FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 8500 A

Product name: MEPISHA

Chemical active substances:

Mepiquat chloride, 50 g/L

(Mepiquat 38 g/L)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

Submission date: February 2021

MS Finalisation date: 09/2021 02/2022

Version history

When	What
09/2021	Assessment
02/2022	RMS reply to the applicant's comment (Reporting Table)

Table of Contents

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Stability of Residues

Mepiquat chloride has been demonstrated to be stable for a period up to 24 months when stored at ≤ -20°C in high-water content and high starch content matrices.

Data gap: storage stability data for high oil content commodities.

RMS reply to the applicant's comment (Reporting Table)

Applicant provided storage stability data only for wheat matrices. These matrices do not belong to the group high oil content commodities. Extrapolation is not possible.

Nevertheless stability studies on oil matrices were presented in EFSA Journal 2015;13(8):4214. These studies cover the stability of mepiquat for a period of 25 months. Therefore, residues in samples taken in the studies submitted by the applicant are not expected to be unstable (harvest: 07/2020, extraction and analysis: 09/2020).

However, it is the responsibility of the applicant to document the stability of the residues. Applicant can refer to the EFSA, 2015 document if mentioned studies are not protected. This should be checked.

Considering that the applicant has initiated storage stability studies, the evaluator accepts the use on oil seed rape, provided that the study report is submitted after registration.

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

Winter wheat, winter barley, spring barley

Proposed uses:

1 application, BBCH 31-39, 0.0285 kg as/ha (mepiquat) it is equal 0.0375 kg as/ha (mepiquat chloride)

EU GAP (representative use):

1 application, BBCH 31-49, 0.7625 kg as/ha (mepiquat chloride) - SANCO/106/08 – rev. 2; 20 May 2008

Proposed GAP is less critical than EU GAP.

The applicant refers to the trials evaluated in the DAR. These trials are done at higher doses than the proposed use.

GAP on which EU a.s. assessment is based: 1 x 0.76 kg as/ha (mepiquat chloride), BBCH 30-39, PHI 50-57d, outdoor.

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.

Winter Oilseed rape

New studies (overdosed) on the magnitude of residue have been submitted by the applicant in the framework of this application. Trials are independent. Analytical method used is accepted. LOQ: 0.01 mg/kg. ~~The studies are not accepted due to the lack of stability data.~~

Considering that the applicant has initiated storage stability studies, the evaluator accepts the use on oil seed rape, provided that the study report is submitted after registration (post registration formal requirement - residues in samples taken in the new studies are not expected to be unstable.)

Magnitude of residues in livestock

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 MEPISHA do not represent unacceptable acute and chronic risks for the consumer.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation MEPISHA/SHA 8500 A are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central Europe for cereals. A list of all intended uses within the Central Europe is given in Part B, Section 0.

Overall conclusion

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

The chronic and the short-term intakes of mepiquat residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, Poland agrees with the authorization of the intended use(s).

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

Data gaps

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

Noticed data gaps are:

- Storage stability data for high oil content commodities (post registration formal requirement - residues in samples taken in the new studies are not expected to be unstable)
- data gap 2
- data gap 3

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**	**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, winter barley, spring barley**	CEU	SHA 8500 A	F	Increase size of capsules, advance harvest, reduction of crop height	SL	3.8 %	Foliar spray	BBCH 31-39	1	NA	0.007125 - 0.01425	200-400	0.0285	-	A
2	**Winter Oilseed rape**	CEU	SHA 8500 A	F	Increase size of capsules, advance harvest, reduction of crop height	SL	3.8 %	Foliar spray	BBCH 31-39	1	NA	0.007125 - 0.01425	200-400	0.0285	-	R

* 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 MEPISHA/SHA 8500 A is composed of Mepiquat chloride.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
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

* an extra factor of 10 was considered since ChE activity was not measured in the study

7.1.2.1 Summary for Mepiquat chloride

Table 7.1-3: 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
1	Winter barley	Yes	Yes	Yes	Yes	Yes		No
1	Spring barley	Yes	Yes	Yes	Yes	Yes		No
2	Winter Oilseed rape	Yes	Yes	Yes	~~Yes~~ No	Yes		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 MEPISHA/SHA 8500 A

Table 7.1-4: Information on MEPISHA/SHA 8500 A (KCA 6.8)

Crop	PHI for MEPISHA/SHA 8500 A proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for MEPISHA/SHA 8500 A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Mepiquat chloride		
Winter wheat	NR	NR		
Winter barley	NR	NR		
Spring barley	NR	NR		
Winter Oilseed	NR	NR		

Crop	PHI for MEPI-SHA/SHA 8500 A proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for MEPI-SHA/SHA 8500 A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Mepiquat chloride		
rape				

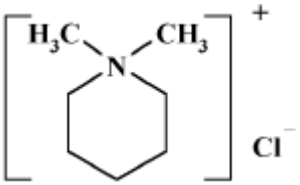
NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Assessment

7.2 Mepiquat chloride

General data on Mepiquat chloride are summarized in the table below (last updated 2019/01/17)

Table 7.2-1: 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 (COMMISSION 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	~~Regulation (EC) No 2019/1791~~ 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

7.2.1 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 forage	High water content	24 months	W. Kerl, C. Mackenroth, 2003 Report No. 2004/1000748 Belgium, 2006 UK, 2008 EFSA, 2008
Wheat grain	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, 2003 Report No. 2004/1000749 Belgium, 2006 UK, 2008 EFSA, 2008
Animal Products			
Ruminant	Liver	26 months	J. Burkey, M. Riley, 1995 Report No. 1995/5096 Belgium, 2006 UK, 2008 EFSA, 2008
Ruminant	Kidney	26 months	
Ruminant	Muscle	26 months	
Ruminant	Fat	26 months	
Poultry	Muscle	26 months	
Ruminant	Milk	26 months	
Poultry	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.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

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

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								
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 Belgium, 2006 EFSA, 2008
Pulses and oilseeds	Cotton	^{14}C Mepiquat-chloride	foliar treatment, F	0.16	1	15, 67	-	A. J. Goetz, 1992 Report No. 1992/5069 Belgium, 2006 EFSA, 2008
Cereals	Wheat	^{14}C Mepiquat-chloride	foliar treatment, G	0.7	1	0, 8, 71	-	U. Rabe, H. Schleuter, 2003 Repor No. 1992/5069 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 Belgium, 2006 EFSA, 2008

Summary of plant metabolism studies reported in the EU

Conclusions drawn from the Addendum to the DAR (January, 2008) are reported below:
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.

7.2.2.2 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	^{14}C Mepiquat-chloride	Bare ground application, G	0.7	29, 120, 365	At maturity	-	P. Veit, W. E. Glaessgen, 2003 Report No. 2003/1001376 Belgium, 2006 EFSA, 2008
Root and tuber vegetables	Radish	^{14}C Mepiquat-chloride	Bare ground application, G	0.7	29, 120, 365	At maturity	-	
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

Conclusions drawn from EFSA Scientific Report (2008) 146, 1-73 are reported below:
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.

7.2.2.3 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		
Pasteurisation (20 minutes, 90°C, pH 4)	Mepiquat chloride (>95%)	M. Singh, 2002 Report No. 2002/5003045 Belgium, 2006 EFSA, 2008
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Mepiquat chloride (>95%)	
Sterilisation (20 minutes, 120°C, pH 6)	Mepiquat chloride (>95%)	

Conclusion on nature of residues in processed commodities

For all solutions tested mepiquat chloride accounted for greater than 95% of the radioactivity. Therefore it can be concluded that mepiquat-chloride did not significantly degrade abiotically under conditions representative of industrial or domestic food processing.

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

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

Endpoints

Plant groups covered	Cereals (wheat, barley), oilseeds (cottton) and fruit (grapes)
Rotational crops covered	Lettuce, wheat and 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	Mepiquat (sum of Mepiquat and its salts, expressed as Mepiquat chloride) (Regulation (EU) 2019/1791)
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.

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

Available data

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label 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, 1988 Giesse, 1988b Grosshans, 1994 Jonas, 1994a, b Kohl, 1989b, 1991 Belgium, 2005 UK, 2008 EFSA, 2015
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	^{14}C Mepiquat chloride	15	18	6	Eggs	daily	Cheng, 1989 Giesse, 1988a Kohl, 1989a Belgium, 2005 UK, 2008 EFSA,
						Excreta	daily	
						Tissues	at sacrifice	

								2015

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Scientific Report (2008) 146, 1-73 are reported below:
The metabolism and distribution in animals was investigated in lactating goats and chickens, using ring labelled 14C- Mepiquat chloride.
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

General residue definition for monitoring of livestock commodities is the sum of mepiquat and its salts, expreesed as mepiquat chloride.

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

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

	Endpoints
Animals covered	Lactating goats 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	Mepiquat (sum of Mepiquat and its salts, expressed as Mepiquat chloride) (Regulation (EU) No. 2019/1791)
Animal residue definition for risk assessment	Sum of Mepiquat and its salts, expressed as Mepiquat chloride (EFSA Scientific report (2008) 146, 1-73)
Conversion factor	1.7 (ruminant liver) 1 (all other livestock commodities)

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 MEPISHA/SHA 8500 A.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
Barley grain → extrapolated to wheat	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	N/A				
	Overall supporting data for cGAP	EU	Grain: 0.09, 0.39, 0.45, 0.53, 0.55, 0.73, 0.75, 1.0, 1.5	0.54	1.5	2.28	Barley: 4 Wheat: 3	Yes
Barley straw → extrapolated to wheat	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	N/A				
	Overall supporting data for cGAP	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	8.95	-	-
Winter oilseed rape	New trials	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.294 kg as/ha, PHI 56 days, outdoor 0.333, 0.355, 0.545, 1.03, 1.33, 2.58, 2.92, 2.94	N/A				
	Overall	EU	0.333, 0.355, 0.463, 0.468, 0.514, 0.545, 0.558, 1.03, 1.33, 1.53,	1.18	3.23		15.0	N/A

	supporting data for cGAP		1.58, 1.95, 2.58, 2.92, 2.94, 3.23					

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

7.2.3.2 Conclusion on the magnitude of residues in plants

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

According to appendix D of EU guidelines, extrapolation to wheat is possible with trials on barley, which is the case here.

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

7.2.4.2 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, 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	2.34	STMR	5.90	HR
Oat straw	2.34	STMR	5.90	HR
Cotton, undelinted seeds	1.70	STMR (EFSA, 2018)	1.70	STMR (EFSA, 2018)
Cotton, meal	3.23	STMR (1.70) * PF (1.9) (EFSA, 2018)	3.23	STMR (1.70) * 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)
Canola (rape seed)	5.84	STMR (3.65) * PF (1.6)	5.84	STMR (3.65) * PF (1.6)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment (EFSA, 2015)	Input value (mg/kg)	Comment (EFSA, 2015)
meal		(EFSA, 2018)		(EFSA, 2018)
Distiller's grain dried	1.98	STMR (0.60) * PF (3.3)	1.98	STMR (0.60) * PF (3.3)
Rape meal	2.0	STMR (1.0) * PF (2)	2.0	STMR (1.0) * PF (2)
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 7.2-11: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: Sum of mepiquat, 4-hydroxymepiquat and their salts, expressed as mepiquat chloride (EFSA, 2015)					
Cattle (all diets)	0.381	0.571	Rye straw	17.05	Y
Cattle (dairy only)	0.381	0.571	Rye straw	14.85	Y
Sheep (all diets)	0.780	1.201	Rye straw	28.27	Y
Sheep (ewe only)	0.612	0.942	Rye straw	28.27	Y
Swine (all diets)	0.145	0.145	Flaxseed/linseed, meal	4.85	Y
Poultry (all diets)	0.442	0.612	Wheat straw	8.94	Y
Poultry (layer only)	0.442	0.612	Wheat straw	8.94	Y

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

zRMS comment:
If data from new oilseed rape studies and barley data from the Table 7.3-9 (and wheat via barley extrapolation) are used as input values, animal intake is as follows (pesticides_mrl_guidelines_animal_model_2017):

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)	0,089	0,175	2,31	4,55	Dairy cattle	Barley	straw	Yes
Cattle (dairy only)	0,089	0,175	2,31	4,55	Dairy cattle	Barley	straw	Yes
Sheep (all diets)	0,146	0,329	3,44	7,75	Lamb	Barley	straw	Yes
Sheep (ewe only)	0,109	0,258	3,27	7,75	Ram/Ewe	Barley	straw	Yes
Swine (all diets)	0,074	0,074	2,45	2,45	Swine (finishing)	Wheat	milled bypdts	Yes
Poultry (all diets)	0,106	0,158	1,55	2,31	Poultry layer	Wheat	straw	Yes
Poultry (layer only)	0,106	0,158	1,55	2,31	Poultry layer	Wheat	straw	Yes

7.2.4.3 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

Table 7.2-12: 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 Journal 2015;13(8):4214)												
Risk assessment residue definitio: sum of Mepiquat and its 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	0.381	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	0.381	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.

7.2.5 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					
Risk assessment residue definitio: sum of Mepiquat and its salts, expressed as Mepiquat chloride					
Rape seed, crude oil	4	0.02	n/a		EFSA Journal 2015;13(8):4214
Rape seed, refined oil	4	0.01	n/a	-	
Rape seed, meal/press cake	4	1.60	n/a	-	
Barley, brewing malt	4	1.07	n/a	-	Reichert, 2003 Report No. 2001/1015065 Schulz, 1995b Report No. 1995/10588 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 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.

7.2.5.2 Conclusion on processing studies

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.

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 **Błąd! Nie można odnaleźć źródła odwołania.**), 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 MEPISHA. 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 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-14: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	23% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo	**Unprocessed commodities:** **Based on children:** 14.45% Wheat 7.48% Barley 6.90% Rapeseeds/canola seeds 6.32% Rye 1.11% Oat **Based on adults:** 8.40% Wheat 6.45% Barley 4.85% Rye 2.64% Rapeseeds/canola seeds 0.64% Oat **Processed commodities:** **Based on children:** 12.1% Wheat / milling (flour) 5.5% Wheat / milling (wholemeal)-baking 4.8% Barley / cooked 3.6% Rye / boiled 3.6% Oat / boiled 3.5% Rye / milling (wholemeal)-baking 3.0% Oat / milling (flakes) 2.9% Rapeseeds / oils 2.4% Barley / milling (flour) **Based on adults:** 9.6% Barley / beer 4.39% Wheat / bread/pizza 3.81% Wheat / pasta 3.49% Wheat / bread (wholemeal)

	1.52% Oat / boiled
NTMDI (% ADI)	-
NEDI (% ADI)	-
NESTI (% ARfD)	-

The proposed uses of Mepiquat chloride in the formulation MEPISHA do not represent unacceptable acute and chronic risks for the consumer.

zRMS comment:
Below consumer risk assessment (EFSA PRIMo rev. 3.1, input: Reg. (EU) 2021/976)

TMDI (% ADI) according to EFSA PRIMo rev. 3.1	23% (based on NL toddler, rape seed/canola seeds (7%))
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1	**Unprocessed commodities:** **Based on children:** 14 % Wheat 7% Barley 7% Rapeseeds/canola seeds **Based on adults:** 8% Wheat 6% Barley 3% Rapeseeds/canola seeds **Processed commodities:** **Based on children:** 12% Wheat / milling (flour) 6% Wheat / milling (wholemeal)-baking 5% Barley / cooked 3% Rapeseeds / oils 2% Barley / milling (flour) **Based on adults:** 10% Barley / beer 4% Wheat / bread/pizza 4% Wheat / pasta 4% Wheat / bread (wholemeal)
NTMDI (% ADI)	-
NEDI (% ADI)	-
NESTI (% ARfD)	-

7.3 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.

Not relevant. The product contains only one active substance

7.4 References

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, 2005. Draft Assessment Report (DAR) Mepiquat Volume 3. Annex B.7: Residues (March 2005)

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	R. Figurski	2020	Magnitude of the residue of mepiquat in oilseed rape (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product Mepiquat 21% + Metconazole 3% SL – two harvest and two decline curve trials in Northern Europe – Poland, 2020. Report No. D-2020-04 GLP Unpublished	N	Sharda
KCP 8.3.2	K. Zagibajło	2020	Determination of the residues of mepiquat chloride in oilseed rape after one application of mepiquat 21% + Metconazole 3% SL in four trials (2 DCS and 2 HS), Poland – 2020. Report No. 20/FSL/12/1PL GLP Unpublished	N	Sharda
KCP 8.3.3	G. Wagner	2020	Determination of the residues of mepiquat in/on oilseed rape after one application of Mepiquat 21% + Metconazole 3% SL in Northern Europe – Hungary in 2020. Report No. 065CPRHU20R04 GLP Unpublished	N	Sharda
KCP 8.3.4	K. Zagibajło	2020	Determination of the residues of Mepiquat chloride in oilseed rape after one application of Mepiquat 21% + Metconazole 3% SL in four trials (2DCS and 2 HS), Hungary – 2020. Report No. 20/FSL/12/1HU GLP Unpublished	N	Sharda

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

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 Mepiquat chloride

A 2.1.1 Stability of residues

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

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

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

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Barley

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA, 2015)	1	0.76 kg as/ha	-	BBCH 31 – 49	-
Intended cGAP (2) (Winter)	1	0.0285 kg as/ha	-	BBCH 31 – 39	-
Intended cGAP (4) (Spring)	1	0.0285 kg as/ha	-	BBCH 31 – 39	-

Table A 2: 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 <u>0.73</u> <u>2.3</u> 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 <u>0.75</u> <u>2.4</u> 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	<u>0.09</u> <u>4.6</u>	54 54	
CEMS-2632/N-EU/France/2005	Spring Barley/Astoria	-	780	210	380	1	BBCH 49	Grain Straw	<u>0.39</u> <u>2.1</u>	56 56	
CEMS-2632/N-EU/France/2005	Spring Barley/Adonis	-	820	220	380	1	BBCH 49	Grain Straw	<u>1.0</u> <u>2.3</u>	49 49	
CEMS-2632/N-EU/France/2005	Spring Barley/Prosat T2	-	790	210	480	1	BBCH 49	Grain Straw	<u>0.53</u> <u>2.5</u>	58 58	

A 2.1.3.2 Oilseed rape

A 2.1.3.2.1 Study 1

Evaluator's comment: Trials are independent.
Sampling days: 22-24 07.2020 (seed)
Date of extractions: 23-24 09.2020
Analytical method used is accepted. LOQ: 0.01 mg/kg. Trials are overdosed.
Data gap: storage stability data (post registration requirement). Residues in samples taken in this study are not expected to be unstable.
Harvest: 07/2020, extraction and analysis: 09/2020

Reference:	KCP 8.3.1
Report	Magnitude of the residue of mepiquat in oilseed rape (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product Mepiquat 21% + Metconazole 3% SL – two harvest and two decline curve trials in Northern Europe – Poland, 2020. R. Figurski, 2020, Report No. D-2020-04
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS

The objective of the field phase is to provide the analytical laboratory with treated specimens resulting from one application at rate of 1,4 L*ha^{-1} of Mepiquat 21% + Metconazole 3% SL (corresponding to 294 g a.s.*ha^{-1} of mepiquat and 42 g a.s.*ha^{-1} of metconazole) regarding open field conditions, at BBCH 31-59. All aspects of a field work were performed in accordance with a typical Good Agricultural Practices.

The field phase happened as anticipated in the study plan and amendments. Two harvest trials and two decline curve trials 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 Mepiquat 21% + Metconazole 3% SL was performed with a boom sprayer on the treated plot at the target dose rate of 1,4 L*ha^{1} (equivalent to 294 g a.s.*ha^{-1} of mepiquat and 42 g a.s.*ha^{-1} of metconazole). The reported dose rate actually ranging from 1,330 to 1,359 L*ha^{-1}.

The target spray volume was 200-400 litres per hectare according to Good Agricultural Practices. The reported spray volume was actually ranging from 380,2 to 387,7 $L*ha^{-1}$.

Application was performed at the following timing at BBCH 31-59.

The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were calculated to verify delivery rates.

In HS trial, RAC specimens for analyses were collected at normal commercial harvest. In decline curve trials (DCS), RAC specimens for analyses (fruit) were collected as follows:

- at 0 days after application just after application (U+T),
- at 35±2 days after application (U+T),
- at 57±2 days after application (U+T).

Sampling date and weights of collected specimens are presented in **Błąd! Nie można odnaleźć źródła odwołania.**, **Błąd! Nie można odnaleźć źródła odwołania.**, **Błąd! Nie można odnaleźć źródła odwołania.**, **Błąd! Nie można odnaleźć źródła odwołania.**, **Błąd! Nie można odnaleźć źródła odwołania.**.

RAC specimens were put in deep freezing conditions at a target temperature of ≤-18°C on the day of sampling, within 12 hours after sampling. All specimens remained deep frozen during storage at the test facility and during shipment to the analytical laboratory Research Institute of Horticulture, Pomologiczna 18St., 96-100 Skierniewice.

Reference:	KCP 8.3.2
Report	Determination of the residues of mepiquat chloride in oilseed rape after one application of mepiquat 21% + Metconazole 3% SL in four trials (2 DCS and 2 HS), Poland – 2020. K. Zagibajło, 2020, Report No. 20/FSL/12/1PL
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of this study was to determine the magnitude of residues of Mepiquat Chloride, according to residue definition: Mepiquat (sum of Mepiquat and its salts, expressed as Mepiquat Chloride) in raw agricultural commodity of oilseed rape (plants, seeds) after one application of Mepiquat 21% + Metconazole 3% SL.
To achieve the objective appropriate analytical method for determination of Mepiquat Chloride was validated in accordance to the guidance document SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. 20/FSL/12/1A.The validated limit of quantification is 0.01 mg/kg for Mepiquat Chloride.
The samples were delivered from field trials conducted in Northern Europe by Fertico Sp. z o.o. Agricultural Research Service Goliany 43 05-620 Błędów, Poland. Field study number: D-2020-04. Field trial number (s): Decline trials: D-2020-04-F03, D-2020-04-F04; Harvest trials: D-2020-04-F01, D-2020-04-F02
Field study title: Magnitude of the Residue of Mepiquat in Oilseed Rape (Raw Agricultural Commodity - -RAC) Grown in Open Field Conditions After One Application of a Formulated Product Mepiquat 21% + Metconazole 3% SL - Two Harvest and Two Decline Curve Trials in Northern Europe - Poland, 2020.
The general principles of the analytical procedure were based on the reference method published by European Commission EU Reference Laboratories for Residues of Pesticides, Single Residue Methods (EURL-SRM: Anastassiades M., D. I. Kolberg, E. Eichhorn, A.-K.Wachtler, A. Benkenstein, , S. Zechmann, D. Mack, C. Wildgrube, A. Barth, I. Sigalov, S. Görlich, D. Dörk, G. Cerchia (2020) Quick Method for the Analysis of Numerous Highly Polar Pesticides in Food Involving Extraction with Acidified Methanol and LC-MS/MS Measurement I. Food of Plant Origin (QuPPe-PO-Method): EU Reference Laboratory for pesticides requiring Single Residue Methods (EURL-SRM), Version 11 .
In brief, the oilseed rape (plants, seeds) samples were extracted with acidified methanol. Then, the extract was shaken. Following centrifugation, an aliquot was diluted. For quantitative analysis the final extract was filtrated and directly analyzed by LC-MS/MS.
Quantification of Mepiquat Chloride determined as Mepiquat was performed with the help of isotopically labeled analogue of the target analyte (ISTD, Mepiquat Iodide D3).
Quantification was performed by use of highly selective liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS). Two selected ion mass transitions for compound were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention times of analyte in extracts corresponds to that of the calibration standards with a tolerance of < ± 0.1 min. also confirmation ratios for Mepiquat in all samples were within ± 30 % of the average found for the standards.
No significant interference above 30 % of LOQ was detected in any of the reagent blanks or control specimen extracts for oilseed rape (plants, seeds) matrices, so that a high level of selectivity was demonstrated and an additional confirmatory method is not necessary.
Determination of Mepiquat Chloride was performed using matrix-matched calibrations standards.
The stability of analyte was not tested specifically. Recoveries of the fortified samples within the acceptable range 70-110% obtained with calibration solution and the use of bracketing standards to insure integrity of the analytical sequence sufficiently demonstrate the stability.

The correlation between the injected concentration ratios of analytes/internal standard and their detector response (peak area ratios) for Mepiquat Chloride determined as Mepiquat was demonstrated to be linear by single determination of matrix-matched calibration standards at twelve concentration levels ranging from 0.00025 µg/mL to 2.5 µg/mL for oilseed rape (plants) and at eleven concentrations levels ranging from 0.00025 µg/mL to 1.25 µg/mL for oilseed rape (seeds) These ranges correspond from 0.002 mg/kg to 20 mg/kg for Mepiquat Chloride (oilseed rape plants) and from 0.002 mg/kg to 10 mg/kg for Mepiquat Chloride (oilseed rape seeds) thus covering the range from no more than 30 % of the LOQ and at least + 20 % of the highest analyte concentration level detected in samples.

SAMPLE EXTRACTION
5.00 g of homogenized oiseed rape (plants, seeds) matrices were weighed into a 50 mL Teflon centrifuge tube. Sample weight was recorded.
If necessary, fortification of the concurrent recovery sample by aliquoting the fortification standard of Mepiquat Chloride onto the matrix was carried out at this step. The tube was shaken in a vortex mixer for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	Concentration (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	1	50
10 x LOQ (0.1 mg/kg)	10	50

Table A 3: Summary of the study 1 trials

Trans-de	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat-ments 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				Mepiquat chloride		
D-2020-04-F01/N-EU/Poland/2020 Zaborowo 09 152 Naru-szewo	Oilseed rape/Tajfun F1	28/08/2019 26/04-01/06/2020 22/07/2020	326	388		25/04/2020	BBCH 59	Seed	1.03	88	
D-2020-04-F02/N-EU/Poland/2020 Nowa Wieś 27 300 Lipsko	Oilseed rape/PT 274 F1	14/09/2019 25/04-01/07/2020 23/07/2020	323	384		25/04/2020	BBCH 59	Seed	0.545	89	
D-2020-04-F03/N-EU/Poland/2020 Łąki 05 870Błonie	Oilseed rape/Sherlock	25/08/2019 25/04-15/05/2020 22/07/2020	322	383		24/04/2020	BBCH 59	Whole plant Whole plant Seed	8.39 0.747 0.355	0 35 89	
D-2020-04-F04/N-EU/Poland/2020 Mokra 96 100 Ski-erniewice	Oilseed rape/Luciano F1	24/08/2019 20/04-10/06/2020 24/07/2020	319	380		24/04/2020	BBCH 59	Whole plant Whole plant Seed	8.81 0.692 0.333	0 35 91	

A 2.1.3.2.2 Study 2

Evaluator's comment: Trials are independent.
Sampling days: 07.2020 (seed)
Date of extractions: 28-29 09.2020
Analytical method used is accepted. LOQ: 0.01 mg/kg. Trials are overdosed.
Data gap: storage stability data (post registration requirement). Residues in samples taken in this study are not expected to be unstable.
Harvest: 07/2020, extraction and analysis: 09/2020

Reference:	KCP 8.3.3
Report	Determination of the residues of mepiquat in/on oilseed rape after one application of Mepiquat 21% + Metconazole 3% SL in Northern Europe – Hungary in 2020. G. Wagner, 2020, Report No. 065CPRHU20R04
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

STUDY DESIGN AND METHODS
Mepiquat 21% + Metconazole 3% SL is a fungicide developed by Sharda Cropchem Ltd. for pest control in different crops. The objective of this study is to provide results from the magnitude of residues of mepiquat in/on oilseed rape 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 Hidegkút (CPRHU20-165-065GR) in Nemesgörzsöny (CPRHU20-166-065GR), in Kám (CPRHU20-167-065GR), and in Sé (CPRHU20-168-065GR)

One application (57 days before harvest) of the formulated product Mepiquat 21% + Metconazole 3% SL (containing nominal concentration of 21 % mepiquat) was applied at a rate of 1.4 L formulated product/ha (294 g active ingredient of mepiquat/ha) onto the crop, under open field condition.

Specimens (whole plant, seed) were collected at 0, 35 and 57 (at NCH) days after application (DAA) in decline trial and at harvest (57 DAA) in harvest trial, frozen and shipped deep frozen to analytical facility of Food Safety Laboratory, Research Institute of Horticulture for residue analysis.

Reference:	KCP 8.3.4
Report	Determination of the residues of Mepiquat chloride in oilseed rape after one application of Mepiquat 21% + Metconazole 3% SL in four trials (2DCS and 2 HS), Hungary – 2020. K. Zagibajło, 2020, Report No. 20/FSL/12/1HU
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of this study was to determine the magnitude of residues of Mepiquat Chloride, according to residue definition: Mepiquat (sum of Mepiquat and its salts, expressed as Mepiquat Chloride) in raw agricultural commodity of oilseed rape (plants, seeds) after one application of Mepiquat 21% + Metconazole 3% SL.

To achieve the objective appropriate analytical method for determination of Mepiquat Chloride was validated in accordance to the guidance document SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. 20/FSL/12/1A.The validated limit of quantification is 0.01 mg/kg for Mepiquat Chloride.

The samples were delivered from field trials conducted in Northern Europe by Fertico Sp. z o.o. Agricultural Research Service Goliany 43 05-620 Błędów, Poland. Field study number: D-2020-04. Field trial number (s): Decline trials: D-2020-04-F03, D-2020-04-F04; Harvest trials: D-2020-04-F01, D-2020-04-F02

Field study title: Magnitude of the Residue of Mepiquat in Oilseed Rape (Raw Agricultural Commodity - -RAC) Grown in Open Field Conditions After One Application of a Formulated Product Mepiquat 21% + Metconazole 3% SL - Two Harvest and Two Decline Curve Trials in Northern Europe - Poland, 2020.
The general principles of the analytical procedure were based on the reference method published by European Commission EU Reference Laboratories for Residues of Pesticides, Single Residue Methods (EURL-SRM: Anastassiades M., D. I. Kolberg, E. Eichhorn, A.-K.Wachtler, A. Benkenstein, , S. Zechmann, D. Mack, C. Wildgrube, A. Barth, I. Sigalov, S. Görlich, D. Dörk, G. Cerchia (2020) Quick Method for the Analysis of Numerous Highly Polar Pesticides in Food Involving Extraction with Acidified Methanol and LC-MS/MS Measurement I. Food of Plant Origin (QuPPe-PO-Method): EU Reference Laboratory for pesticides requiring Single Residue Methods (EURL-SRM), Version 11 .
In brief, the oilseed rape (plants, seeds) samples were extracted with acidified methanol. Then, the extract was shaken. Following centrifugation, an aliquot was diluted. For quantitative analysis the final extract was filtrated and directly analyzed by LC-MS/MS.
Quantification of Mepiquat Chloride determined as Mepiquat was performed with the help of isotopically labeled analogue of the target analyte (ISTD, Mepiquat Iodide D3).
Quantification was performed by use of highly selective liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS). Two selected ion mass transitions for compound were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention times of analyte in extracts corresponds to that of the calibration standards with a tolerance of < ± 0.1 min. also confirmation ratios for Mepiquat in all samples were within ± 30 % of the average found for the standards.
No significant interference above 30 % of LOQ was detected in any of the reagent blanks or control specimen extracts for oilseed rape (plants, seeds) matrices, so that a high level of selectivity was demonstrated and an additional confirmatory method is not necessary.
Determination of Mepiquat Chloride was performed using matrix-matched calibrations standards.
The stability of analyte was not tested specifically. Recoveries of the fortified samples within the acceptable range 70-110% obtained with calibration solution and the use of bracketing standards to insure integrity of the analytical sequence sufficiently demonstrate the stability.

The correlation between the injected concentration ratios of analytes/internal standard and their detector response (peak area ratios) for Mepiquat Chloride determined as Mepiquat was demonstrated to be linear by single determination of matrix-matched calibration standards at twelve concentration levels ranging from 0.00025 µg/mL to 2.5 µg/mL for oilseed rape (plants) and at eleven concentrations levels ranging from 0.00025 µg/mL to 1.25 µg/mL for oilseed rape (seeds) These ranges correspond from 0.002 mg/kg to 20 mg/kg for Mepiquat Chloride (oilseed rape plants) and from 0.002 mg/kg to 10 mg/kg for Mepiquat Chloride (oilseed rape seeds) thus covering the range from no more than 30 % of the LOQ and at least + 20 % of the highest analyte concentration level detected in samples.

SAMPLE EXTRACTION
5.00 g of homogenized oiseed rape (plants, seeds) matrices were weighed into a 50 mL Teflon centrifuge tube. Sample weight was recorded.
If necessary, fortification of the concurrent recovery sample by aliquoting the fortification standard of Mepiquat Chloride onto the matrix was carried out at this step. The tube was shaken in a vortex mixer for 1 min. and allowed to stand for about 5 min. Fortification details are given below:

Fortification level	Concentration (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	1	50

10 x LOQ (0.1 mg/kg)	10	50

Table A 4: Summary of the study trials

Trans-de	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat-ments 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				Mepiquat chloride		
CPRHU20-165-065GR/N-EU/Hungary/2020 Hidegkút	Oilseed rape/Inspiration	30/08/2019 074-05/2020 07/2020	308	315		15/05/2020	BBCH 72	Seed	2.94	57	
CPRHU20-166-065GR/N-EU/Hungary/2020 Nemesgörzsöny	Oilseed rape/DK Exception	01/09/2019 03-05/2020 07/2020	271	277		15/05/2020	BBCH 72	Seed	2.92	57	
CPRHU20-167-065GR/N-EU/Hungary/2020 Kám	Oilseed rape/DK Expression	30/08/2019 04-05/2020 07/2020	289	295		15/05/2020	BBCH 72	Whole plant Seed Seed	4.35 1.35 1.33	0 35 57	
CPRHU20-168-065GR/N-EU/Hungary/2020 Sé	Oilseed rape/DK Expansion	02/09/2019 04-05/2020 07/2020	318	325		15/05/2020	BBCH 72	Whole plant Seed Seed	3.54 3.57 2.58	0 35 57	

A 2.1.4 Magnitude of residues in livestock

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

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

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

A 2.1.6 Magnitude of residues in representative succeeding crops

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

A 2.1.7 Other/Special Studies

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

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 Mepiquat chloride

A 3.1.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Mepiquat (sum of mepiquat and its salts, expressed as 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:	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	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	23%	NL toddler	45.89	7%	Rapeseeds/canola seeds	6%	Wheat	6%	Sunflower seeds	0.6%	6%
	22%	GEMS/Food G08	44.42	10%	Sunflower seeds	6%	Wheat	2%	Rapeseeds/canola seeds	0.3%	8%
	22%	GEMS/Food G15	43.77	11%	Sunflower seeds	7%	Wheat	2%	Barley	0.3%	8%
	22%	RO general	43.21	13%	Sunflower seeds	8%	Wheat	0.4%	Milk: Cattle	0.2%	8%
	21%	GEMS/Food G07	41.83	8%	Sunflower seeds	6%	Wheat	4%	Rapeseeds/canola seeds	0.3%	8%
	19%	NL child	37.53	7%	Sunflower seeds	6%	Wheat	3%	Rapeseeds/canola seeds	0.4%	6%
	17%	GEMS/Food G06	34.31	11%	Wheat	5%	Sunflower seeds	0.8%	Cotton seeds	0.3%	11%
	16%	DK child	32.42	8%	Rye	7%	Wheat	0.6%	Oat	0.2%	7%
	15%	GEMS/Food G10	30.22	6%	Wheat	5%	Sunflower seeds	2%	Rapeseeds/canola seeds	0.3%	7%
	13%	FR child 3 15 yr	26.71	7%	Wheat	5%	Sunflower seeds	0.8%	Milk: Cattle	0.3%	7%
	12%	PT general	24.25	6%	Wheat	6%	Sunflower seeds	0.2%	Rye	0.2%	6%
	12%	IE adult	23.09	4%	Sunflower seeds	3%	Wheat	3%	Linseeds	0.3%	3%
	11%	DE child	22.91	6%	Wheat	2%	Sunflower seeds	1%	Rye	0.4%	6%
	11%	GEMS/Food G11	21.05	5%	Wheat	2%	Sunflower seeds	2%	Barley	0.4%	7%
	10%	IT toddler	20.85	10%	Wheat	0.3%	Sunflower seeds	0.0%	Barley	0.1%	10%
	10%	NL general	20.75	4%	Sunflower seeds	3%	Wheat	2%	Rapeseeds/canola seeds	0.2%	3%
	10%	ES child	19.60	7%	Wheat	2%	Sunflower seeds	0.4%	Milk: Cattle	0.2%	7%
	9%	FR toddler 2 3 yr	18.03	5%	Wheat	3%	Sunflower seeds	1%	Milk: Cattle	0.2%	5%
	7%	UK toddler	14.03	6%	Wheat	0.7%	Milk: Cattle	0.1%	Oat	0.2%	6%
	7%	DE general	13.89	3%	Wheat	1%	Sunflower seeds	1%	Barley	0.2%	4%
	7%	ES adult	13.81	4%	Wheat	2%	Sunflower seeds	1.0%	Barley	0.1%	5%
	7%	DE women 14-50 yr	13.40	3%	Wheat	1%	Sunflower seeds	0.7%	Rye	0.2%	4%
	6%	IT adult	12.98	6%	Wheat	0.2%	Sunflower seeds	0.0%	Barley	0.1%	6%
	6%	FR adult	12.31	3%	Wheat	2%	Sunflower seeds	0.2%	Mustard seeds	0.2%	3%
	6%	SE general	12.15	5%	Wheat	0.4%	Rye	0.4%	Milk: Cattle	0.2%	5%
	6%	UK infant	12.07	4%	Wheat	1%	Milk: Cattle	0.4%	Oat	0.2%	4%
	5%	FI 3 yr	9.42	2%	Wheat	1.0%	Rye	0.9%	Oat	0.2%	2%
	5%	LT adult	9.15	2%	Rye	2%	Wheat	0.8%	Sunflower seeds	0.1%	2%
	4%	FI 6 yr	7.32	1%	Wheat	0.9%	Rye	0.5%	Oat	0.1%	2%
	3%	UK vegetarian	6.87	3%	Wheat	0.1%	Milk: Cattle	0.1%	Oat	0.1%	3%
	3%	UK adult	5.69	3%	Wheat	0.1%	Milk: Cattle	0.1%	Barley	0.1%	3%
	3%	DK adult	5.62	2%	Wheat	0.8%	Rye	0.2%	Milk: Cattle	0.1%	2%
	2%	FI adult	4.85	1%	Rye	0.5%	Wheat	0.3%	Coffee beans	0.3%	0.5%
	2%	FR infant	4.83	1%	Wheat	0.6%	Milk: Cattle	0.5%	Sunflower seeds	0.1%	1%
	2%	IE child	3.88	2%	Wheat	0.1%	Milk: Cattle	0.0%	Oat	0.0%	2%
	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 (sum of mepiquat and its salts, expressed as mepiquat chloride) is unlikely to present a public health concern.

EFSA PRIMo rev. 3.1, input: Reg. (EU) 2021/976

EFSA PRIMo revision 3.1; 2019/03/19

Mepiquat

LOQs (mg/kg) range from: to:

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	45,86	7%	Rapeseeds/canola seeds	6%	Wheat	6%	Sunflower seeds		
	22%	GEMS/Food G08	44,48	10%	Sunflower seeds	6%	Wheat	2%	Rapeseeds/canola seeds		
	22%	GEMS/Food G15	43,81	11%	Sunflower seeds	7%	Wheat	2%	Barley		
	22%	RO general	43,20	13%	Sunflower seeds	8%	Wheat	0,4%	Milk: Cattle		
	21%	GEMS/Food G07	42,00	8%	Sunflower seeds	6%	Wheat	4%	Rapeseeds/canola seeds		
	19%	NL child	37,50	7%	Sunflower seeds	6%	Wheat	3%	Rapeseeds/canola seeds		
	17%	GEMS/Food G06	34,61	11%	Wheat	5%	Sunflower seeds	0,9%	Cotton seeds		
	16%	DK child	32,42	8%	Rye	7%	Wheat	0,6%	Oat		
	15%	GEMS/Food G10	30,34	6%	Wheat	5%	Sunflower seeds	2%	Rapeseeds/canola seeds		
	13%	FR child 3 15 yr	26,70	7%	Wheat	5%	Sunflower seeds	0,8%	Milk: Cattle		
	12%	PT general	24,25	6%	Wheat	6%	Sunflower seeds	0,2%	Rye		
	12%	IE adult	23,07	4%	Sunflower seeds	3%	Wheat	3%	Linseeds		
	11%	DE child	22,90	6%	Wheat	2%	Sunflower seeds	1%	Rye		
	11%	GEMS/Food G11	21,14	5%	Wheat	2%	Sunflower seeds	2%	Barley		
	10%	IT toddler	20,85	10%	Wheat	0,3%	Sunflower seeds	0,0%	Barley		
	10%	NL general	20,73	4%	Sunflower seeds	3%	Wheat	2%	Rapeseeds/canola seeds		
	10%	ES child	19,60	7%	Wheat	2%	Sunflower seeds	0,4%	Milk: Cattle		
	9%	FR toddler 2 3 yr	18,03	5%	Wheat	3%	Sunflower seeds	1%	Milk: Cattle		
	7%	UK toddler	14,03	6%	Wheat	0,7%	Milk: Cattle	0,1%	Oat		
	7%	DE general	13,89	3%	Wheat	1%	Sunflower seeds	1%	Barley		
	7%	ES adult	13,81	4%	Wheat	2%	Sunflower seeds	1,0%	Barley		
	7%	DE women 14-50 yr	13,40	3%	Wheat	1%	Sunflower seeds	0,7%	Rye		
	6%	IT adult	12,98	6%	Wheat	0,2%	Sunflower seeds	0,0%	Barley		
	6%	FR adult	12,30	3%	Wheat	2%	Sunflower seeds	0,2%	Mustard seeds		
	6%	SE general	12,15	5%	Wheat	0,4%	Rye	0,4%	Milk: Cattle		
	6%	UK infant	12,07	4%	Wheat	1%	Milk: Cattle	0,4%	Oat		
	5%	FI 3 yr	9,42	2%	Wheat	1,0%	Rye	0,9%	Oat		
	5%	LT adult	9,15	2%	Rye	2%	Wheat	0,8%	Sunflower seeds		
	4%	FI 6 yr	7,32	1%	Wheat	0,9%	Rye	0,5%	Oat		
	3%	UK vegetarian	6,87	3%	Wheat	0,1%	Milk: Cattle	0,1%	Oat		
	3%	UK adult	5,68	3%	Wheat	0,1%	Milk: Cattle	0,1%	Barley		
	3%	DK adult	5,62	2%	Wheat	0,8%	Rye	0,2%	Milk: Cattle		
	2%	FI adult	4,85	1%	Rye	0,5%	Wheat	0,3%	Coffee beans		
	2%	FR infant	4,83	1%	Wheat	0,6%	Milk: Cattle	0,5%	Sunflower seeds		
	2%	IE child	3,88	2%	Wheat	0,1%	Milk: Cattle	0,0%	Oat		
	0,3%	PL general	0,54	0,2%	Sunflower seeds	0,0%	Potatoes	0,0%	Apples		

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

A 3.1.2 IEDI calculations

Not relevant.

A 3.1.3 IESTI calculations - Raw commodities

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

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

Show results 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 new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---				**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				IESTI new				IESTI new			
Highest % of ARfD/ADI	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)
14%	Wheat	3 / 3	43	8%	Wheat	3 / 3	25	14%	Wheat	3 / 3	43	8%	Wheat	3 / 3	25
7%	Barley	4 / 4	22	6%	Barley	4 / 4	19	7%	Barley	4 / 4	22	6%	Barley	4 / 4	19
7%	Rapeseeds/canola	15 / 15	21	5%	Rye	3 / 3	15	7%	Rapeseeds/canola	15 / 15	21	5%	Rye	3 / 3	15
6%	Rye	3 / 3	19	3%	Rapeseeds/canola seeds	15 / 15	7.9	6%	Rye	3 / 3	19	3%	Rapeseeds/canola seeds	15 / 15	7.9
1%	Oat	3 / 3	3.3	0.6%	Oat	3 / 3	1.9	1%	Oat	3 / 3	3.3	0.6%	Oat	3 / 3	1.9
Expand/collapse list															
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)**							

A 3.1.4 IESTI calculations - Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
12%	Wheat / milling (flour)	3 / 3	36
6%	Wheat / milling (wholemea	3 / 3	17
5%	Barley / cooked	4 / 4	15
4%	Rye / boiled	3 / 3	11
4%	Oat / boiled	3 / 3	11
4%	Rye / milling (wholemeal)-l	3 / 3	11
3%	Oat / milling (flakes)	3 / 3	9.0
3%	Rapeseeds / oils	15 / 30	8.8
2%	Barley / milling (flour)	4 / 4	7.2
#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			

Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Barley / beer	4 / 0.8	29
4%	Wheat / bread/pizza	3 / 3	13
4%	Wheat / pasta	3 / 3	11
3%	Wheat / bread	3 / 3	10
2%	Oat / boiled	3 / 3	4.6
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI new			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
12%	Wheat / milling (flour)	3 / 3	36
6%	Wheat / milling	3 / 3	17
5%	Barley / cooked	4 / 4	15
4%	Rye / boiled	3 / 3	11
4%	Oat / boiled	3 / 3	11
4%	Rye / milling (wholemeal)-	3 / 3	11
3%	Oat / milling (flakes)	3 / 3	9.0
3%	Rapeseeds / oils	15 / 30	8.8
2%	Barley / milling (flour)	4 / 4	7.2
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI new			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Barley / beer	4 / 0.8	29
4%	Wheat / bread/pizza	3 / 3	13
4%	Wheat / pasta	3 / 3	11
3%	Wheat / bread (wholemeal)	3 / 3	10
2%	Oat / boiled	3 / 3	4.6
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride) is unlikely to present a public health risk.

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

IESTI, EFSA PRIMo rev. 3.1, input: Reg. (EU) 2021/976, proposed uses

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
14%	Wheat	3 / 3	43
7%	Barley	4 / 4	22
7%	Rapeseeds/canola	15 / 15	21

Expand/collapse list

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

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Wheat	3 / 3	25
6%	Barley	4 / 4	19
3%	Rapeseeds/canola seeds	15 / 15	7,9

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
12%	Wheat / milling (flour)	3 / 3	36
6%	Wheat / milling (wholemea	3 / 3	17
5%	Barley / cooked	4 / 4	15
3%	Rapeseeds / oils	15 / 30	8,8
2%	Barley / milling (flour)	4 / 4	7,2

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Barley / beer	4 / 0,8	29
4%	Wheat / bread/pizza	3 / 3	13
4%	Wheat / pasta	3 / 3	11
3%	Wheat / bread	3 / 3	10

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

Additional information provided by the applicant

Not relevant, no additional information provided.