FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 126085 A

Product name: MEPCY

Chemical active substances:

Chlormequat chloride, 345 g/L

Mepiquat chloride, 115 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem Ltd.

Submission date: February 2022

MS Finalisation date: May 2023, August 2023

Version history

When	What
December 2022	Applicant update
May 2023	ZRMs evaluated updated dRR by Applicant
July 2023	Applicant update
August 2023	Final Registration Report

Table of Contents

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, 0.69 kg a.s./ha (chlormequat chloride)

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)

These trials are done at higher doses than the proposed one. Despite this, the studies are accepted as “worst case situation”.

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 Chlormequat 34.5% + Mepiquat 11.5% SL do not represent unacceptable acute and chronic risks for the consumer.

<u>Mepiquat chloride</u>

Stability of Residues

Residues of Mepiquat-chloride are stable for at least 24 months in wheat forage, wheat grain and wheat straw and for at least 12 months in bran, flour, wholemeal bread, pot barley, brewing malt and beer.

Residues of Mepiquat-chloride are stable for at least 26 months in cow liver, cow kidney, cow muscle, cow fat, chicken muscle, milk and eggs.

Additional studies are not required.

Metabolism in plants and animals

The metabolism in plants and livestock for the active substance was reviewed during the Annex I inclusion process.

Plant and animal residue definition for monitoring Mepiquat (sum of Mepiquat and its salts, expressed as Mepiquat chloride) (Reg. (EU) 2021/976)

Plant residue definition for risk assessment Sum of Mepiquat and its salts, expressed as Mepiquat chloride (EFSA Scientific report (2008) 146, 1-73)

Animal residue definitions for risk assessment (EFSA Journal 2018;16(7):5380):

For risk assessment, the residue definition was set as the sum of mepiquat, 4-hydroxy mepiquat and their salts, expressed as mepiquat chloride (EFSA, 2008). Based on the metabolism data, EFSA derived a conversion factor for monitoring to risk assessment of 1.7 in ruminant liver. In all other animal matrices and since the parent mepiquat was the only significant compound of the total residues, a conversion factor of 1 was deemed to be sufficient.

Additional data are not required for the proposed uses.

Magnitude of residues in plants

Proposed uses:

1 application, BBCH 29-32, 0.23 kg a.s./ha (Mepiquat chloride)

Applicant refers to EU unprotected data.

Trials GAP: 1 x 0.76 kg as/ha, BBCH 30-39

Sufficient trials on barley are available to support the proposed uses. According to the SANTE/2019/12752 extrapolation to wheat is possible.

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

Uses are accepted.

Magnitude of residues in livestock

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.

Magnitude of residues in processed commodities

Studies investigating the magnitude of residues in processed commodities of cereals were reported in the EU review. Processing factors for enforcement and risk assessment were derived in processed products of barley, wheat and rape seed. The data provided are sufficient to support the proposed uses.

Magnitude of residues in representative succeeding crops

Based on the confined rotational crop study evaluated during the peer review, significant residues are not expected in the succeeding crops. Rotational crop field trials are therefore not required.

Estimation of exposure through diet and other means

The proposed uses of Mepiquat chloride in the formulation Chlormequat 34.5% + Mepiquat 11.5% SL do not represent unacceptable acute and chronic risks for the consumer. Calculation is accepted.

Other / special studies

Wheat have not melliferous capacity. Studies are not required.

Combined exposure and risk assessment

The Hazard Index is <1. Thus combined exposure to all active substances in Chlormequat 34.5% + Mepiquat 11.5% SL is not expected to present a consumer risk. No further refinement of the assessment is required.

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 Chlormequat 34.5% + Mepiquat 11.5% SL are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central Zone for winter wheat. A list of all intended uses within the Central Zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of Mepiquat chloride or 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~~.
Proposed label restriction: do not use straw from wheat treated with chlormequat as horticultural growth medium in cultivation of fungi.

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 a) a.s. 1 b) a.s. 2**	**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**		
1	**Winter wheat**	CEU	SHA 126085 A	F	Reduction of height to prevent lodging	SL	a) 34.5% b) 11.5%	Foliar spray	BBCH 29-32	1	-	0.1725 chlormequat chloride + 0.0575 mepiquat chloride – 0.345 chlormequat chloride + 0.115 mepiqat chloride	200-400	0.69 Chlormequat chloride + 0.23 Mepi-quat chloride	-	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 Chlormequat 34.5% + Mepiquat 11.5% SL is composed of Chlormequat chloride and Mepiquat chloride.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of Chlormequat and Mepiquat

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 god study	100
Mepiquat chloride					
ADI	EFSA	2008	0.2 mg/kg bw/d	12-month dietary study in dogs	100
ARfD	EFSA	2008	0.3 mg/kg bw	Development neurotoxicity study in rats	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 Mepiquat chloride

Table 7.1-4: Summary for Mepiquat 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

7.1.2.3 Summary for Chlormequat 34.5% + Mepiquat 11.5% SL

Table 7.1-5: Information on Chlormequat 34.5% + Mepiquat 11.5% SL (KCA 6.8)

Crop	PHI for SHA 126085 A proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for SHA 126085 A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Chlormequat chloride	Mepiquat chloride		
Winter wheat	NR	NR	NR		

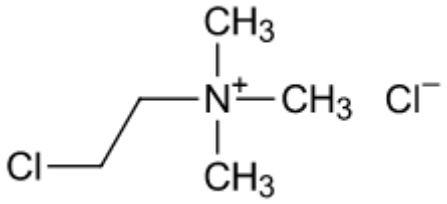
NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Assessment

7.2 Chlormequat chloride

General data on Chlormequat chloride are summarized in the table below (last updated 2022/02/17).

Table 7.2-1: General information on Chlormequat chloride

Active substance (ISO Common Name)	Chlormequat chloride
IUPAC	2-chloroethyltrimethylammonium chloride
Chemical structure	
Molecular formula	$C_5H_{13}Cl_2N$
Molar mass	158.1 g/mol
Chemical group	Quarternary ammonium compound
Mode of action (if available)	Inhibits cell elongation
Systemic	Yes
Companies	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 ≤ - 18°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		

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 treatment, 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-^{14}C]-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 ((trimethylammonio)acetate) 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

The definition for plants 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	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
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
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

* 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-^{14}C]-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-^{14}C]-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, 0.041and 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.

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	-

7.2.2.4 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 position	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 livestock 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 recov-

ered 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

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

7.2.2.5 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	-
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 Chlormequat 34.5% + Mepiquat 11.5% SL 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: 1.512 kg 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: <0.01, 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: 1.512 kg 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	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	4.258	31.30	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 (EFSA, 2016)**	**Input value (mg/kg)**	**Comment (EFSA, 2016)**
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 (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 by-pdts	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) - Animal model 2017.

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 4 until day 28

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 0), 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 126085 A, 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 rev.3.1	**With MRL values from ~~Reg. (EU) No 2020/1565:~~ Reg. (EU) 2022/1290:** 222% based on DK child
IEDI (% ADI) according to EFSA PRIMo rev.3.1	**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
IESTI (% ARfD) according to EFSA PRIMo rev.3.1	**Unprocessed commodities:** Results for children: Wheat: 15% Results for adults: Wheat: 9% **Processed commodities:** Results for children: Wheat/ milling (flour): 13% Wheat/ milling (wholemeal)-baking: 6% Results for adults: Wheat/ bread/ pizza: 5% Wheat/ pasta: 4% Wheat/ bread (wholemeal): 4%
NTMDI (% ADI)	-
NEDI (% ADI)	-
NESTI (% ARfD)	-

The proposed uses of Chlormequat chloride in the formulation Chlormequat 34.5% + Mepiquat 11.5% 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 commodities:

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

The proposed uses of Chlormequat chloride in the formulation Chlormequat 34.5% + Mepiquat 11.5% SL do not represent unacceptable acute and chronic risks for the consumer.

EFSA PRIMo revision 3.1; 2021/01/06

Chlormequat chloride

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

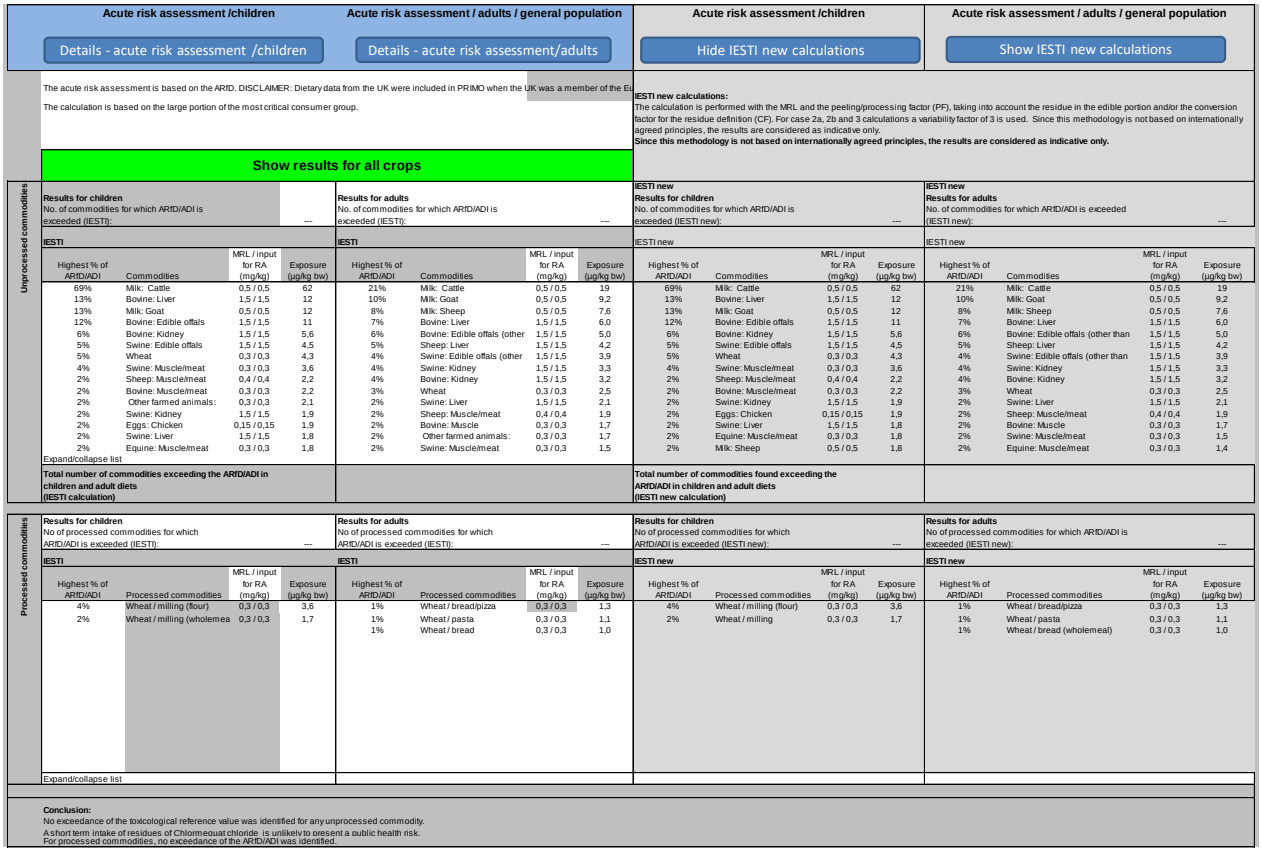
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	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		FRUIT AND TREE NUTS				

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/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 | Acute risk assessment /children | Acute risk assessment / adults / general population

Details - acute risk assessment /children | Details - acute risk assessment/adults | Hide IESTI new calculations | Show IESTI new calculations

The acute risk assessment is based on the ARfD. 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.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children (IESTI)				Results for adults (IESTI)				Results for children (IESTI new)				Results for adults (IESTI new)			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI new):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI new):			---
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)	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)
69%	Milk: Cattle	0,5 / 0,5	62	21%	Milk: Cattle	0,5 / 0,5	19	69%	Milk: Cattle	0,5 / 0,5	62	21%	Milk: Cattle	0,5 / 0,5	19
13%	Bovine: Liver	1,5 / 1,5	12	10%	Milk: Goat	0,5 / 0,5	9,2	13%	Bovine: Liver	1,5 / 1,5	12	10%	Milk: Goat	0,5 / 0,5	9,2
13%	Milk: Goat	0,5 / 0,5	12	8%	Milk: Sheep	0,5 / 0,5	7,6	13%	Milk: Goat	0,5 / 0,5	12	8%	Milk: Sheep	0,5 / 0,5	7,6
12%	Bovine: Edible offals	1,5 / 1,5	11	7%	Bovine: Liver	1,5 / 1,5	6,0	12%	Bovine: Edible offals	1,5 / 1,5	11	7%	Bovine: Liver	1,5 / 1,5	6,0
6%	Bovine: Kidney	1,5 / 1,5	5,6	6%	Bovine: Edible offals (other	1,5 / 1,5	5,0	6%	Bovine: Kidney	1,5 / 1,5	5,6	6%	Bovine: Edible offals (other than	1,5 / 1,5	5,0
5%	Swine: Edible offals	1,5 / 1,5	4,5	5%	Sheep: Liver	1,5 / 1,5	4,2	5%	Swine: Edible offals	1,5 / 1,5	4,5	5%	Sheep: Liver	1,5 / 1,5	4,2
5%	Wheat	0,3 / 0,3	4,3	4%	Swine: Edible offals (other	1,5 / 1,5	3,9	5%	Wheat	0,3 / 0,3	4,3	4%	Swine: Edible offals (other than	1,5 / 1,5	3,9
4%	Swine: Muscle/meat	0,3 / 0,3	3,6	4%	Swine: Kidney	1,5 / 1,5	3,3	4%	Swine: Muscle/meat	0,3 / 0,3	3,6	4%	Swine: Kidney	1,5 / 1,5	3,3
2%	Sheep: Muscle/meat	0,4 / 0,4	2,2	4%	Bovine: Kidney	1,5 / 1,5	3,2	2%	Sheep: Muscle/meat	0,4 / 0,4	2,2	4%	Bovine: Kidney	1,5 / 1,5	3,2
2%	Bovine: Muscle/meat	0,3 / 0,3	2,2	3%	Wheat	0,3 / 0,3	2,5	2%	Bovine: Muscle/meat	0,3 / 0,3	2,2	3%	Wheat	0,3 / 0,3	2,5
2%	Other farmed animals:	0,3 / 0,3	2,1	2%	Swine: Liver	1,5 / 1,5	2,1	2%	Swine: Kidney	1,5 / 1,5	1,9	2%	Swine: Liver	1,5 / 1,5	2,1
2%	Swine: Kidney	1,5 / 1,5	1,9	2%	Sheep: Muscle/meat	0,4 / 0,4	1,9	2%	Eggs: Chicken	0,15 / 0,15	1,9	2%	Sheep: Muscle/meat	0,4 / 0,4	1,9
2%	Eggs: Chicken	0,15 / 0,15	1,9	2%	Bovine: Muscle	0,3 / 0,3	1,7	2%	Swine: Liver	1,5 / 1,5	1,8	2%	Bovine: Muscle	0,3 / 0,3	1,7
2%	Swine: Liver	1,5 / 1,5	1,8	2%	Other farmed animals:	0,3 / 0,3	1,7	2%	Equine: Muscle/meat	0,3 / 0,3	1,8	2%	Swine: Muscle/meat	0,3 / 0,3	1,5
2%	Equine: Muscle/meat	0,3 / 0,3	1,8	2%	Swine: Muscle/meat	0,3 / 0,3	1,5	2%	Milk: Sheep	0,5 / 0,5	1,8	2%	Equine: Muscle/meat	0,3 / 0,3	1,4
Expand/collapse list															
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)**							

Processed commodities

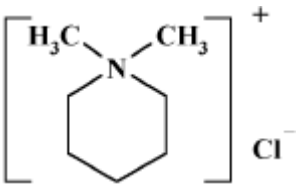
Results for children (IESTI)				Results for adults (IESTI)				Results for children (IESTI new)				Results for adults (IESTI new)			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Wheat / milling (flour)	0,3 / 0,3	3,6	1%	Wheat / bread/pizza	0,3 / 0,3	1,3	4%	Wheat / milling (flour)	0,3 / 0,3	3,6	1%	Wheat / bread/pizza	0,3 / 0,3	1,3
2%	Wheat / milling (wholemea	0,3 / 0,3	1,7	1%	Wheat / pasta	0,3 / 0,3	1,1	2%	Wheat / milling	0,3 / 0,3	1,7	1%	Wheat / pasta	0,3 / 0,3	1,1
				1%	Wheat / bread	0,3 / 0,3	1,0					1%	Wheat / bread (wholemeal)	0,3 / 0,3	1,0
Expand/collapse list															

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Chlormequat chloride is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

7.3 Mepiquat chloride

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

Table 7.3-1: General information on Mepiquat chloride

Active substance (ISO Common Name)	Mepiquat chloride
IUPAC	1,1-dimethylpiperidinium chloride
Chemical structure	
Molecular formula	$C_7H_{16}ClN$
Molar mass	149.7 g/mol
Chemical group	Quaternary ammonium compound
Mode of action (if available)	Inhibits biosynthesis of gibberellic acid
Systemic	Yes
Company	BASF
Rapporteur Member State (RMS)	RMS: Finland Co-RMS: Estonia
Approval status	Approved Date of (01/03/2009) and reference to decision (COM-

	MISSION DIRECTIVE 2008/108/EC - REGULATION (EU) No 540/2011)
Restriction	Only uses as plant growth regulator may be authorised
Review Report	SANCO/106/08 – rev. 2 20 May 2008
Current MRL regulation	Reg. (EU) 2021/976
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) 146, 1-73)
EFSA Journal: conclusion on article 12	Yes (EFSA Journal 2015;13(8):4214)
Current MRL applications on intended uses	EFSA-Q-2009-00119 All commodities Status: Reasoned opinion available (EFSA Journal 2015;13(8):4214)

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, YYYY - see list of references

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.3-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat forage	High water content	24 months	W. Kerl, C. Mackenroth, 2003a Report No. 2003/1001370 DAR, Belgium, 2006 EFSA, 2008
Wheat grain and straw	High starch content	24 months	
Wheat product (bran, flour, wholemeal bread, pot barley, brewing malt, beer)	High starch content	12 months	W. Kerl, C. Mackenroth, 2003b Report No. 2003/1001372 DAR, Belgium, 2006 EFSA, 2008
Animal Products			
Ruminant	Cow liver	26 months	J.,Burkey, M. Riley, 1995 Report No. 1995/5096 DAR, Belgium, 2006 EFSA, 2008
Ruminant	Cow kidney	26 months	
Ruminant	Cow muscle	26 months	
Ruminant	Cow fat	26 months	
Poultry	Hen muscle	26 months	

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Ruminant	Cow milk	26 months	
Poultry	Hen eggs	26 months	

Conclusion on stability of residues during storage

Residues of Mepiquat-chloride are stable for at least 24 months in wheat forage, wheat grain and wheat straw and for at least 12 months in bran, flour, wholemeal bread, pot barley, brewing malt and beer.
Residues of Mepiquat-chloride are stable for at least 26 months in cow liver, cow kidney, cow muscle, cow fat, chicken muscle, milk and eggs.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

No data was submitted and required at EU level during the EU review of Mepiquat chloride.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-3: 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								
Fruits and fruiting vegetable	Grapes	^{14}C Mepiquat-chloride	foliar treatment, F	1.1	2	98	-	J. R. Patel, N. F. Wood, 1985 Report No. 1985/5003 DAR, Belgium, 2006 EFSA, 2008
Pulses and oilseeds	Cotton	^{14}C Mepiquat-chloride	foliar treatment, F	0.16	1	15, 67	-	A. J. Goetz, 1992, 1993 Report No. 1992/5069; 1993/5141 DAR, Belgium, 2006 EFSA, 2008
Cereals	Wheat	^{14}C Mepiquat-	foliar treatment,	0.7	1	0, 8, 71	-	U. Rabe, H. Schleuter,

		chloride	G					2003 Repor No. 2003/1001377 DAR, Belgium, 2006 EFSA, 2008
	Barley	^{14}C Mepiquat-chloride	foliar treatment, G	0.91	1	16, 37, 52	-	R. Huber, 1979b Report No. 1979/10152 DAR, Belgium, 2006 EFSA, 2008

Summary of plant metabolism studies reported in the EU

The metabolism of Mepiquat-chloride was investigated in wheat, barley, cotton and grapes, by applying ring labelled [^{14}C] Mepiquat-chloride as a foliar application, at a rate of 0.7 kg as/ha (0.9N) to wheat; 0.91 kg as/ha (1.2N) to barley; 0.16 kg as/ha to cotton seed and 1.1 kg as/ha to grapes. At harvest the total [^{14}C] residues (expressed as parent equivalent) were 0.78 mg/kg in wheat grain; 10 mg/kg in wheat straw; 1.8 mg/kg barley grain; 5.1 mg/kg barley straw; cotton seed 0.96 mg/kg and 1.1 mg/kg grapes.
On extraction and characterisation, one major component was identified in the crops at harvest as parent Mepiquat-chloride, which accounted for at least 59% of the total radioactivity in the crops at harvest. Several unknown polar metabolites were isolated, which individually did not represent more than 5% (0.04 mg/kg) of the total radioactivity in the crops. The remaining unextractable radioactivity in the crops accounted for less than 7% (0.05 mg/kg) of the total radioactivity in the crops at harvest, with the exception of wheat straw (10% - 1.0 mg/kg) and barley straw (18% - 0.9 mg/kg). The unextractable radioactivity in the crops at harvest was probably associated with the fragmentation of the ring and the natural incorporation of these fragments into the plant tissue.

Conclusion on metabolism in primary crops

The residue definition for both enforcement and risk assessment in plant products is the sum of Mepiquat and its salts, expressed as Mepiquat chloride.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-4: 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	^{14}C Mepiquat-chloride	Bare ground application, G	0.7	29, 120, 365	At maturity	-	P. Veit, W. E. Glaessgen, 2003 Report No.

Root and tuber vegetables	Radish	^{14}C Mepiquat-chloride	Bare ground application, G	0.7	29, 120, 365	At maturity	-	2003/1001376 DAR, Belgium, 2006 EFSA, 2008
Cereals	Wheat	^{14}C Mepiquat-chloride	Bare ground application, G	0.7	29, 120, 365	At maturity	-	

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

Summary of plant metabolism studies reported in the EU

Mepiquat has a DT_{90} of less than 100 days and therefore the submission of rotational crop data was not a requirement. Nevertheless, the metabolism and distribution in rotational crops was investigated in lettuce, wheat and radish. The crops were grown in soil that had been treated with ring labelled ^{14}C -Mepiquat chloride, at 0.9 N rate compared to cGAP rate. The plant-back intervals were 29 days, 120 days and 365 days, respectively.
The enrichment of radioactivity in the plants indicated uptake of residues from the soil. Total residue levels in wheat and radish crops were similar for the plant-back intervals 29 and 120 days, but had significantly dropped in the crops planted after 365 days. At the 120 days plant-back interval the TRR in the mature edible crop parts reached 0.03 mg/kg in radish roots and 0.44 in wheat grain and was comparable to the levels found in the non-edible crop parts, i.e. in radish tops (0.04 mg/kg) and in wheat straw (0.36 mg/kg). In lettuce, however no total residues above 0.01 mg/kg were found at all three plant-back intervals.
On characterisation of the extractable radioactivity one component was identified in the crops at harvest as Mepiquat, however with one exception (wheat chaff, 120 days) the levels were all below 0.01 mg/kg. Two polar metabolites were isolated, which individually were present at levels of less than 0.05 mg/kg in the crops, and thus were not further identified. The remaining extractable radioactivity was probably associated with metabolites (free, conjugated and incorporated) resulting from the fragmentation of the ring. The unextractable radioactivity in the crops accounted for less than 0.05 mg/kg and was probably associated with fragments of the ring that had been incorporated into natural plant products.
No rotational crop residue trial data was submitted. Though there was enrichment to significant levels of total radioactivity in the edible part of rotated crops, Mepiquat per se was not found to be present at levels greater than 0.01 mg/kg. Moreover, in the rotational crop metabolism study the application was made to bare soil and does not reflect the conditions in practice, i.e. the interception by cereals at GS 31 to GS 49 (70% to 90% of applied substance).
Therefore, it is not expected that residues above the LOQ of the analytical method for monitoring (0.05 mg/kg) will occur in rotational crops in practice.

Conclusion on metabolism in rotational crops

The metabolic pattern depicted in rotational crops was found to be more extensive than in primary crops. However, as no relevant residues are expected in the succeeding crops, a specific residue definition is not necessary.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Mepiquat chloride (>95%)	M. Singh, 2002

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Mepiquat chloride (>95%)	Report No. 2002/5003045 Belgium, 2006 EFSA, 2008
Sterilisation (20 minutes, 120°C, pH 6)	Mepiquat chloride (>95%)	

Conclusion on nature of residues in processed commodities

For all processed conditions (pasteurisation; baking, boiling and brewing and sterilisation) it can be conducted that mepiquat chloride is stable.

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

Table 7.3-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (wheat, barley)
	Oilseeds (cottton)
	Fruit (grapes)
Rotational crops covered	Leafy vegetables (lettuce)
	Cereals (wheat)
	Root and tuber vegetables (radish)
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
Plant residue definition for monitoring	Sum of Mepiquat and its salts, expressed as Mepiquat chloride (Regulation (EU) 2021/976)
Plant residue definition for risk assessment	Sum of Mepiquat and its salts, expressed as Mepiquat chloride (EFSA Scientific report (2008) 146, 1-73)
Conversion factor from enforcement to RA	None

7.3.2.5 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 7.3-7: Summary of animal metabolism studies

Group	Species	Label position	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 Mepiquat chloride	1	19	5	Milk	twice daily	Cheng T., 1988, Report No.: 1988/0605 Giesse U., 1988b, Report No.: 1988/0616 Grosshans, F. 1994, Report No.: 1994/10029 Jonas W., 1994a, b, Report No.: 1994/10044; 1994/10045 Kohl W., 1989b, 1991, Report No.: 1989/0424; 1990/10385 DAR, Belgium, 2006 EFSA, 2015
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	^{14}C Mepiquat chloride	15	18	6	Eggs	daily	Cheng T., 1989, Report No.: 1988/0606 Giesse U., 1988a Report No.: 1988/0604 Kohl W., 1989a, Report No.: 1989/0312 DAR, Belgium, 2006 EFSA, 2015
						Excreta	daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

For lactating goats dosed at a rate of ca 20 mg/kg bw the majority of the administered radioactivity was excreted, mainly with urine and faeces (76%) and less than 0.1% in the milk. Additional 22% was assumed to be present in the gastrointestinal tract due to the short period between the last dose and sacrifice. Only 2% was recovered in the tissues.
On extraction and characterisation one major component was identified in the milk and tissues as Mepiquat, representing 78-94% (milk 44%) of the total radioactivity in the milk and tissues. Several other metabolites were identified, plus several unknowns, which individually were present at levels of at or less than 0.1 mg/kg, with the exception of methyl piperidine which was present at a level of 0.5 mg/kg in kidney and 4-hydroxy-mepiquat which was present at a level of 6.9 mg/kg in liver. On further characterisation of the milk 53% of the total radioactivity was found to be associated with proteins; fats and carbohydrates, indicating the fragmentation of the ring and the natural incorporation of these fragments into proteins, fats and carbohydrates.

For chickens dosed at a rate of ca 20 mg/kg bw the majority, around 90% of administered radioactivity was recovered in the excreta; and individually less than 0.1% were present in the eggs and tissues. Among

the tissues analysed, kidney (2.8 mg/kg), liver (1.3 mg/kg) and eggs (1.3 mg/kg) had the highest residue levels. Levels in fat and skin (0.8 mg/kg) and muscle (0.3 mg/kg) were lower. After dosing for 6 consecutive days a plateau was not reached in the eggs. The tissue to plasma radioactivity concentration ratio indicated greater tendency for short-term bioaccumulation in kidney, liver and eggs.
On characterisation of the extractable radioactivity one major component was identified in the excreta, eggs and tissues as Mepiquat, representing 70-99% of the total radioactivity. In extracts of skin and muscle the metabolite methyl piperidine was found up to 9% of the TRR and in addition several minor metabolites, which individually were present at low levels and therefore not further identified

Conclusion on metabolism in livestock

Residue definition for monitoring of livestock commodities is set as the sum of mepiquat and its salts, expreesed as mepiquat chloride. For risk assessment, the residue definition should also include the metabolite 4-hydroxy mepiquat-chloride and is therefore proposed as the sum of mepiquat, 4-hydroxy mepiquat and their salts, expressed as mepiquat chloride.

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

Table 7.3-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats and laying hens
Time needed to reach a plateau concentration	3 days in milk Eggs: no plateau reached after 6 days, however the animal transfer study indicated that a plateau was reached after 10 days.
Animal residue definition for monitoring	Sum of Mepiquat and its salts, expressed as Mepiquat chloride (Regulation (EU) No. 2021/976)
Animal residue definition for risk assessment	Sum of mepiquat, 4-hydroxy-mepiquat-chloride and their salts, expressed as mepiquat chloride EFSA, 2018
Conversion factor	1.7 (ruminant liver) 1 (all other livestock commodities)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of Chlormequat 34.5% + Mepiquat 11.5% SL 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~~	~~Study on - going.~~	N/A				
Barley grain → extrapolated to wheat grain	Belgium, 2006 EFSA, 2008	N-EU	GAP on which EU a.s. assessment is based: 1 x 0.76 kg as/ha, BBCH 30-39, PHI 50-57d, outdoor Grain: 0.09, 0.39, 0.45, 0.53, 0.55, 0.73, 0.75, 1.0, 1.5					
	Overall supporting data for cGAP	N-EU	Grain: 0.09, 0.39, 0.45, 0.53, 0.55, 0.73, 0.75, 1.0, 1.5	0.55	1.5	2.281	3.0 (wheat) 4.0 (barley)	yes
~~Wheat straw~~	~~New trials~~	~~N-EU~~	~~Study on - going.~~	N/A				
Barley straw → extrapolated to wheat straw	Belgium, 2006 EFSA, 2008	N-EU	GAP on which EU a.s. assessment is based: 1 x 0.76 kg as/ha, BBCH 32-49, PHI 50-57d, outdoor Straw: 1.1, 1.2, 2.1, 2 x 2.3, 2.4, 2.5, 4.6, 5.9					
	Overall supporting	N-EU	Straw: 1.1, 1.2, 2.1, 2 x 2.3, 2.4, 2.5, 4.6, 5.9	2.3	5.9	8.951	-	-

	data for cGAP							

* Source of EU MRL: Regulation (EU) No. ~~2019/1791~~ Reg. (EU) 2021/976

7.3.3.2 Conclusion on the magnitude of residues in plants

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

~~To cover uses on wheat trials on-going.~~
According to ~~appendix D~~ SANTE/2019/12752 of EU guidelines, extrapolation from barley to wheat is possible with 9 N-EU trials ("before forming of the edible part" - before stage BBCH 51).

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

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

7.3.4.2 Dietary burden calculation

Table 7.3-10: 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 (EFSA, 2015)	Input value (mg/kg)	Comment (EFSA, 2015)
Risk assessment residue definition: Sum of mepiquat, 4-hydroxymepiquat and their salts, expressed as mepiquat chloride (EFSA, 2015)				
Barley straw	2.30	STMR	5.90	HR
Oat straw	2.30	STMR	5.90	HR
Cotton, undelinted seeds	1.76	STMR (EFSA, 2018)	1.76	STMR (EFSA, 2018)
Cotton, meal	3.34	STMR (1.76) * PF (1.9) (EFSA, 2018)	3.34	STMR (1.76) * PF (1.9) (EFSA, 2018)
Flaxseed/Linseed	18.40	STMR (11.50) * PF (1.6) (EFSA, 2018)	18.40	STMR (11.50) * PF (1.6) (EFSA, 2018)
Sunflower,meal	23.75	STMR (12.50) * PF (1.9) (EFSA, 2018)	23.75	STMR (12.50) * PF (1.9) (EFSA, 2018)
Rye straw	28.30	STMR	50.10	HR
Wheat straw	28.30	STMR	50.10	HR
Barley grain	0.70	STMR	0.70	STMR
Oat grain	0.70	STMR	0.70	STMR
Rye grain	0.60	STMR	0.60	STMR
Wheat grain	0.60	STMR	0.60	STMR
Brewer’s grain	2.31	STMR (0.70) * PF (3.3)	2.31	STMR (0.70) * PF (3.3)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment (EFSA, 2015)	Input value (mg/kg)	Comment (EFSA, 2015)
Canola (rape seed) meal	5.84	STMR (3.65) * PF (1.6) (EFSA, 2018)	5.84	STMR (3.65) * PF (1.6) (EFSA, 2018)
Distiller's grain dried	1.98	STMR (0.60) * PF (3.3)	1.98	STMR (0.60) * PF (3.3)
Rape meal	5.84	STMR (3.65) * PF (1.6)	5.84	STMR (3.65) * PF (1.6)
Wheat gluten meal	1.08	STMR (0.60) * PF (1.8)	1.08	STMR (0.60) * PF (1.8)
Wheat milled by-pdts	4.20	STMR (0.60) * PF (7)	4.20	STMR (0.60) * PF (7)

Table 7.3-11: Results of the dietary burden calculation (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 mepiquat, 4-hydroxymepiquat and their salts, expressed as mepiquat chloride (EFSA, 2015)					
Cattle (all diets)	0.380	0.571	Rye straw	17.03	Y
Cattle (dairy only)	0.380	0.571	Rye straw	14.84	Y
Sheep (all diets)	0.780	1.201	Rye straw	28.25	Y
Sheep (ewe only)	0.611	0.942	Rye straw	28.25	Y
Swine (all diets)	0.145	0.145	Flaxseed/linseed, meal	4.82	Y
Poultry (all diets)	0.440	0.610	Wheat straw	8.91	Y
Poultry (layer only)	0.440	0.610	Wheat straw	8.91	Y

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

7.3.4.3 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

Table 7.3-12: 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 Journal 2015;13(8):4214)												
Risk assessment residue definition: Sum of mepiquat, 4-hydroxymepiquat and their salts, expressed as mepiquat chloride												
Pig meat	0.145	0.145	0.42		< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	0.05*	1
Pig fat			0.42		< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	0.05*	1
Pig liver			0.42		0.14	0.19	0.14	0.19	< 0.05	< 0.05	0.05*	1.7
Pig kidney			0.42		0.15	0.20	0.15	0.20	< 0.05	< 0.05	0.05*	1
Ruminant meat	0.380	0.571	2.09		0.10	0.12	0.10	0.12	0.06	0.09	0.09	1
Ruminant fat			2.09		0.05	0.05	0.05	0.05	0.05	0.05	0.06	1
Ruminant liver			2.09		0.63	0.73	0.63	0.73	0.24	0.48	0.50	1.7
Ruminant kidney			2.09		0.93	1.2	0.93	1.2	0.30	0.71	0.80	1
Milk	0.380	0.571	2.09		0.05[e]	N/A	0.05[e]	N/A	< 0.05	0.05	0.06	1

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 until day 24

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.

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

7.3.5.1 Available data for all crops under consideration

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

Table 7.3-13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Risk assessment residue definitio: sum of Mepiquat and its salts, expressed as Mepiquat chloride					
Barley, brewing malt	4	1.07	n/a	-	Reichert, 2003 Report No. 2001/1015065 Schulz, 1995b Report No. 1995/10588 DAR, Belgium, 2006 EFSA, 2015
Barley, beer	4	0.18	n/a		
Barley, pot/pearl	4	0.81	n/a		
Barley, bran	4	3.46	n/a		
Wheat, whole-meal flour	4	0.94	n/a		Schulz, 2003a Report No. 2001/1009089 Schulz, 1995c Report No. 1995/10985, DAR, Belgium, 2006 EFSA, 2015
Wheat (and rye), whole-meal bread	4	0.74	n/a		
Wheat (and rye), white flour	4	0.17	n/a		
Wheat (and rye), bran	4	3.46	n/a		

* 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.

7.3.5.2 Conclusion on processing studies

Processing studies carried out on barley and wheat showed that residues of mepiquat chloride in the processed samples had not increased significantly with the exception of wheat and barley bran which had increased by a factor of 3 (the mean factor for all bran fractions).

7.3.6 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 0), no study dealing with magnitude of

residues in succeeding crops is needed.

7.3.7 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 Chlormequat 34.5% + Mepiquat 11.5% SL. Therefore, other special studies are not needed.

7.3.8 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).

7.3.8.1 Input values for the consumer risk assessment

Table 7.3-14: 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 Mepiquat and its salts, expressed as Mepiquat chloride				
Input values for the consumer risk assessment used in PRiMo was MRL values from Reg. (EU) No 2021/976				

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-15: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev.3.1	23% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo rev.3.1	-
IESTI (% ARfD) according to EFSA PRIMo rev.3.1	**Unprocessed commodities:** Based on children: Wheat: 14% Based on adults: Wheat: 8% **Processed commodities:** Based on children: Wheat/milling (flour): 12% Wheat/milling (wholemeal)-baking: 6% Based on adults: Wheat/bread/pizza: 4% Wheat/pasta: 4% Wheat/bread: 3%
NTMDI (% ADI)	-
NEDI (% ADI)	-

NESTI (% ARfD)	-

The proposed uses of Mepiquat chloride in the formulation Chlormequat 34.5% + Mepiquat 11.5% SL do not represent unacceptable acute and chronic risks for the consumer.

7.4 Combined exposure and risk assessment

From a scientific point of view, it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised "scientific methods accepted by the Authority to assess such effects are available."
Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

The product is a mixture of two active substances and for at least two of them an acute reference dose has been allocated. Therefore, combined acute exposure can be considered.

7.4.1 Acute consumer risk assessment from combined exposure

In a first step, dose-addition of residues of the individual active substances is assumed by making use of the Hazard Index (HI) concept. The Hazard Quotient (HQ) is calculated for all active substances in the PPP that are acutely toxic by performing deterministic IESTI/NESTI calculations with the calculation models EFSA PRIMO (rev.3.1) and appropriate national models, if required, and dividing the individual exposure levels by the respective ARfD. Addition of the individual HQs irrespective of any considerations on phenomenological effects or mode(s)/mechanisms of action results in the HI. The results of the HQ/HI calculations are summarized in the following table.

Table 7.4-1: Acute consumer risk assessment from combined exposure

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo)	HQ (based on NESTI according to national model)*
Wheat (Based on children)	Chlormequat	0.15	NR
	Mepiquat	0.14	
	Cumulative risk Wheat (HI)	**0.29**	
Wheat (Based on adults)	Chlormequat	0.09	
	Mepiquat	0.08	
	Cumulative risk Wheat (HI)	**0.17**	

* if national model wanted, otherwise to be deleted

The Hazard Index is <1. Thus combined exposure to all active substances in Chlormequat 34.5% + Mepiquat 11.5% SL is not expected to present a consumer risk. No further refinement of the assessment is required.

7.4.2 Chronic consumer risk assessment from combined exposure

The uses under consideration provide only a minor contribution to the overall chronic exposure of con-

sumers to pesticide residues. The issue requires a more universal consideration and possibly the generic usage of monitoring data. A harmonised approach is not yet available, and currently no specific consideration is warranted in the scope of this evaluation.

7.5 References

Chlormequat chloride:

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)

DAR, 2007. Draft Assessment Report (DAR) Chlormequat-chloride Volume 3, Annex B.7: Residues (April 2007)

Mepiquat chloride:

EFSA (European Food Safety Authority), 2008. Conclusions regarding the peer review of the pesticide risk assessment of the active substance Mepiquat. 14 April 2008 (EFSA Scientific Report (2008) 146, 1-73)

EFSA (European Food Safety Authority), 2015. Review of the existing maximum residue levels (MRLs) for Mepiquat according to Article 12 of Regulation (EC) No 396/2005. 24 August 2015 (EFSA Journal 2015;13(8):4214)

DAR, 2006. Draft Assessment Report (DAR) Mepiquat Volume 3. Part 3, Annex B.7: Residues (February 2006)

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
	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 GLP, Published	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), Germany and United Kingdom, 2003 (study code 161200). BASF AG, DocID 2004/1015956 GLP, Published	N	CCC Task Force
	Mackenroth, C.	2003	Residue data symmary from supervised firld trials in cereals BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. 2003/1004687 Published	N	BASF

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
	Oberdorf K.,	2004	Supplementary residues information BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. 2004 Published	N	BASF
	Rawle N.W.	2006	Residues of mepiquat chloride in barley at harvest following a single application of Terpal, France – 2005 Report Number CEMR-2632 GLP, published	N	BASF

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	0.69 kg as/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 od 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

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	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment 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, expressed as chlormequat chloride)		
	(a)	(b)				(c)				(d)	(e)
D-2020-27-F01/Poland/N-EU/2020 Błonie	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. 25.05-04.062020 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

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):	Yes - "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

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):	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 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 treatment or no. of treatments and last date	Growth stage at last treatment 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, expressed as chlormequat chloride)		
	(a)	(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 Starw	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 20: 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	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment 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)
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 jonting	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	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)
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 (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: g a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): Chlormequat	PHI (days) (d)	Details on trial (e)
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 1st 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	0.453 31.3	94 94	
N-EU/France/2004	Winter wheat/Cap Horn		1520 BAS 062 00 W	150		05/05/2004	GS 34	Grain Straw	0.744 4.06	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	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)
N-EU/UK/2004	Spring wheat/Paragon		1520 BAS 062 00 W	150		02/06/2004	GS 37	Grain Straw	0.804 13.8	78 78	OAT/01/04 Raunft, E., Mackenroth, C., 2005
			1500 BAS 062 03 W					Grain Straw	0.762 18.8	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 0.26 16.73	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 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

A 2.2 Mepiquat chloride

A 2.2.1 Stability of residues

A 2.2.1.1 Stability of residues during storage of samples

A 2.2.1.1.1 Storage stability of residues in plant products

A 2.2.1.1.2 Storage stability of residues in animal products

A 2.2.2 Nature of residues in plants, livestock and processed commodities

A 2.2.2.1 Nature of residue in plants

A 2.2.2.1.1 Nature of residue in primary crops

A 2.2.2.1.2 Nature of residue in rotational crops

A 2.2.2.1.3 Nature of residues in processed commodities

A 2.2.2.2 Nature of residues in livestock

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Wheat (Extrapolated from Barley)

Table A 4: 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	0.23 kg as/ha	-	BBCH 29 – 32	-

Table A 5: Summary of the study in N-EU

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Mepiquat chloride		

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Mepiquat chloride		
80/11058/N-EU/Belgium/1978	Spring Barley	-	760	-	-	1	BBCH 31-32	Grain Straw	0.02 <0.03	85 85	
80/11058/N-EU/Belgium/1978	Spring Barley	-	760	-	-	1	BBCH 37-39	Grain	0.03	64	
80/11059/N-EU/Belgium/1978	Spring Barley	-	760	-	-	1	BBCH 31-32	Grain Straw	<0.02 0.17	90 90	
80/11059/N-EU/Belgium/1978	Spring Barley	-	760	-	-	1	BBCH 37-39	Grain Straw	<0.02 0.22	75 75	
78/10980/N-EU/France/1978	Spring Barley	-	760	600	127	1	BBCH 37	Grain Straw	0.29 1.4	75 75	
78/10984/N-EU/France/1978	Spring Barley	-	760	600	127	1	BBCH 39	Grain Straw	0.18 4.1	54 54	
78/10992/N-EU/France/1978	Spring Barley	-	760	600	127	1	BBCH 37	Grain Straw	0.05 4.6	67 67	
79/11046/N-EU/UK/1979	Spring Barley	-	760	250	304	1	BBCH 32	Grain Straw	<0.1 3.3	84 84	
79/11053/N-EU/Norway/1979	Spring Barley	-	760	-	-	1	BBCH 30-31	Grain Straw	0.31 0.59	100 100	
79/11053/N-EU/Norway/1979	Spring Barley	-	760	-	-	1	BBCH 32-37	Grain Straw	0.58 2.2	89 89	
79/11054/N-EU/Norway/1979	Spring Barley	-	760	-		1	HHCU 37-39	Grain Straw	0.61 10	84 84	
79/11054/N-EU/Norway/1979	Spring Barley	-	760	-	-	1	BBCH 37-39	Grain Straw	0.45 3.3	84 84	
80/11043-44/N-EU/France/1980	Winter Barley	-	760	600	127	1	-	Grain Straw Grain Straw	0.18 0.26 0.14 0.76	84 84 84 84	
78/10940/N-EU/UK/1978	Winter Barley	-	760	250	304	1	BBCH 37-39	Grain Straw	0.63 2.2	81 81	
78/10947/N-	Winter Barley	-	760	250	304	1	BBCH 32-37	Grain	0.30	86	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Mepiquat chloride		
EU/UK/1978								Straw	0.32	86	
79/11032/N-EU/UK/1979	Winter Barley	-	760	250	304	1	BBCH 32-36	Grain Straw	0.53 0.36	85 85	
79/11042/N-EU/UK/1979	Winter Barley	-	760	250	304	1	BBCH 32-36	Grain Straw	0.17 2.7	102 102	
79/11035/N-EU/UK/1979	Winter Barley	-	760	250	304	1	BBCH 32-36	Grain Straw	0.31 3.4	87 87	
79/11043/N-EU/UK/1979	Winter Barley	-	760	250	304	1	BBCH 32-36	Grain	0.10	77	
80/11050/N-EU/UK/1980	Winter Barley	-	760	250	304	1	BBCH 32	Grain Straw	0.05 0.66	81 81	
81/10991/N-EU/Germany/1981	Winter Barley	-	760	400	190	1	BBCH 49	Whole plant Whole plant Whole plant Grain Straw Grain Straw	7.2 6.2 4.8 1.5 5.9 0.44 5.7	0 22 42 57 57 64 64	
81/10383/N-EU/Germany/1981	Winter Barley	-	760	400	190	1	BBCH 49	Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw	8.8 2.9 2.2 0.82 3.3 0.55 1.1 0.50 1.2	0 20 30 40 40 50 50 60 60	
81/10992/N-EU/Germany/1981	Winter Barley	-	760	400	190	1	BBCH 49	Whole plant Whole plant Whole plant Whole plant Grain Straw Grain Straw	6.6 0.77 0.71 0.69 0.45 1.2 0.27 0.92	0 20 30 40 50 50 74 74	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Mepiquat chloride		
81/10997/N-EU/Germany/1981	Winter barley	-	760	400	190	1	BBCH 49	Whole plant Whole plant Grain Straw Grain Straw Grain Straw Grain Straw	10 1.7 1.0 3.8 1.1 5.6 0.73 2.3 0.31 0.99	0 20 30 30 40 40 50 50 62 62	
81/11001/N-EU/Germany/1981	Winter Barley	-	760	400	190	1	BBCH 49	Whole plant Whole plant Whole plant Grain Straw Grain Straw Grain Straw	28 1.6 0.72 1.8 2.3 0.75 2.4 0.19 3.8	0 21 31 42 42 53 53 67 67	
CEMS-2632/N-EU/France/2005	Spring Barley/Scarlett	-	790	310	255	1	BBCH 49	Grain Straw	0.09 4.6	54 54	
CEMS-2632/N-EU/France/2005	Spring Barley/Astoria	-	780	210	380	1	BBCH 49	Grain Straw	0.39 2.1	56 56	
CEMS-2632/N-EU/France/2005	Spring Barley/Adonis	-	820	220	380	1	BBCH 49	Grain Straw	1.0 2.3	49 49	
CEMS-2632/N-EU/France/2005	Spring Barley/Prosat T2	-	790	210	480	1	BBCH 49	Grain Straw	0.53 2.5	58 58	

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.2.6 Magnitude of residues in representative succeeding crops

A 2.2.7 Other/Special Studies

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 Chlormequat chloride

A 3.1.1 TMDI calculations (Reg. (EU) 2020/1565)

efsa
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	ARfD (mg/kg bw):	0.09
Source of ADI:		Source of ARfD:	
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

TMDI/NEDI/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)	Exposure resulting from commodities not under assessment (in % of ADI)
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	8%	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	48%	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	78%	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	28.79	38%	Wheat	15%	Milk: Cattle	10%	Rye	0.4%	
59%	IE adult	23.79	40%	Wheat	7%	Oat	5%	Milk: Cattle	0.4%	
59%	NL general	23.77	34%	Wheat	11%	Milk: Cattle	5%	Barley	0.3%	
59%	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	20.38	22%	Rye	18%	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	0.8%	
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/NEDI/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

Chlromequat

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.04	ARfD (mg/kg bw):	0.05
Source of ADI:		Source of ARfD:	
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

TMDI/NEDI/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)	Exposure resulting from commodities not under assessment (in % of ADI)
222%	DK child	88.72	110%	Rye	77%	Wheat	16%	Milk: Cattle		77%
184%	NL toddler	73.70	75%	Milk: Cattle	69%	Wheat	17%	Rapeseeds/canola seeds		69%
135%	GEMS/Food G06	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	47.88	72%	Wheat	31%	Milk: Cattle	8%	Rapeseeds/canola seeds		72%
119%	GEMS/Food 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%	GEMS/Food G15	46.12	80%	Wheat	14%	Barley	9%	Milk: Cattle		80%
112%	GEMS/Food G07	44.72	74%	Wheat	11%	Barley	10%	Rapeseeds/canola seeds		74%
107%	UK infant	42.69	46%	Milk: Cattle	46%	Wheat	9%	Oat		46%
105%	RO general	42.13	89%	Wheat	15%	Milk: Cattle	0.9%	Swine: Muscle/meat		89%
99%	UK toddler	39.53	69%	Wheat	26%	Milk: Cattle	2%	Oat		69%
99%	GEMS/Food G10	39.40	69%	Wheat	10%	Barley	7%	Milk: Cattle		69%
97%	ES child	38.75	78%	Wheat	16%	Milk: Cattle	1%	Bovine: Muscle/meat		78%
96%	FR toddler 2 3 yr	38.58	54%	Wheat	37%	Milk: Cattle	2%	Oat		54%
92%	GEMS/Food 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	36%	Wheat	4%	Milk: Cattle	2%	Oat		36%
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: Muscle/meat		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/NEDI/IEDI was in the range of 0 % to 221.8 % of the ADI.
For 12 diet(s) the ADI is exceeded.

A 3.1.2 IEDI calculations (Reg. (EU) 2020/1565)

Chlormequat

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

Toxicological reference values

ADI (mg/kg bw/day):	0.04	ARfD (mg/kg bw):	0.09
Source of ADI:		Source of ARfD:	
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 : ---

TMDI/NEDI/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)	Exposure resulting from commodities not under assessment (in % of ADI)
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%	GEMS/Food G07	9.77	10%	Wheat	10%	Rapeseeds/canola seeds	1%	Barley	0.4%	
22%	NL child	8.68	10%	Wheat	8%	Rapeseeds/canola seeds	0.7%	Bovine: Muscle/meat	0.7%	
21%	GEMS/Food G08	8.47	10%	Wheat	6%	Rapeseeds/canola seeds	2%	Rye	0.4%	
20%	GEMS/Food G06	8.03	17%	Wheat	0.6%	Rapeseeds/canola seeds	0.5%	Cotton seeds	0.5%	
18%	GEMS/Food G15	7.39	11%	Wheat	4%	Rapeseeds/canola seeds	1%	Barley	0.4%	
18%	GEMS/Food 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%	GEMS/Food 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	3.68	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%	
0.6%	PL general	0.24	0.3%	Cultivated fungi	0.1%	Potatoes	0.1%	Apples	0.1%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) 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

Chlromequat

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.04	ARfD (mg/kg bw):	0.09
Source of ADI:		Source of ARfD:	
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 : ---

TMDI/NEDI/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)	Exposure resulting from 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%	GEMS/Food G08	16.07	16%	Barley	10%	Wheat	6%	Rapeseeds/canola seeds		10%
39%	GEMS/Food G07	15.71	11%	Barley	10%	Wheat	10%	Rapeseeds/canola seeds		10%
34%	GEMS/Food G15	13.64	14%	Barley	11%	Wheat	4%	Rapeseeds/canola seeds		11%
31%	GEMS/Food 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%	GEMS/Food 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%	GEMS/Food G08	8.78	17%	Wheat	1%	Barley	0.6%	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	6.66	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%
6%	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/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Chlromequat is unlikely to present a public health concern.

A 3.1.3 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 No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	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)
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):			1	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):			---
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)		

A 3.1.4 IESTI calculations - Processed commodities (Reg. (EU) 2020/1565)

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
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
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
Expand/collapse list							

After refinement with Input Values from EFSA 2016

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
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!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
Expand/collapse list							

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

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
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
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
Expand/collapse list							

After refinement with Input Values from EFSA 2016

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
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!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
Expand/collapse list							

A 3.2 Mepiquat chloride

A 3.2.1 TMDI calculations

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

Mepiquat chloride

LOQs (mg/kg) range from:	0.02	to:	0.10
Toxicological reference values			
ADI (mg/kg bw/day):	0.2	ARfD (mg/kg bw):	0.3
Source of ADI:		Source of ARfD:	
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: ---

TMDI/NEDI/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)	Exposure resulting from commodities not under assessment (in % of ADI)
23%	NL toddler	45.89	7%	Rapeseeds/canola seeds	6%	Wheat	6%	Sunflower seeds	0.4%	
22%	GEMS/Food G08	44.49	10%	Sunflower seeds	6%	Wheat	2%	Rapeseeds/canola seeds	0.2%	
22%	GEMS/Food G15	43.82	11%	Sunflower seeds	7%	Wheat	2%	Barley	0.2%	
22%	RO general	43.21	13%	Sunflower seeds	8%	Wheat	0.4%	Milk: Cattle	0.1%	
21%	GEMS/Food G07	42.01	8%	Sunflower seeds	6%	Wheat	4%	Rapeseeds/canola seeds	0.2%	
19%	NL child	37.53	7%	Sunflower seeds	6%	Wheat	3%	Rapeseeds/canola seeds	0.3%	
17%	GEMS/Food G06	34.62	11%	Wheat	5%	Sunflower seeds	0.9%	Cotton seeds	0.2%	
16%	DK child	32.42	8%	Rye	7%	Wheat	0.6%	Oat	0.1%	
15%	GEMS/Food G10	30.35	6%	Wheat	5%	Sunflower seeds	2%	Rapeseeds/canola seeds	0.2%	
13%	FR child 3 15 yr	26.71	7%	Wheat	5%	Sunflower seeds	0.8%	Milk: Cattle	0.2%	
12%	PT general	24.25	6%	Wheat	6%	Sunflower seeds	0.2%	Rye	0.1%	
12%	IE adult	23.09	4%	Sunflower seeds	3%	Wheat	3%	Linseeds	0.2%	
11%	DE child	22.91	6%	Wheat	2%	Sunflower seeds	1%	Rye	0.3%	
11%	GEMS/Food G11	21.15	5%	Wheat	2%	Sunflower seeds	2%	Barley	0.3%	
10%	IT toddler	20.85	10%	Wheat	0.3%	Sunflower seeds	0.0%	Barley	0.1%	
10%	NL general	20.75	4%	Sunflower seeds	3%	Wheat	2%	Rapeseeds/canola seeds	0.1%	
10%	ES child	19.60	7%	Wheat	2%	Sunflower seeds	0.4%	Milk: Cattle	0.1%	
9%	FR toddler 2 3 yr	18.03	5%	Wheat	3%	Sunflower seeds	1%	Milk: Cattle	0.2%	
7%	UK toddler	14.03	6%	Wheat	0.7%	Milk: Cattle	0.1%	Oat	0.1%	
7%	DE general	13.89	3%	Wheat	1%	Sunflower seeds	1%	Barley	0.2%	
7%	ES adult	13.81	4%	Wheat	2%	Sunflower seeds	1.0%	Barley	0.1%	
7%	DE women 14-50 yr	13.40	3%	Wheat	1%	Sunflower seeds	0.7%	Rye	0.2%	
6%	IT adult	12.98	6%	Wheat	0.2%	Sunflower seeds	0.0%	Barley	0.1%	
6%	FR adult	12.31	3%	Wheat	2%	Sunflower seeds	0.2%	Mustard seeds	0.1%	
6%	SE general	12.15	5%	Wheat	0.4%	Rye	0.4%	Milk: Cattle	0.1%	
6%	UK infant	12.07	4%	Wheat	1%	Milk: Cattle	0.4%	Oat	0.1%	
5%	FI 3 yr	9.42	2%	Wheat	1.0%	Rye	0.9%	Oat	0.1%	
5%	LT adult	9.15	2%	Rye	2%	Wheat	0.8%	Sunflower seeds	0.0%	
4%	FI 6 yr	7.32	1%	Wheat	0.9%	Rye	0.5%	Oat	0.1%	
3%	UK vegetarian	6.87	3%	Wheat	0.1%	Milk: Cattle	0.1%	Oat	0.1%	
3%	UK adult	5.69	3%	Wheat	0.1%	Milk: Cattle	0.1%	Barley	0.1%	
3%	DK adult	5.62	2%	Wheat	0.8%	Rye	0.2%	Milk: Cattle	0.1%	
2%	FI adult	4.85	1%	Rye	0.5%	Wheat	0.3%	Coffee beans	0.3%	
2%	FR infant	4.83	1%	Wheat	0.6%	Milk: Cattle	0.5%	Sunflower seeds	0.1%	
2%	IE child	3.88	2%	Wheat	0.1%	Milk: Cattle	0.0%	Oat	0.0%	
0.3%	PL general	0.54	0.2%	Sunflower seeds	0.0%	Potatoes	0.0%	Apples	0.1%	

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

A 3.2.2 IEDI calculations

Not relevant.

A 3.2.3 IESTI calculations - Raw commodities

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): ---			
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)
14%	Wheat	3 / 3	43	8%	Wheat	3 / 3	25
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A 3.2.4 IESTI calculations - Processed commodities

Processed commodities	**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
	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)
	12%	Wheat / milling (flour)	3 / 3	36	4%	Wheat / bread/pizza	3 / 3	13
	6%	Wheat / milling (wholemeal)	3 / 3	17	4%	Wheat / pasta	3 / 3	11
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	3%	Wheat / bread (wholemeal)	3 / 3	10
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	Expand/collapse list							

Appendix 4 Additional information provided by the applicant

No additional information provided by the applicant.