to the Draft Assessment Report (DAR), Chlormequat, July 2008

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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 8.3.1.1	D. Gąszczyk	2021	Quantitative analysis of Chlormequat chloride residues in winter wheat in field conditions (Raw Agricultural Commodity) after one application of a formulated product Chlormequat chloride 720 SL – two harvest and two decline trials in Northern Europe – Poland, 2020, Report No.: PB-2021-35 Fertice Sp z o.o. – Laboratorium GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.1.2	D. Gąszczyk	2021	Quantitative analysis of Chlormequat chloride residues in winter wheat in field conditions (Raw Agricultural Commodity) after one application of a formulated product Chlormequat chloride 720 SL – two harvest and two decline trials in Northern Europe – Hungary, 2020, Report No.: PB-2021-31 Fertice Sp z o.o. – Laboratorium GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 8.3.1.1-2	Michał Tartanus	2022	Magnitude of the residue of chlormequat chloride in winter wheat (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product Chlormequat chloride 720 SL – two harvest and two decline curve trials in Northern Europe – Poland, 2020, Report No.: D-2020-27 Fertico Sp. z o.o. Agricultural Research Service GLP Unpublished	N	Sharda Cropchem Ltd.

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 8.3.1.2-2	Gábor Wágner	2022	Determination of the residues of chlormequat chloride in/on winter wheat after one application of chlormequat chloride 720 SL in Northern Europe - Hungary in 2020. Report No.: 065CPRHU20R28 CPR Europe Kft. GLP Unpublished	N	Sharda Cropchem Ltd.

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
	Zietz E.	2004	Determination of the storage stability of chlormequat chloride in cereal (grain and straw) and selected processed fractions of wheat and barley. Institut Fresenius, Project no. IF-101/23411-00 GLP, Unpublished	N	CCC Task Force
	Zenide D.	2002	Freezer storage stability of Chlormequat-Chloride in milk, eggs and edible tissues. Battelle, Project no. A-51-01-01 GLP, Unpublished	N	CCC Task Force
	Keller E.	1990	Radioactive residues and studies on the metabolism of ¹⁴ C-chlormequat chloride (ccc, BAS 062W in spring wheat. BASF AG, Report no. BASF 90/0299 GLP, Unpublished	N	CCC Task Force
	Veit P.	2003	Confined Rotational Crop study with ¹⁴ C-Chlormequatchloride. BASF AG, Report no. doc.	N	CCC Task Force

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
			2003/1004686 GLP, Unpublished		
	Hofmann M.	1992	Rotational-Crop-Studie mit 14C-Chlormequat-chlorid. BASF AG, Report no. doc. 92/10223 GLP, Unpublished	N	BASF AG
	Adam D.	2004	14C-Chlormequat-chloride: simulated processing. RCC Ltd, Report no. 854870 GLP, Unpublished	N	Nufarm
	Phillips M., McCombe W.S., Gedik L.	2003a	Report Amendment 1: The distribution and metabolism of [14C]-Chlormequat Chloride in the lactating goat. Report No.: 20589 GLP, Unpublished	N	CCC Task Force
	Phillips M., McCombe W.S., Gedik L.	2004	Report Amendment 1: The distribution and metabolism of [14C]-Chlormequat Chloride in the lactating goat. Report No.: 200554 GLP, Unpublished	N	CCC Task Force
	Phillips M., McCombe W.S., Gedik L.	2003a	The distribution and metabolism of [14C]-Chlormequat Chloride in the lying hen. Report No.: 20357 GLP, Unpublished	N	CCC Task Force
	Raunft E., Mackenroth C.	2005	Study on the residue behaviour of chlormequat-chlorid in wheat after application of BAS 062 00 W and BAS 062 03 W under field conditions in Germany, France (N&S) and the United Kingdom, 2004 (study code 176257). BASF AG, Report no. 2005/1014176 Trial ref: ACK/03/04 Trial ref: FAN/03/04 Trial ref: OAT/01/04 GLP, Unpublished	N	CCC Task Force
	Schulz H.	2005	Study on the residue behaviour of BAS 062 W in cereals after application of BAS 062 24 W and BAS 062 03 W under field conditions in France (S and N),	N	CCC Task Force

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
			Germany and United Kingdom, 2003 (study code 161200). BASF AG, DocID 2004/1015956 Trial ref: DU2/07/03 GLP, Unpublished		
	Zietz E., Klimmek S.	2004	Determination of the residues of chlormequat chloride in wheat and in the processed fractions bran, flour, whole-meal and bread following one treatment under field conditions in Germany Season 2001. Institut Fresenius, Report no. IF-101/11753-00 GLP, Unpublished	N	Nufarm

The following tables are to be completed by MS.

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 Chlormequat chloride

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

A 2.1.1.1.2 Storage stability of residues in animal products

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

A 2.1.2.1.2 Nature of residue in rotational crops

A 2.1.2.1.3 Nature of residues in processed commodities

A 2.1.2.2 Nature of residues in livestock

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Wheat

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)
Intended cGAP (1)	1	0.936-1.51 kg a.s./ha	-	BBCH 29-32	-

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

A 2.1.3.1.1 Study 1

Comments of zRMS: Study is accepted

Reference: KCP 8.3.1.1-2

Report: Magnitude of the residue of chlormequat chloride in winter wheat (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product Chlormequat chloride 720 SL – two harvest and two decline curve trials in Northern Europe – Poland, 2020, Michał Tartanus, 2022, Report No.: D-2020-27

Guideline(s): Yes
-Commission of the European Communities (Directorate General for Agriculture) Doc 7029/VI/95 rev.6. General recommendations for the design, preparation and realization of residue trials.
-509 OECD GUIDELINE FOR THE TESTING OF CHEMICALS- CROP FIELD TRIAL. Adopted 7 September 2009.

Deviations: No

GLP: Yes

Acceptability: Yes

Two harvest trials and two decline curves trial were established in central Poland. Trials consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negatively impacted the integrity and validity of this study.

One foliar application of Chlormequat chloride 720 SL was performed with a boom sprayer on the treated plot at a target dose rate of 2.1 L/ha (equivalent to 1512 g a.s./ha of chlormequat). Four trials were conducted in Poland in 2020. The field phase was performed in Błonie (D-2020-27-F01), in Stara Żelazna (D-2020-27-F02), in Stare Olszyny (D-2020-27-F03) and in Mokra (D-2020-27-F04). The target spray volume was 200-400 litres per hectare according to Good Agricultural Practices. The application was performed at BBCH 29-31.

In HS trials, RAC specimens for analyses were collected at normal commercial harvest. In decline curve trials (DCS), RAC specimens for analyses (whole plants, seeds and straw) were collected as follows:

- At 20 days before the normal commercial harvest (U+T)
- At 10 days before the normal commercial harvest (U+T)
- At the normal commercial harvest (U+T)

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.1.1
Report	Quantitative analysis of Chlormequat chloride residues in winter wheat in field conditions (Raw Agricultural Commodity) after one application of a formulated product Chlormequat chloride 720 SL – two harvest and two decline trials in Northern Europe – Poland, 2020, Dorota Gąszczyk, 2021, Report No.: PB-2021-35
Guideline(s):	Yes SANTE/12682/2019 SANTE/2020/12830, rev. 1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Preparation of samples on winter wheat whole plant, grain and straw

Portion A was taken for preparation in treated and untreated samples. Analytical samples were prepared for the determination of chlormequat chloride residues in winter wheat whole plant, grain and straw samples by LC-MS/MS. Two control samples (K1, K2) from each untreated sample, three treated samples (T1, T2, T3) from each of treated samples, six fortified samples F1-F3 (at fortification level 0.01 mg/kg) and F4-F6 (at fortification level 0.1 mg/kg) from untreated samples and calibration curves on matrix from an untreated sample were prepared.

Weighing

Samples were mixed and weighted into 50 ml PP flacons in a weighting room, using a scale Radwag PS 1000.X2. Weighting 5 g +/- 0.05 g (winter wheat whole plant and grain) or 2 g +/- 0.05 g (winter wheat straw) of a homogenous sample.

Addition of acetonitrile

To each sample, 10 ml of water and 10 ml of 1% HCOOH in methanol were added to receive a final volume of 20 ml. The tube was closed and shaken vigorously by hand in room temperature for 1 min to 3 min. Then samples were shaken vigorously for 15 min using shaker and centrifuged for 5 min at 5500 rpm. Fortified samples were prepared by the addition of a proper amount of standard solution R1 (1 µg/ml) and R0 (10 µg/ml) and to the spiked sample, 10 ml of water and proper amount of 1% HCOOH in methanol were added to the final volume of 20 ml.

Preparation of analytical sample for chromatographic analysis

A clear methanol layer of sample at the volume of 0.5 ml and 10 µl of Chlormequat chloride D4 (10 µg/ml) was transferred into an Eppendorf tube. Samples were diluted to the final volume of 1 ml by water. Additionally, samples were centrifuged for 10 min at 9 rpm. Prepared samples were filtered with 0.22 µm PTFE into the injection vial for LC-MS/MS.

Chromatographic parameters

Solvent used for preparing samples: acetonitrile, methanol

Autosampler: with cooling (constant temperature 10°C)

Injection volume: 2µL

Injection mode: 200 µL/min

Chromatographic column: ZORBAX HILIC Plus with dimensions of 2.1 x 100 mm and gran diameter 3.5 µm, series number USCJP02725

Binary pump:

solvent A: 20mM ammonium formate, 0.4% formic acid in water,
 solvent B: acetonitrile with LC-MS purity,
 flow rate: 0.5 mL/min

Parameters of MS-Triple Quadrupole Acquisition Method

Analyte	Rt [min]	Ion Transitions	Collision Energy [V]	Cell Accelerator Voltage	Fragmentor	Polarity
Chlormequat chloride	4.48	122 → 63.1	22	4	127	Positive
		122 → 58.2	30			
Chlormequat chloride D4	4.48	126 → 67	20	4	75	Positive
		126 → 58	25			

Accuracy and precision

Accuracy was determined based on the amplification of control samples prepared from untreated samples with known amounts of standards using solutions R1 (1 µg/mL) and R0 (10 µg/mL).

Precision was determined by repeatability (relative standard deviation - RSD).

The average recovery values for the 0.01 mg/kg and 0.1 mg/kg gain levels were in the range of 70-120% and therefore comply with the standard acceptance criteria in the SANTE guidelines. All RSD values for the testes fortification levels 0.01 mg/kg and 0.1 mg/kg were <20%.

Table A 2: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Chlormequat (sum of chlormequat and its salts, ex- pressed as chlormequat chlo- ride)		
D-2020-27- F01/Poland/N- EU/2020 Blonie	Winter wheat	1. 08.10.2019 2. 07-15.06.2020 3. 31.07.2020	1512	400	-	14.04.2020	BBCH 30	Grain Starw	0.2389 1.6438	106 106	Analytical part Report No.: PB-2021-35 LOD: 0.00015 mg/kg LOQ: 0.01 mg/kg
D-2020-27- F02/Poland/N- EU/2020 Stara Żelazna	Winter wheat	1. 21.10.2019 2. 25.05-04.06.2020 3. 10-17.08.2020	1512	400	-	18.04.2020	BBCH 31	Grain Straw	0.0463 1.2510	111 111	Analytical part Report No.: PB-2021-35 LOD: 0.00015 mg/kg LOQ: 0.01 mg/kg
D-2020-27- F03/Poland/N- EU/2020 Stare Olszyny	Winter wheat	1. 02.10.2019 2. 04-14.06.2020 3. 06.08.2020	1512	400	-	06.04.2020	BBCH 31	Whole plant Whole plant Grain Straw	0.1750 0.3591 0.0759 0.7995	102 112 122 122	Analytical part Report No.: PB-2021-35 LOD: 0.00015 mg/kg LOQ: 0.01 mg/kg
D-2020-27- F04/Poland/N- EU/2020 Mokra	Winter wheat	1. 05.10.2019 2. 06-15.06.2020 3. 06.08.2020	1512	400	-	06.04.2020	BBCH 31	Whole plant Whole plant Grain Straw	0.4635 0.9680 0.0064 (<LOQ) 1.8011	99 108 120 120	Analytical part Report No.: PB-2021-35 LOD: 0.00015 mg/kg LOQ: 0.01 mg/kg

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.3.1.2 Study 2

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.1.2-2
Report	Determination of the residues of chlormequat chloride in/on winter wheat after one application of chlormequat chloride 720 SL in Northern Europe - Hungary in 2020, Gábor Wágner, 2022, Report No.: 065CPRHU20R28
Guideline(s):	<p>Yes</p> <ul style="list-style-type: none"> - "Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997. - OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in 14 June 2021) - European Community Guidelines SANCO 7525/VI/95 – Rev 10.3, 13 June 2017: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of this study is to provide results from the magnitude of residues of Chlormequat Chloride 720 SL in/on winter wheat in order to support the registration of the plant protection product applied according to Good Laboratory Practice (GLP).

Four trials were conducted in Hungary in 2020. The field phase was performed in Nemesvámos (CPRHU20-223-065GR), in Pápa (CPRHU20-224-065GR), in Szombathely (CPRHU20-225-065GR) and in Kám (CPRHU20-226-065GR).

One application (between 29-31 BBCH of the crop) of the formulated product Chlormequat Chloride 720 SL (containing nominal concentration of 72 % chlormequat chloride) was applied at a rate of 2.1 L formulated product/ha (1512 g active ingredient/ha) onto the crop, under open field condition.

Specimens (whole plant, seed, straw) were collected at 20 and 10 days before harvest (DBH) and at harvest in decline trial and at harvest in harvest trial, frozen and shipped deep frozen to analytical facility of Fertico for residue analysis.

There was no unusual event that affected this phase of the study.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.1.2
Report	Quantitative analysis of Chlormequat chloride residues in winter wheat in field conditions (Raw Agricultural Commodity) after one application of a formulated product Chlormequat chloride 720 SL – two harvest and two decline trials in Northern Europe – Hungary, 2020, Dorota Gąszczyk, 2021, Report No.: PB-2021-31
Guideline(s):	<p>Yes</p> <p>SANTE/12682/2019</p> <p>SANTE/2020/12830, rev. 1</p>
Deviations:	No
GLP:	Yes

Acceptability: Yes

Preparation of samples on winter wheat whole plant, grain and straw

Portion A was taken for preparation in treated and untreated samples. Analytical samples were prepared for the determination of chlormequat chloride residues in winter wheat whole plant, grain and straw samples by LC-MS/MS. Two control samples (K1, K2) from each untreated sample, three treated samples (T1, T2, T3) from each of treated samples, six fortified samples F1-F3 (at fortification level 0.01 mg/kg) and F4-F6 (at fortification level 0.1 mg/kg) from untreated samples and calibration curves on matrix from an untreated sample were prepared.

Weighing

Samples were mixed and weighted into 50 ml PP flacons in a weighting room, using a scale Radwag PS 1000.X2. Weighting 5 g +/- 0.05 g (winter wheat whole plant and grain) or 2 g +/- 0.05 g (winter wheat straw) of a homogenous sample.

Addition of acetonitrile

To each sample, 10 ml of water and 10 ml of 1% HCOOH in methanol were added to receive a final volume of 20 ml. The tube was closed and shaken vigorously by hand in room temperature for 1 min to 3 min. Then samples were shaken vigorously for 15 min using shaker and centrifuged for 5 min at 5500 rpm. Fortified samples were prepared by the addition of a proper amount of standard solution R1 (1 µg/ml) and R0 (10 µg/ml) and to the spiked sample, 10 ml of water and proper amount of 1% HCOOH in methanol were added to the final volume of 20 ml.

Preparation of analytical sample for chromatographic analysis

A clear methanol layer of sample at the volume of 0.5 ml and 10 µl of Chlormequat chloride D4 (10 µg/ml) was transferred into an Eppendorf tube. Samples were diluted to the final volume of 1 ml by water. Additionally, samples were centrifuged for 10 min at 9 rpm. Prepared samples were filtered with 0.22 µm PTFE into the injection vial for LC-MS/MS.

Chromatographic parameters

Solvent used for preparing samples: acetonitrile, methanol

Autosampler: with cooling (constant temperature 10°C)

Injection volume: 2 µL

Injection mode: 200 µL/min

Chromatographic column: ZORBAX HILIC Plus with dimensions of 2.1 x 100 mm and gran diameter 3.5 µm, series number USCJP02725

Binary pump:

solvent A: 20mM ammonium formate, 0.4% formic acid in water,

solvent B: acetonitrile with LC-MS purity,

flow rate: 0.5 mL/min

Parameters of MS-Triple Quadrupole Acquisition Method

Analyte	Rt [min]	Ion Transitions	Collision Energy [V]	Cell Accelerator Voltage	Fragmentor	Polarity
Chlormequat chloride	4.48	122 → 63.1	22	4	127	Positive
		122 → 58.2	30			
Chlormequat chloride D4	4.48	126 → 67	20	4	75	Positive
		126 → 58	25			

Accuracy and precision

Accuracy was determined based on the amplification of control samples prepared from untreated samples with known amounts of standards using solutions R1 (1 µg/mL) and R0 (10 µg/mL).

Precision was determined by repeatability (relative standard deviation - RSD).

The average recovery values for the 0.01 mg/kg and 0.1 mg/kg gain levels were in the range of 70-120% and therefore comply with the standard acceptance criteria in the SANTE guidelines. All RSD values for the testes fortification levels 0.01 mg/kg and 0.1 mg/kg were <20%.

Table A 3: Summary of the study 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Chlormequat (sum of chlormequat and its salts, ex- pressed as chlormequat chloride)		
(a)	(b)	(b)				(c)				(d)	(e)
CPRHU20-223- 065GR/Hungary/N- EU/2020 Nemesvámos	Winter wheat	1. 15.10.2019 2. end of May 2020 3. July 2020	1512	300	-	30.04.2020	BBCH 31	Grain Straw	0.3020 5.0014	63 63	Analytical part Report No.: PB-2021-31 LOD: 0.00015 mg/kg LOQ: 0.01 mg/kg
CPRHU20-224- 065GR/Hungary/N- EU/2020 Pápa	Winter wheat	1. 05.10.2019 2. end of May 2020 3. July 2020	1512	300	-	30.04.2020	BBCH 31	Grain Straw	0.2976 4.4560	63 63	Analytical part Report No.: PB-2021-31 LOD: 0.00015 mg/kg LOQ: 0.01 mg/kg
CPRHU20-225- 065GR/Hungary/N- EU/2020 Szombathely	Winter wheat	1. 17.10.2019 2. end of May 2020 3. July 2020	1512	300	-	30.04.2020	BBCH 31	Whole plant Whole plant Grain Straw	1.1107 1.0050 0.3582 0.3434	43 54 64 64	Analytical part Report No.: PB-2021-31 LOD: 0.00015 mg/kg LOQ: 0.01 mg/kg
CPRHU20-226- 065GR/Hungary/N- EU/2020 Kám	Winter wheat	1. 17.10.2019 2. end of May 2020 3. July 2020	1512	300	-	30.04.2020	BBCH 29	Whole plant Whole plant Grain Straw	1.2661 0.7652 0.3258 4.8074	43 54 64 64	Analytical part Report No.: PB-2021-31 LOD: 0.00015 mg/kg LOQ: 0.01 mg/kg

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Table A 4: Summary of the studies in N-EU

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Chlormequat		
	(a)	(b)				(c)				(d)	(e)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Chlormequat		
N-EU/UK/1978	Winter wheat/Flanders	-	1620	225		08/05/1978	6-7 leaf early jointing	Grain Straw	<0.1 1.2	112 112	
N-EU/UK/1978	Winter wheat/Maris Huntsman	-	1620	225		01/06/1978	7-8 leaf early jointing	Grain Straw	0.43 2.0	105 105	
N-EU/UK/1978	Winter wheat/Maris Huntsman	-	1680	-	-	03/05/1978		Grain Straw	<0.1 1.0	100 100	
N-EU/UK/1978	Winter wheat/Maris Huntsman	-	3360	-	-	03/05/1978	-	Grain Straw	<0.1 2.0	100 100	
	Winter wheat/sportsman	-	3360	-	-	16/05/1978	-	Grain Straw	<0.1 2.0	91 91	
N-EU/Austria/1992	Winter wheat/Ikarus	-	1380	300		06/05/1992	GS 32	Whole plant Whole plant Plant without ear Ear Straw Grain	23 3.4 3.5 3.4 0.53 0.07	0 14 29 29 79 79	
N-EU/Austria/1992	Winter wheat/Ikarus		1440	300		06/05/1992	GS 32	Whole plant Whole plant Plant without ear Ear Straw Grain	24 4.9 2.3 6.3 0.86 0.08	0 14 29 29 79 79	
N-EU/Germany/1986	Winter wheat/Kanzler		1380	300		29/04/1986	GS 22-25	Plant Plant Plant Plant Straw Grain	134 8.6 1.7 1.4 0.5 0.14	0 31 52 65 129 129	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Chlormequat		
N-EU/Germany/1986	Winter wheat/Kanzler		1380	400		05/05/1986		Plant Plant Plant Plant Straw Grain	100 1.0 0.8 0.3 0.9 0.17	0 29 49 63 94 94	
N-EU/Germany/1973	Winter wheat/Diplomat		1150	-	-	18/04/1973		Plant Plant Plant Plant Straw Grain	423 3.71 1.55 0.73 0.29 0.07	0 28 56 84 106 106	
N-EU/Germany/1973	Winter wheat/Diplomat		1150	-	-	13/04/1973		Plant Plant Plant Plant Straw Grain	503 40.2 2.20 0.80 1.62 0.09	0 29 56 84 119 119	
N-EU/Germany/1974	Winter wheat/Caribo		1150	-	-	21/05/1973	G/H	Plant Plant Plant Straw Grain	304 1.55 0.60 0.68 0.16	0 58 84 99 99	
N-EU/Germany/1974	Winter wheat/Caribo		1150	-	-	18/04/1974	G/H	Plant Plant Plant Plant Straw Grain	11.4 3.14 0.68 0.55 0.12 0.12	0 27 57 76 135 135	
N-EU/Germany/1974	Winter wheat/Diplomat		1150	450		22/04/1974	G	Plant Plant Plant Plant Straw Grain	17.0 2.07 1.00 0.56 0.41 0.20	0 28 57 84 122 122	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Chlormequat		
N-EU/UK/1976	Winter wheat/Flinor		1610	250		28/04/1978	GS 6 (=31)	Straw Grain	5.4 0.05	93 93	
N0EU/UK/1977	Winter wheat/Armada		1610	250		30/04/1977	GS 5-6 (=30- 31)	Whole plant Grain Straw	1.4 0.3 0.5	51 131 131	
N-EU/UK/1977	Winter wheat/Maris Huntsman		1610	250		24/03/1977	GS 5 (=30)	Whole plant Whole plant Grain	3.9 1.9 0.2	61 93 164	
N-EU/UK/1977	Winter wheat/Maris Huntsman		1610	250		29/04/1977	GS 5-6 (=30- 31)	Whole plant Whole plant Straw Grain	4.4 2.7 2.6 <0.05	32 60 125 125	
N-EU/UK/1978	Spring wheat/Sappo		800	225		08/06/1978	7-8leaf 1 st joint	Grain Straw	<0.1 1.5	95 95	
N-EU/UK/1978	Spring wheat/Maris Dove		840	-	-	30/05/1978	-	Straw Grain	0.05 0.1	87 87	
N-EU/UK/1978	Spring wheat/Maris Dove		1680	-	-	30/05/1978	-	Straw Grain	1.0 0.5	87 87	
N-EU/Germany/2004	Winter wheat/Thasos		1520 BAS 062 00 W	150		08/05/04	GS 37	Grain Straw	0.331 26.0	94 94	ACK/03/04 Raunft, E., Mackenroth, C., 2005
			1500 BAS 062 03 W					Grain Straw	<u>0.453</u> <u>31.3</u>	94 94	
N-EU/France/2004	Winter wheat/Cap Horn		1520 BAS 062 00 W	150		05/05/2004	GS 34	Grain Straw	<u>0.744</u> <u>4.06</u>	68 68	FAN/03/04 Raunft, E., Mackenroth, C., 2005
			1500 BAS 062 03 W					Grain Straw	0.728 3.11	68 68	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Chlormequat		
N-EU/UK/2004	Spring wheat/Paragon		1520 BAS 062 00 W	150		02/06/2004	GS 37	Grain Straw	<u>0.804</u> 13.8	78 78	OAT/01/04 Raunft, E., Mackenroth, C., 2005
			1500 BAS 062 03 W					Grain Straw	0.762 <u>18.8</u>	78 78	
N-EU/Germany/2003	Winter wheat/Transit		700 BAS 062 24 W	100		15/05/03	GS 37	Whole plant Ears Shoots Grain Straw	15.16 0.20 7.20 <u>0.26</u> <u>16.73</u>	0 18 18 57 57	
			1500 BAS 062 03 W					Whole plant Ears Shoots Grain Straw	20.92 0.73 8.53 0.20 13.39	0 18 18 57 57	

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies


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

A 2.1.6 Magnitude of residues in representative succeeding crops

A 2.1.7 Other/Special Studies

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations (Reg. (EU) 2020/1565)



European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Chlormequat

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw/day): 0.04 ARID (mg/kg bw): 0.05

Source of ADI: Source of ARID:

Year of evaluation: Year of evaluation:

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 : 12						Exposure resulting from MRLs set at the LOQ (in % of ADI)		
	Calculated exposure (% of ADI)	MS Diet	Exposure (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	
TMDI/IEDI calculation (based on average food consumption)	222%	DK child	88.72	110%	Rye	77%	Wheat	16%	Milk: Cattle	0.2%
	184%	NL toddler	73.70	75%	Milk: Cattle	69%	Wheat	17%	Rapeseeds/canola seeds	0.9%
	135%	GEMS/Food G08	53.95	127%	Wheat	3%	Milk: Cattle	1%	Barley	0.5%
	125%	DE child	49.98	74%	Wheat	25%	Milk: Cattle	16%	Rye	0.7%
	120%	NL child	47.88	72%	Wheat	31%	Milk: Cattle	6%	Rapeseeds/canola seeds	0.7%
	119%	GEMS/Food G08	47.51	71%	Wheat	16%	Barley	12%	Rye	0.4%
	117%	IT toddler	46.77	116%	Wheat	0.2%	Barley	0.1%	Cultivated fungi	0.2%
	117%	FR child 3-15 yr	46.73	80%	Wheat	29%	Milk: Cattle	3%	Oat	0.4%
	115%	GEMS/Food G15	46.12	80%	Wheat	14%	Barley	9%	Milk: Cattle	0.4%
	112%	GEMS/Food G07	44.72	74%	Wheat	11%	Barley	10%	Rapeseeds/canola seeds	0.4%
	107%	UK infant	42.69	48%	Milk: Cattle	46%	Wheat	9%	Oat	0.2%
	105%	RO general	42.13	89%	Wheat	15%	Milk: Cattle	0.9%	Swine: Muscle/meat	0.3%
	99%	UK toddler	39.53	69%	Wheat	26%	Milk: Cattle	2%	Oat	0.3%
	99%	GEMS/Food G10	39.40	69%	Wheat	10%	Barley	7%	Milk: Cattle	0.4%
	97%	ES child	38.75	76%	Wheat	16%	Milk: Cattle	1%	Bovine: Muscle/meat	0.3%
	96%	FR toddler 2-3 yr	38.58	54%	Wheat	37%	Milk: Cattle	2%	Oat	0.4%
	92%	GEMS/Food G11	36.76	63%	Wheat	14%	Barley	10%	Milk: Cattle	0.5%
	82%	SE general	32.74	56%	Wheat	15%	Milk: Cattle	6%	Rye	0.3%
	75%	DE general	30.12	33%	Wheat	15%	Milk: Cattle	12%	Rye	0.4%
	74%	PT general	29.48	69%	Wheat	3%	Rye	1%	Oat	0.2%
	73%	IT adult	29.16	72%	Wheat	0.2%	Barley	0.1%	Cultivated fungi	0.2%
	72%	DE women 14-50 yr	26.79	38%	Wheat	15%	Milk: Cattle	10%	Rye	0.4%
	59%	IE adult	23.79	40%	Wheat	7%	Oat	5%	Milk: Cattle	0.4%
	58%	NL general	23.77	34%	Wheat	11%	Milk: Cattle	5%	Barley	0.3%
	58%	FI 3 yr	23.43	22%	Oat	21%	Wheat	13%	Rye	0.2%
	58%	ES adult	23.26	41%	Wheat	9%	Barley	6%	Milk: Cattle	0.2%
	51%	LT adult	20.36	22%	Rye	16%	Wheat	5%	Milk: Cattle	0.1%
	48%	FR adult	19.10	39%	Wheat	6%	Milk: Cattle	0.6%	Oat	0.2%
	44%	FI 6 yr	17.41	17%	Wheat	12%	Rye	12%	Oat	0.2%
	43%	UK vegetarian	17.28	36%	Wheat	4%	Milk: Cattle	2%	Oat	0.1%
	39%	DK adult	15.53	20%	Wheat	11%	Rye	7%	Milk: Cattle	0.1%
	36%	FR infant	14.37	21%	Milk: Cattle	14%	Wheat	0.3%	Swine: Muscle/meat	0.2%
	36%	UK adult	14.20	29%	Wheat	4%	Milk: Cattle	0.6%	Oat	0.1%
	26%	FI adult	10.40	14%	Rye	6%	Wheat	5%	Oat	0.6%
	26%	IE child	10.30	20%	Wheat	4%	Milk: Cattle	0.4%	Oat	0.0%
	0.6%	PL general	0.24	0.3%	Cultivated fungi	0.1%	Potatoes	0.1%	Apples	0.1%

Conclusion:
The estimated TMDI/IEDI was in the range of 0 % to 221.8 % of the ADI.
For 12 diet(s) the ADI is exceeded.


New TMDI calculations based on new MRL Regulation (Reg. (EU) 2022/1290):

 European Food Safety Authority EFSA PRIMo revision 3.1; 2019/03/19		Chlomequat				Input values					
		LOQs (mg/kg) range from:		to:		Details - chronic risk assessment					
		Toxicological reference values				Supplementary results - chronic risk assessment					
		ADI (mg/kg bw/day): 0.04		ARID (mg/kg bw): 0.05		Details - acute risk assessment/children					
Source of ADI:		Source of ARID:		Details - acute risk assessment/adults							
Year of evaluation:		Year of evaluation:									
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
		No of diets exceeding the ADI : 12				Exposure resulting from					
	Calculated exposure (% of ADI)	MS Diet	Exposure (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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/IEDI calculation (based on average food consumption)	222%	DK child	68.72	110%	Rye	77%	Wheat	16%	Milk: Cattle		77%
	184%	NL toddler	73.70	75%	Milk: Cattle	69%	Wheat	17%	Rapeseeds/canola seeds		69%
	135%	GEM/IFood G08	53.95	127%	Wheat	3%	Milk: Cattle	1%	Barley		127%
	125%	DE child	49.98	74%	Wheat	25%	Milk: Cattle	16%	Rye		74%
	120%	NL child	47.68	72%	Wheat	31%	Milk: Cattle	8%	Rapeseeds/canola seeds		72%
	119%	GEM/IFood G08	47.51	71%	Wheat	16%	Barley	12%	Rye		71%
	117%	IT toddler	46.77	116%	Wheat	0.2%	Barley	0.1%	Cultivated fungi		116%
	117%	FR child 3-15 yr	46.73	80%	Wheat	29%	Milk: Cattle	3%	Oat		80%
	115%	GEM/IFood G15	46.12	80%	Wheat	14%	Barley	9%	Milk: Cattle		80%
	112%	GEM/IFood G07	44.72	74%	Wheat	11%	Barley	10%	Rapeseeds/canola seeds		74%
	107%	UK infant	42.69	48%	Milk: Cattle	46%	Wheat	9%	Oat		48%
	105%	RO general	42.13	89%	Wheat	15%	Milk: Cattle	0.9%	Swine: Musclemeat		89%
	99%	UK toddler	39.53	69%	Wheat	26%	Milk: Cattle	2%	Oat		69%
	99%	GEM/IFood G10	39.40	69%	Wheat	10%	Barley	7%	Milk: Cattle		69%
	97%	ES child	38.75	78%	Wheat	16%	Milk: Cattle	1%	Bovine: Musclemeat		78%
	96%	FR toddler 2-3 yr	38.58	54%	Wheat	37%	Milk: Cattle	2%	Oat		54%
	92%	GEM/IFood G11	36.76	63%	Wheat	14%	Barley	10%	Milk: Cattle		63%
	82%	SE general	32.74	56%	Wheat	15%	Milk: Cattle	6%	Rye		56%
	75%	DE general	30.12	33%	Wheat	15%	Milk: Cattle	12%	Rye		33%
	74%	PT general	29.48	69%	Wheat	3%	Rye	1%	Oat		69%
	73%	IT adult	29.16	72%	Wheat	0.2%	Barley	0.1%	Cultivated fungi		72%
	72%	DE women 14-50 yr	28.79	38%	Wheat	15%	Milk: Cattle	10%	Rye		38%
	59%	IE adult	23.79	40%	Wheat	7%	Oat	5%	Milk: Cattle		40%
	59%	NL general	23.77	34%	Wheat	11%	Milk: Cattle	5%	Barley		34%
	59%	FI 3 yr	23.43	22%	Oat	21%	Wheat	13%	Rye		21%
	58%	ES adult	23.26	41%	Wheat	9%	Barley	6%	Milk: Cattle		41%
	51%	LT adult	20.36	22%	Rye	18%	Wheat	5%	Milk: Cattle		18%
	48%	FR adult	19.10	39%	Wheat	6%	Milk: Cattle	0.6%	Oat		39%
	44%	FI 6 yr	17.41	17%	Wheat	12%	Rye	12%	Oat		17%
	43%	UK vegetarian	17.28	38%	Wheat	4%	Milk: Cattle	2%	Oat		38%
	39%	DK adult	15.53	20%	Wheat	11%	Rye	7%	Milk: Cattle		20%
	36%	FR infant	14.37	21%	Milk: Cattle	14%	Wheat	0.3%	Swine: Musclemeat		14%
	36%	UK adult	14.20	29%	Wheat	4%	Milk: Cattle	0.6%	Oat		29%
	26%	FI adult	10.40	14%	Rye	6%	Wheat	5%	Oat		6%
26%	IE child	10.30	20%	Wheat	4%	Milk: Cattle	0.4%	Oat		20%	
0.6%	PL general	0.24	0.3%	Cultivated fungi	0.1%	Potatoes	0.1%	Apples			
Conclusion: The estimated TMDI/IEDI was in the range of 0 % to 221.8 % of the ADI. For 12 diet(s) the ADI is exceeded.											

A 3.2 IEDI calculations (Reg. (EU) 2020/1565)

 European Food Safety Authority EFSA PRIMo revision 3.1; 2019/03/19		Chlormequat LOQs (mg/kg) range from: 0.01 to: 0.05 Toxicological reference values ADI (mg/kg bw/day): 0.04 ARID (mg/kg bw): 0.05 Source of ADI: Source of ARID: Year of evaluation: Year of evaluation:				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 : ---						Exposure resulting from			
	Calculated exposure (% of ADI)	MS Diet	Exposure (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	MRLs set at the LOQ (in % of ADI)	Commodities not under assessment (in % of ADI)
TMDI/NIEDI calculation (based on average food consumption)	34%	NL toddler	13.80	17%	Rapeseeds/canola seeds	9%	Wheat	2%	Oat	0.9%	
	31%	DK child	12.34	15%	Rye	11%	Wheat	3%	Oat	0.2%	
	24%	GEMSiFood G07	9.77	10%	Wheat	10%	Rapeseeds/canola seeds	1%	Barley	0.4%	
	22%	NL child	8.88	10%	Wheat	8%	Rapeseeds/canola seeds	0.7%	Bovine: Muscle/meat	0.7%	
	21%	GEMSiFood G08	8.47	10%	Wheat	8%	Rapeseeds/canola seeds	2%	Rye	0.4%	
	20%	GEMSiFood G08	8.03	17%	Wheat	0.8%	Rapeseeds/canola seeds	0.5%	Cotton seeds	0.5%	
	18%	GEMSiFood G15	7.39	11%	Wheat	4%	Rapeseeds/canola seeds	1%	Barley	0.4%	
	18%	GEMSiFood G10	7.20	9%	Wheat	5%	Rapeseeds/canola seeds	1.0%	Barley	0.4%	
	16%	IT toddler	6.55	16%	Wheat	0.1%	Cultivated fungi	0.1%	Pears	0.2%	
	16%	DE child	6.49	10%	Wheat	2%	Rye	2%	Oat	0.7%	
	15%	FR child 3-15 yr	5.93	11%	Wheat	1%	Bovine: Muscle/meat	0.6%	Oat	0.4%	
	13%	RO general	5.39	12%	Wheat	0.3%	Milk: Cattle	0.2%	Bovine: Muscle/meat	0.3%	
	13%	SE general	5.19	8%	Wheat	3%	Bovine: Muscle/meat	0.8%	Rye	0.3%	
	13%	ES child	5.17	11%	Wheat	1%	Bovine: Muscle/meat	0.3%	Milk: Cattle	0.3%	
	12%	GEMSiFood G11	4.97	9%	Wheat	1%	Barley	0.5%	Bovine: Muscle/meat	0.5%	
	12%	UK toddler	4.91	9%	Wheat	1.0%	Bovine: Muscle/meat	0.5%	Milk: Cattle	0.3%	
	12%	NL general	4.76	5%	Wheat	5%	Rapeseeds/canola seeds	0.5%	Bovine: Muscle/meat	0.3%	
	12%	UK infant	4.70	6%	Wheat	2%	Oat	1.0%	Milk: Cattle	0.2%	
	11%	FI 3 yr	4.44	4%	Oat	3%	Wheat	2%	Rye	0.2%	
	11%	PT general	4.32	9%	Wheat	0.4%	Rye	0.3%	Wine grapes	0.2%	
	11%	FR toddler 2-3 yr	4.27	7%	Wheat	0.9%	Bovine: Muscle/meat	0.7%	Milk: Cattle	0.4%	
	10%	IT adult	4.12	10%	Wheat	0.1%	Cultivated fungi	0.0%	Pears	0.2%	
	10%	IE adult	3.93	6%	Wheat	1%	Oat	0.5%	Cultivated fungi	0.4%	
	9%	DE general	3.77	5%	Wheat	2%	Rye	0.9%	Barley	0.4%	
	9%	DE women 14-50 yr	3.66	5%	Wheat	1%	Rye	0.8%	Oat	0.4%	
	8%	FI 6 yr	3.17	2%	Oat	2%	Wheat	2%	Rye	0.2%	
	8%	ES adult	3.17	6%	Wheat	0.8%	Barley	0.6%	Bovine: Muscle/meat	0.2%	
	7%	FR adult	2.88	5%	Wheat	0.5%	Bovine: Muscle/meat	0.3%	Wine grapes	0.2%	
	7%	LT adult	2.80	3%	Rye	3%	Wheat	0.7%	Oat	0.1%	
	6%	UK vegetarian	2.44	5%	Wheat	0.4%	Oat	0.3%	Cultivated fungi	0.1%	
	5%	UK adult	2.14	4%	Wheat	0.5%	Bovine: Muscle/meat	0.1%	Cultivated fungi	0.1%	
	5%	DK adult	2.12	3%	Wheat	1%	Rye	0.4%	Bovine: Muscle/meat	0.1%	
	5%	FI adult	1.91	2%	Rye	1%	Oat	0.8%	Wheat	0.8%	
	3%	IE child	1.27	3%	Wheat	0.1%	Milk: Cattle	0.1%	Oat	0.0%	
3%	FR infant	1.22	2%	Wheat	0.4%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.2%		
0.8%	PL general	0.24	0.3%	Cultivated fungi	0.1%	Potatoes	0.1%	Apples	0.1%		
Conclusion: The estimated long-term dietary intake (TMDI/NIEDI) was below the ADI. The long-term intake of residues of Chlormequat is unlikely to present a public health concern.											

New IEDI calculations based on new MRL Regulation (Reg. (EU) 2022/1290):

 European Food Safety Authority EFSA PRIMo revision 3.1; 2019/03/19		Chlomequat				Input values					
		LOQs (mg/kg) range from:		to:		Details - chronic risk assessment Supplementary results - chronic risk assessment					
		Toxicological reference values									
		ADI (mg/kg bw/day):		0.04		ARID (mg/kg bw):		0.09			
Source of ADI:		Source of ARID:		Details - acute risk assessment/children		Details - acute risk assessment/adults					
Year of evaluation:		Year of evaluation:									
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
No of diets exceeding the ADI : ---											
TMDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (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)	commodities not under assessment (in % of ADI)
	45%	DK child	17.85	15%	Rye	14%	Oat	11%	Wheat		11%
	44%	NL toddler	17.75	17%	Rapeseeds/canola seeds	9%	Wheat	7%	Oat		9%
	40%	GEMSiFood G08	16.07	16%	Barley	10%	Wheat	6%	Rapeseeds/canola seeds		10%
	39%	GEMSiFood G07	15.71	11%	Barley	10%	Wheat	10%	Rapeseeds/canola seeds		10%
	34%	GEMSiFood G15	13.64	14%	Barley	11%	Wheat	4%	Rapeseeds/canola seeds		11%
	31%	GEMSiFood G10	12.29	10%	Barley	9%	Wheat	5%	Rapeseeds/canola seeds		9%
	29%	FI 3 yr	11.74	22%	Oat	3%	Wheat	2%	Rye		3%
	27%	GEMSiFood G11	10.98	14%	Barley	9%	Wheat	2%	Oat		9%
	25%	NL child	9.86	10%	Wheat	8%	Rapeseeds/canola seeds	2%	Oat		10%
	24%	DE child	9.41	10%	Wheat	8%	Oat	2%	Rye		10%
	22%	GEMSiFood G08	8.78	17%	Wheat	1%	Barley	0.8%	Rapeseeds/canola seeds		17%
	22%	DE general	8.68	9%	Barley	5%	Wheat	4%	Oat		5%
	20%	UK infant	7.89	9%	Oat	6%	Wheat	1.0%	Milk: Cattle		6%
	19%	FR child 3-15 yr	7.71	11%	Wheat	3%	Oat	1%	Bovine: Muscle/meat		11%
	19%	NL general	7.46	5%	Barley	5%	Wheat	5%	Rapeseeds/canola seeds		5%
	18%	FI 6 yr	7.32	12%	Oat	2%	Wheat	2%	Rye		2%
	17%	IE adult	6.79	7%	Oat	6%	Wheat	0.8%	Sheep: Liver		6%
	17%	ES adult	6.68	9%	Barley	6%	Wheat	0.6%	Bovine: Muscle/meat		6%
	17%	IT toddler	6.62	16%	Wheat	0.2%	Barley	0.1%	Cultivated fungi		16%
	16%	DE women 14-50 yr	6.44	5%	Wheat	4%	Oat	3%	Barley		5%
	15%	RO general	5.85	12%	Wheat	0.9%	Swine: Muscle/meat	0.3%	Milk: Cattle		12%
	15%	ES child	5.84	11%	Wheat	1%	Bovine: Muscle/meat	0.9%	Swine: Muscle/meat		11%
	14%	UK toddler	5.70	9%	Wheat	2%	Oat	1.0%	Bovine: Muscle/meat		9%
	14%	FR toddler 2-3 yr	5.60	7%	Wheat	2%	Oat	0.9%	Bovine: Muscle/meat		7%
	13%	SE general	5.31	8%	Wheat	3%	Bovine: Muscle/meat	0.8%	Rye		8%
	12%	PT general	4.87	9%	Wheat	1%	Oat	0.5%	Barley		9%
	12%	LT adult	4.63	3%	Oat	3%	Rye	3%	Wheat		3%
	10%	IT adult	4.18	10%	Wheat	0.2%	Barley	0.1%	Cultivated fungi		10%
	9%	FI adult	3.61	5%	Oat	2%	Rye	0.8%	Wheat		0.8%
	9%	FR adult	3.44	5%	Wheat	0.6%	Oat	0.5%	Swine: Muscle/meat		5%
	8%	UK vegetarian	3.18	5%	Wheat	2%	Oat	0.3%	Barley		5%
8%	UK adult	2.56	4%	Wheat	0.6%	Oat	0.5%	Bovine: Muscle/meat		4%	
6%	DK adult	2.52	3%	Wheat	1%	Rye	0.7%	Swine: Muscle/meat		3%	
4%	IE child	1.52	3%	Wheat	0.4%	Oat	0.1%	Swine: Muscle/meat		3%	
3%	FR infant	1.38	2%	Wheat	0.4%	Milk: Cattle	0.3%	Swine: Muscle/meat		2%	
0.6%	PL general	0.24	0.3%	Cultivated fungi	0.1%	Potatoes	0.1%	Apples			
Conclusion: The estimated long-term dietary intake (TMDI/IEDI) was below the ADI. The long-term intake of residues of Chlomequat is unlikely to present a public health concern.											

A 3.3 IESTI calculations - Raw commodities (Reg. (EU) 2020/1565)

Show results of IESTI calculation only for crops with GAPs under assessment								
Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): 1				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	112%	Wheat	7 / 7	101	65%	Wheat	7 / 7	59
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation): 1								

After refinement with Input Values from EFSA 2016

Show results of IESTI calculation only for crops with GAPs under assessment												
Unprocessed commodities	Results for children					Results for adults						
	No. of commodities for which ARfD/ADI is exceeded (IESTI):					No. of commodities for which ARfD/ADI is exceeded (IESTI):						
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	IESTI					IESTI						
	Highest % of ARfD/ADI		Commodities		MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI		Commodities		MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	15%		Wheat		7 / 0.96	14	9%		Wheat		7 / 0.96	8.1
Expand/collapse list												
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)												

New IESTI calculations – Raw commodities based on new MRL Regulation (Reg. (EU) 2022/1290):

Show results of IESTI calculation only for crops with GAPs under assessment									
Unprocessed commodities	Results for children					Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):					No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	1					---			
	IESTI					IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)		Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	112%	Wheat	7 / 7	101		65%	Wheat	7 / 7	59
Expand/collapse list									
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)					1				

After refinement with Input Values from EFSA 2016

Show results of IESTI calculation only for crops with GAPs under assessment										
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):				
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	IESTI					IESTI				
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)		Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
	15%	Wheat	7 / 0.96	14		9%	Wheat	7 / 0.96	8.1	
Expand/collapse list										
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)										

[illegible]

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	IESTI				IESTI			
	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)
	13%	Wheat / milling (flour)	7 / 0.96	12	5%	Wheat / bread/pizza	7 / 0.96	4.2
6%	Wheat / milling (wholemeal)-baking	7 / 0.96	5.3	4%	Wheat / pasta	7 / 0.96	3.7	
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	4%	Wheat / bread (wholemeal)	7 / 0.96	3.4	
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	
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Processed commodities	Results for children				Results for adults				
	No of processed commodities for which ARfD/ADI is exceeded (ESTI):				No of processed commodities for which ARfD/ADI is exceeded (ESTI):				
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IESTI				IESTI					
	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)
	94%	Wheat / milling (flour)	7 / 7	85		34%	Wheat / bread/pizza	7 / 7	31
	43%	Wheat / milling (wholemeal)-baking	7 / 7	39		30%	Wheat / pasta	7 / 7	27
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!		27%	Wheat / bread (wholemeal)	7 / 7	24
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Processed commodities	Results for children					Results for adults				
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):					No of processed commodities for which ARfD/ADI is exceeded (IESTI):				
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	IESTI					IESTI				
	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)	
	13%	Wheat / milling (flour)	7 / 0.96	12		5%	Wheat / bread/pizza	7 / 0.96	4.2	
6%	Wheat / milling (wholemeal)-baking	7 / 0.96	5.3		4%	Wheat / pasta	7 / 0.96	3.7		
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No additional information provided by the applicant.