FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

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
05.2023	Assessment by zRMS based on draft document of the applicant
August 2023	Final version of RR after commenting period.

Table of Contents

8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g saf-ener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	CEU	**Winter wheat**	F	Reduction of height to prevent lodging	Foliar spray	BBCH 29-32	a) 1 b) 1	NA	a) 2.0 b) 2.0	a) 0.69 chlomequat chloride + 0.23 mepiquat chloride b) 0.69 chlomequat chloride + 0.23 mepiquat chloride	200-400			A

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

** 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 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Table 8.1-2: Assessed (critical) uses during approval of Chlormequat concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg as/hL min-max	Water L/ha min/max	g or kg as/ha min-max		
1	See foot-note 1)	**Winter wheat**	F	Plant growth regulator	Spraying	32 2)	1	NA	0.33-1.0	150-450	1.5	See footnote 3)	[1] [2]
2	See foot-note 1)	**Spring wheat**	F	Plant growth regulator	Spraying	31 2)	1	NA	0.33-1.0	150-450	1.5	See footnote 3)	[1] [2]
3	See foot-note 1)	**Triticale**	F	Plant growth regulator	Spraying	37 2)	1	NA	0.33-1.0	150-450	1.5	See footnote 3)	[1] [2]
4	See foot-note 1)	**Durum wheat**	F	Plant growth regulator	Spraying	31 2)	1	NA	0.33-1.0	150-450	1.5	See footnote 3)	[1] [2]
5	See foot-note 1)	**Spelt wheat**	F	Plant growth regulator	Spraying	32 2)	1	NA	0.33-1.0	150-450	1.5	See footnote 3)	[1] [2]
6	See foot-note 1)	**Rye**	F	Plant growth regulator	Spraying	37 2)	1	NA	0.33-1.0	150-450	1.5	See footnote 3)	[1] [2]
7	See foot-note 1)	**Oats**	F	Plant growth regulator	Spraying	49 2)	1	NA	0.33-1.0	150-450	1.5	See footnote 3)	[1] [2]
8	See foot-note 1)	**Winter barley**	F	Plant growth regulator	Spraying	30 2)	1	NA	0.33-1.0	150-450	1.5	See footnote 3)	[1] [2]
9	See foot-note 1)	**Spring barley**	F	Plant growth regulator	Spraying	30 2)	1	NA	0.33-1.0	150-450	1.5	See footnote 3)	[1] [2]
10	France	**Winter wheat**	F	Plant growth regulator	Spraying	32 2)	1	NA	0.22-0.67	150-450	1.0	See	[1] [2]

	(NEU and SEU)											footnote 3)	
11	France (NEU and SEU)	**Spring wheat**	F	Plant growth regulator	Spraying	31 2)	1	NA	0.22-0.67	150-450	1.0	See footnote 3)	[1] [2]
12	France (NEU and SEU)	**Durum wheat**	F	Plant growth regulator	Spraying	31 2)	1	NA	0.33-1.0	150-450	1.5	See footnote 3)	[1] [2]
13	France (NEU and SEU)	**Rye**	F	Plant growth regulator	Spraying	37 2)	1	NA	0.27-0.80	150-450	1.2	See footnote 3)	[1] [2]
14	France (NEU and SEU)	**Oats**	F	Plant growth regulator	Spraying	49é1	1	NA	0.31-0.93	150-450	1.4	See footnote 3)	[1] [2]

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** 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
[1] Data gaps were identified in section 5 (ecotoxicology)
[2] Data gaps were identified in section 3 (residue)
[3] MRLs only provisionally proposed and the risk assessment provisionally carried out due to data gaps identified in section 3 (residues)

1) Austria, Belgium, Denmark, Finland, Germany, Ireland, Luxembourg, The Netherlands, Sweden, United Kingdom, Poland, Czech Republic, Slovenia, Slovakia, Estonia, Lithuania and Latvia
2) co-formulations of Chlormequat chloride with other a.i.'s where Chlormequat chloride is applied at reduced rates, are to be applied up to GS 49
3) fixed by approved use

Table 8.1-3: Assessed (critical) uses during approval of Mepiquat concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel-opmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg as/hL min-max	Water L/ha min/max	g or kg as/ha min-max		
1	Belgium, Denmark, Finland, France, Ireland,	**Cereals**	F	Stem stabilisation	Spraying	BBCH 31-39	1	NA	**0.127-0.508***** 0.065-0.258*****	150-600	**0.7625***** 0.3875*****	[2]	[1]

	Luwembourg, Sweden, United King-dom												

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

[1] Residue trial data base for cereals incomplete, consumer risk assessment and MRL proposal for the use in the broad category of cereals cannot be finalised. Complete data is available only to support a use in barley and based on this data no risk to consumer is expected
[2] covered by conditions of use

zRMS comments:

All comments and conclusions of the zRMS are presented in grey. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information is struck through and shaded for transparency.

In following text, simplified names of active substances were used:
Chlormequat instead Chlormequat chloride
Mepiquat instead mepiquat chloride.

8.2 Metabolites considered in the assessment

Not relevant.

8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Chlormequat

Table 8.3-1: Summary of aerobic degradation rates for Chlormequat - laboratory studies

Chlormequat, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**X^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Refer-ence**
Speyer 2.2	Loamy sand[d)]	5.8	20	40	31.8	105.6	31.8[c)]	4.63	SFO	EFSA Scietific Report (2008) 179, 1-77 and Confirmatory Data – Chlormequat (May 2014)
Itingen	Silt loam	7.4	20	40	48.4[a)]	120.0	44.7	8.31	SFOP	
Collombey	Loamy sand	7.5	20	40	34.6	114.9	34.6[c)]	4.33	SFO	
Les Evouettes	Silt loam	7.7	20	40	27.0	89.7	23.1	5.44	SFO	
Speyer 5M	Sandy loam		20	40	12.3	41.0	11.0	10.9	SFO	
Itingen III	Cla loam		20	40	23.4[b)]	77.6	23.4[c)]	7.11	FOMC	
Speyer 2.2	Loamy sand		20	40	40.2	133.6	40.2[c)]	4.9	SFO	
Geometric mean (n=7)							**27.5**			
pH-dependency:							No			

a) Calculated from Slow phase degradation of the DFOP model
b) Calculated from the DT90/3.32 of the FOMM model
c) Value not corrected because the study moisture value was higher than the reference
d) RMS notes that the soil classification has been reassessed which has resulted in Speyer 2.2 being referred to as loamy sand instead of sandy loam. This has been accepted.

8.3.1.2 Mepiquat

Table 8.3-2: Summary of aerobic degradation rates for Mepiquat - laboratory studies

Mepiquat, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**r2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Neuhofen	Loamy sand	6.8*	20	40	31	102	23	0.92	SFO, non-linear regerssion	EFSA Scientific Report (2008) 146, 1-73
Holly Springs	Loamy sand	5.7	25	75% FC at 1/3 bar	6	18	5	0.96		
Bruch West	Sandy loam	7.5	20	40	40	133	37	0.97		
Li35b	Sandy loam	7.0	20	40	11	37	8	0.98		
Lufa 2.2	Loamy sand	5.8	20	40	11	36	11	0.97		
Meckenheim	Loamy sand	6.8*	20	40	20	65	14	0.99		
Bruch West	Loamy sand	7.5	10	40	83	277	-	0.95		
Geometric mean (n=6)							**13.2** (Q_{10} = 2.2)			
pH-dependency:							No			

*** determined in $CaCl_2$**

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Chlormequat

An anaerobic degradation study in soil was not considered necessary because of the relatively short DT_{50} values for Chlormequat-chloride in the four study soils: 26.8 to 33.9 days and because it is only moderately mobile in soil and therefore unlikely to reach anaerobic soil layers (DAR Chlormequat-chloride – Volume 3, Annex B.8: Environmental Fate and Behaviour – April 2007).

8.3.2.2 Mepiquat

In laboratory anaerobic metabolism studies and soil photodegradation studies Mepiquat-chloride was observed to undergo insignificant degradation, and no DT_{50} values could be calculated (EFSA Scientific Report (2008) 146, 1-73).

8.4 Field studies (KCP 9.1.1.2)

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

8.4.1.1 Chlormequat

The DT_{50} for the degradation of Chlormequat-chloride in soil, as determined in the laboratory soil degradation studies is < 60 days. Furthermore, only one application is envisaged. For these reasons, field studies are not considered necessary. Since there is a clear and reliable estimation of the degradation behaviour in the soil. Chlormequat-chloride residues in the soil can be reliably calculated. Therefore, soil residues testing in the field is not required and no information was submitted (DAR Chlormequat-chloride – Volume 3, Annex B.8: Environmental fate and behaviour – April 2007).

8.4.1.2 Mepiquat

Field dissipation studies were not required for Mepiquat-chloride since aerobic degradation in the laboratory resulted in half-lives between 6 and 40 days at 20 to 25°C. Laboratory degradation was therefore below the trigger of 60 day (DAR Mepiquat-chloride – Volume 3, Annex B.8: Environmental fate and behaviour – March 2005).

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

8.4.2.1 Chlormequat

No data available.

8.4.2.2 Mepiquat

For the same reason of relatively rapid laboratory degradation, no soil residue testing or soil accumulation testing was required or performed (DAR Mepiquat-chloride – Volume 3, Annex B.8: Environmental fate and behaviour – March 2005).

8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.5.1 Chlormequat

Table 8.5-1: Summary of soil adsorption/desorption for Chlormequat

Chlormequat							
Soil name	**Soil type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Bromsgrove	Sandy loam	1.7	5.0	1.34	78.8	0.60	Confirmatory data – Chlormequat (May 2014)
Evesham 3	Clay loam	1.6	7.3	4.51	282	0.99	
Warsop	Loamy sand	0.6	3.9	0.63	105	0.92	
Hodnet	Sandy loam/ Sandy clay loam	1.9	5.9	1.16	61.1	0.93	
Geometric mean (n=4)					**109.3**	-	
Arithmetic mean (n=4)					132	0.86	
pH-dependency					No		

8.5.2 Mepiquat

Table 8.5-2: Summary of soil adsorption/desorption for Mepiquat

Mepiquat							
Soil na<<me	**Soil type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Greenville	Loam	0.6	6.3	9.88	1563	0.958	EFSA Scientific Report (2008) 146, 1-73
Woodland	Clay	1.1	6.6	12.00	1099	0.991	
Dinuba	Sand loam	0.5	6.8	25.00	4833	0.946	
Hokkaido Tokachi	Clay loam	2.6	6.2	1.71	67	0.972	
Aichi, Japan	Sandy clay loam	0.8	7.1	5.49	722	0.953	
Miyazaki, Japan	Sand	1.5	7.2	1.69	113	0.988	
Pfungstadt (22°C)		0.6	7.3*	13.36	2304	0.972	
Pfungstadt (18°C)		0.6	7.3*	17.06	2942	0.980	
Neuhofen (22°C)		2.7	6.1*	5.74	216	0.963	
Neuhofen (18°C)		2.7	6.1*	7.41	278	0.933	
Lufa 2.1 (22°C)		0.5	6.8*	3.90	765	0.976	
Lufa 2.1 (18°C)		0.5	6.8*	5.17	1014	0.914	
Median					890	0.968	
Geometric mean (n=12)					**702.02**	-	
Arithmetic mean (n=12)					-	0.962	
pH-dependency					No pH dependence		

*** pH determined in KCl**

8.5.3 Column leaching (KCP 9.1.2.1)

Chlormequat	No column leaching study was submitted because there is sufficient data on the adsorption of Chlormequat chloride to soil available. Ages residues leaching: Aged for (d): 15 d Time period (d): 15 d Elution (mL): 393 mL Analysis of soil residues post ageing (soil residues pre-leaching): 48% soil extractable residue, 20% bound residue; < 10% unidentified metabolite; 33% mineralized to $^{14}CO_2$ Leachate: 0.29-0.49% of AR for a loamy sand in leachate.
Mepiquat	Column leaching: No data submitted – none required. Aged residues leaching: Guideline: BBA IV: 4-2, 1996 and SETAC 1995 Aged for: 30 d Time period: 2 d Precipitation: 200 mm Leachate: 0.1% total radioactivity in leachate All radioactivity presents as active substance > 60% total radioactivity retained in top 24 cm

8.5.4 Lysimeter studies (KCP 9.1.2.2)

Chlormequat	No study submitted or considered necessary.
Mepiquat	No data submitted, none required.

8.5.5 Field leaching studies (KCP 9.1.2.3)

Chlormequat	No study submitted or considered necessary.
Mepiquat	No data submitted, none required.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.6.1 Chlormequat

Table 8.6-1: Summary of degradation in water/sediment of Chlormequat

Chlormequat Distribution (max. in water 107.1% at day 0 and max. in sediment 63.3% after 30 days)										
Water/ sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**St. (r^2)**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**St. (r^2)**	**$DissT_{50}$ sed. (d)**	**Method of calc.**	**Evaluated on EU level y/n/ Reference**
River	8.47/7.27	0.9	10.4	0.98	0.5	5.4	0.94	n.d.	First order	EFSA

Chlormequat Distribution (max. in water 107.1% at day 0 and max. in sediment 63.3% after 30 days)										
Water/ sediment system	**pH water/ sed.**	**DegT$_{50}$ whole syst. (d)**	**DegT$_{90}$ whole syst. (d)**	**St. (r^2)**	**DissT$_{50}$ water (d)**	**DissT$_{90}$ water (d)**	**St. (r^2)**	**DissT$_{50}$ sed. (d)**	**Method of calc.**	**Evaluated on EU level y/n/ Reference**
									SQRT	Scientific Report (2008) 179, 1-77 and Confimatory data (May 2014)
Pond	7.97/6.89	**6.6**	21.9	0.98	0.5	5.3	0.97	n.d.	First order SQRT (water)/ first order (whole system)	
Geometric mean (n=2)		2.4	15.1		0.5	5.3		-		

8.6.2 Mepiquat

Table 8.6-2: Summary of degradation in water/sediment of Mepiquat

Mepiquat Distribution (max. sediment 56.2% after 14 days)										
Water/sediment system	**pH water/ sed.**	**DegT$_{50}$ whole syst. (d)**	**DegT$_{90}$ whole syst. (d)**	**St. (r^2)**	**DissT$_{50\text{-}90}$ water (d)**	**Kinetic, Fit**	**DissT$_{50\text{-}90}$ sed. (d)**	**St. (r^2)**	**Method of calc.**	**Evaluated on EU level y/n/ Reference**
Kellmetschweiher, Germany	8.5/5.8	32	107	0.99	Nd.*	-	25-83	0.94	SFO, non-linear regrassion	EFSA Scientific Report (2008) 146, 1-73
Ranschgraben, Germany	7.8/4.8	33	109	0.99	Nd.*	-	22-73	0.97		
Geometric mean (n=2)		32.5	108				23.5	77.8		

*** The dissipation DT$_{50}$ value from the water phase was 6 and 9 days in the two systems respectively.**

8.7 Predicted Environmental Concentrations in soil (PEC$_{soil}$) (KCP 9.1.3)

zRMS comments:

PECsoil calculations has been accepted for the active substances mepiquat and chlormequat for single application and for the dose proposed in GAP.
The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific Report (2008) 146, 1-73 and Scientific Report (2008) 179, 1-77 and Confirmatory data (May 2014).
The interception used in the calculation PECs was 20% and is in line with the proposed the proposed BBCH of crops ((EFSA guidance was published, (2014;12(5):3662).)

Initial PECsoil (mg/kg) for **Winter wheat**
Chlormequat: **0.736**
Mepiquat: **0.245**
Chlormequat 34.5% + Mepiquat 11.5% SL: **2.321**

8.7.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

8.7.2 Active substances and relevant metabolite

Table 8.7-1: Input parameters related to application for PEC_{soil} calculations

Use No.	1
Crop	**Winter wheat**
Application rate (g as/ha)	Chlormequat: 690 Mepiquat:230
Number of applications/interval	1/-
Crop interception (%)	20
Depth of soil layer (relevant for plateau concentration) (cm)	20 cm (tillage)

Table 8.7-2: Input parameter for active substances for PEC_{soil} calculation

Compound	**Molecular weight (g/mol)**	**Max. occur-rence (%)**	**DT_{50} (days)**	**Value in accordance to EU endpoint y/n/ Reference**
Chlormequat	158.1 g/mol	-	40.2 d (longest lab. DT_{50} corrected to 20°C)	EFSA Scientific Report (2008) 179, 1-77 and Confimatory data (March 2014)
Mepiquat	149.7 g/mol	-	40 d (worst-case, lab. value)	EFSA Scientific Report (2008) 146, 1-73

8.7.2.1 Chlormequat

Table 8.7-3: PEC_{soil} for Chlormequat on winter wheat

PEC_{soil} (mg/kg)		**Winter wheat**	
		Single application	
		Actual	TWA
Initial		0.736	-
Short term	24h	0.723	0.730
	2d	0.711	0.723
	4d	0.687	0.711
Long term	7d	0.652	0.693
	14d	0.578	0.654
	21d	0.512	0.617
	28d	0.454	0.584

	50d	0.322	0.501
	100d	0.131	0.351

8.7.2.2 Mepiquat

Table 8.7-4: PEC_{soil} for Mepiquat on winter wheat'

PEC_{soil} (mg/kg)		Winter wheat	
		Single application	
		Actual	TWA
Initial		0.245	-
Short term	24h	0.241	0.243
	2d	0.237	0.241
	4d	0.229	0.237
Long term	7d	0.217	0.231
	14d	0.192	0.218
	21d	0.170	0.206
	28d	0.151	0.194
	50d	0.107	0.167
	100d	0.043	0.117

8.7.2.3 PEC_{soil} of Chlormequat 34.5% + Mepiquat 11.5% SL

Since Chlormequat 34.5% + Mepiquat 11.5% SL is rapidly broken down into its constituent parts on contact with soil and/or crop material, it is appropriate to calculate the PEC_S following a single application only, using the following equation:

$$PEC_S(mg/kg) = \frac{\text{Application rate (g/ha)} \times (1\text{-F})}{100 \times \text{Soil depth (cm)} \times \text{Soil dry bulk density (g/cm}^3)}$$

Table 8.7-5: PEC_{soil} for Chlormequat 34.5% + Mepiquat 11.5% SL on winter wheat

Preparation	Application rate (g/ha)	Crop interception (%)	PEC_{act} (mg/kg)
Chlormequat + Mepiquat / Chlormequat 34.5% + Mepiquat 11.5% SL	2176*	20	2.321

* based on density value of 1.088

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

zRMS comments:

The PECgw calculations has been accepted for the active substances mepiquat and chlormequat for the proposed applications of the product.
The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific Report (2008) 146, 1-73 and Scientific Report (2008) 179, 1-77 and Confirmatory data (May 2014).

The interception used in the calculation PECs was 20% and is in line with the proposed the proposed BBCH of crops ((EFSA guidance was published, (2014;12(5):3662).)
Used in simulations PUF value of 0 was assumed for all compounds is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance.
The geometrical values of DT50 and Koc calculated from the list endpoints were used in the calculations of PECgw.

The PECgw at 1 meter depth were always lower than the trigger value for drinking water of 0.1 µg/L.
No major metabolites (≥10%) were detected in the soil study, so metabolites consideration in groundwater is not required.

Newertheless, additional simulations may be required by the cMS that do not accept calculations performed using FOCUS models.

8.8.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

8.8.2 Active substances and relevant metabolite (KCP 9.2.4.1)

Table 8.8-1: Input parameters related to application for PEC_{gw} calculations

Use No.	1
Crop	**Winter wheat**
Application rate (g as/ha)	Chlormequat: 690 Mepiquat:230
Number of applications/interval (d)	1/-
Crop interception (%)	20
Frequency of application	annual
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4

It should be noted that as recommended in the Generic Guidance for Tier 1 FOCUS Ground Water Assessments (FOCUS 2011), a corrected application rate is calculated taking into account the interception by the crop canopy. Therefore, the substance is applied directly to the ground in the models, thus avoiding the internal interception routines in the models. The corrected application rate is 552 g Chlormequat/ha and 184 g Mepiquat/ha.

Table 8.8-2: Application dates used for groundwater risk assessment

Crop	Scenario	Application dates (absolute)*
Winter wheat (BBCH 29)	Châteaudun	14.04
	Hamburg	03.05
	Jokioinen	13.05
	Kremsmünster	23.04
	Okehampton	20.04
	Piacenza	18.03
	Porto	27.01
	Sevilla	04.01
	Thiva	15.01

***Application dates according to AppDate 3.06 (28 June 2019)**

8.8.2.1 Chlormequat

Table 8.8-3: Input parameters related to active substance Chlormequat for PEC_{gw} calculations

Compound	Chlormequat	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	158.1	EFSA Scientific Report (2008) 179, 1-77 Addendum to the DAR (July 2008) EFSA Scientific Report (2008) 179, 1-77 and Confirmatory data (May 2014)
Water solubility (mg/L):	500000	
Saturated vapour pressure (Pa):	1×10^{-7} (worst-case)	
DT_{50} in soil (d)	27.5 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n=7)	
K_{foc} (mL/g)/K_{fom}	109.3 (geomean, n=4) / 63.4 132 (arithmetic mean from 4 different soils	
1/n	0.86 (arithmetic mean, n=4)	
Plant uptake factor	0	

Table 8.8-4: PEC_{gw} for Chlormequat on winter wheat (with FOCUS PEARL 5.5.5 & FOCUSPELMO 6.6.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)	
		FOCUS PEARL	FOCUS PELMO
Winter wheat	Châteaudun	<0.001	<0.001
	Hamburg	0.014	0.010
	Jokioinen	<0.001	<0.001
	Kremsmünster	0.028	0.004
	Okehampton	0.019	0.012
	Piacenza	0.004	0.002
	Porto	0.003	0.009
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001

8.8.2.2 Mepiquat

Table 8.8-5: Input parameters related to active substance Mepiquat for PEC_{gw} calculations

Compound	Mepiquat	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	149.7	EFSA Scientific report (2008) 146, 1-73
Water solubility (mg/L):	> 500000	
Saturated vapour pressure (Pa):	1.0 x 10^{-8} at 20°C)	
DT_{50} in soil (d)	13.2 (geomean of normalised lab values, 20°C, 10 kPa or pF2 with Q10 of 2.2, n=6)	
K_{foc} (mL/g)/K_{fom}	702.02 / 407.2 (geomean, n=12)	
1/n	0.962 (arithmetic mean, n=12)*	
Plant uptake factor	0	

***For calculations, as not K_f specification will be used, 1 instead of 0.962 has been used according to the EFSA conclusions as worst-case.**

Table 8.8-6: PEC_{gw} for Mepiquat on winter wheat (with FOCUS PEARL 5.5.5 & FOCUSPELMO 6.6.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)	
		FOCUS PEARL	FOCUS PELMO
Winter wheat	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	Jokioinen	<0.001	<0.001
	Kremsmünster	<0.001	<0.001

	Okehampton	<0.001	<0.001
	Piacenza	<0.001	<0.001
	Porto	<0.001	<0.001
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

zRMS comments:

PECsw/sed calculations has been accepted for the active substances mepiquat and chlormequat for proposed use of product in GAP.

The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific Report (2008) 146, 1-73 and Scientific Report (2008) 179, 1-77 and Confirmatory data (May 2014).
Used in simulations PUF value of 0 was assumed for all compounds was in line with recommendations of the most recent version of the FOCUS Groundwater Guidance. The geometrical values of DT50 and Koc calculated from the list endpoints were used in the calculations of PECsw/sed.

The calculations of PECsw/sed was performed by FOCUS STEPS 1-2 v3.2

8.9.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

8.9.2 Active substances, relevant metabolite and the formulation (KCP 9.2.5)

Table 8.9-1: Input parameters related to application for $PEC_{SW/SED}$ calculations

Plant protection product	Chormequat 34.5% + Mepiquat 11.5% SL
Use No.	1
Crop	**Winter wheat**
Application rate (kg as/ha)	Chlormequat: 690 Mepiquat: 230
Number of applications/interval (d)	1/-
Application window	March-May (average crop cover)
Application method	Foliar spray
CAM (Chemical application method)	2*
Soil depth (cm)	4 cm*
Models used for calculation	FOCUS STEPS 1-2 v3.2

***Not applicable at Step 1-2.**

8.9.2.1 Chlormequat

Table 8.9-2: Input parameters related to active substance Chlormequat for $PEC_{sw/sed}$ calculations STEP 1/2

Compound	**Chlormequat**	**Value in accordance to EU endpoint y/n/ Reference**
Molecular weight (g/mol)	158.1	EFSA Scientific Report (2008) 179, 1-77 EFSA Scientific Report (2008) 179, 1-77 and Confirmatory data (May 2014)
Water solubility (mg/L)	500000	
K_{foc} (mL/g)	109.3 (geomean, n=4)	
$DT_{50,soil}$ (d)	27.5 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58, n=7)	
$DT_{50,water}$ (d)	6.6 (worst-case whole system, n=2)	
$DT_{50,sed}$ (d)	1000 (default)	
$DT_{50,whole\ system}$ (d)	6.6 (worst-case whole system, n=2)	
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment: 63.3	

$PEC_{sw/sed}$

Table 8.9-3: FOCUS Steps 1/2 PEC_{sw} and PEC_{sed} for Chlormequat following single application of Chlormequat 34.5% + Mepiquat 11.5% SL on winter wheat

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1	---	207.09	Drainage/runoff	83.25	219.41
Step 2					
Southern Europe	March-May	61.99	Drainage/runoff	27.22	67.57
Northern Europe		32.95	Drainage/runoff	14.44	35.85

8.9.2.2 Mepiquat

Table 8.9-4: Input parameters related to active substance Mepiquat for $PEC_{sw/sed}$ calculations STEP 1/2

Compound	**Mepiquat**	**Value in accordance to EU endpoint y/n/ Reference**
Molecular weight (g/mol)	149.7	ESA Scientific report (2008)146, 1-73
Saturated vapour pressure (Pa)	1×10^{-8} at 20 °C	
Water solubility (mg/L)	> 500000	

Compound	**Mepiquat**	**Value in accordance to EU endpoint y/n/ Reference**
K_{foc} (mL/g)	702.02 (geomean, n=12) / 407.20	
$DT_{50,soil}$ (d)	13.2 (geomean of lab. data, n=6, normalisation to 10 kPa or pF2, 20°C with Q_{10} of 2.2)	
$DT_{50,water}$ (d)	1000 (default)	
$DT_{50,sed}$ (d)	25 (worst-case from two systems)	
$DT_{50,whole\ system}$ (d)	33 (worst-case from two systems)	
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment: 56.2	

$PEC_{sw/sed}$

Table 8.9-5: FOCUS Steps 1, 2 and 3 PEC_{sw} and PEC_{sed} for Mepiquat following single application of Chlormequat 34.5% + Mepiquat 11.5% SL on winter wheat

Scenario **FOCUS**	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1	---	41.72	Drainage/runoff	32.93	279.73
Step 2					
Southern Europe	March-May	11.54	Drainage/runoff	9.97	77.83
Northern Europe		6.40	Drainage/runoff	5.45	42.22

8.9.2.3 $PEC_{sw/sed}$ of Chlormequat 34.5% + Mepiquat 11.5% SL

The PEC_{SW} for Chlormequat 34.5% + Mepiquat 11.5% SL was calculated using the following equation:

$$PEC_{SW}\,(\mu g/L) = \frac{\%Drift_{90th\ \%ile} \times Application\ rate\ (g/ha)}{Water\ depth\ (cm) \times 10}$$

The application of Chlormequat 34.5% + Mepiquat 11.5% SL is 2 L/ha, corresponding to 2176 g/ha (taking into account a density of 1.088 g/cm^3) for winter wheat. The depth of the static water body was assumed to be 30 cm. The resulting maximum instantaneous PEC_{SW} value is presented in the table 8.9-6.

Table 8.9-6: PEC_{sw} for Chlormequat 34.5% + Mepiquat 11.5% SL following single application to winter wheat

Crop	**Distance (m)**	**Drift (%)**	**Max PEC_{sw} (µg/L)**
Winter wheat	1	2.77	20.092

The PEC_{sed} for Chlormequat 34.5% + Mepiquat 11.5% SL was calculated using the following equation:

$$PEC_{sed}\,(\mu g/kg\,dw) = \frac{\%Drift_{90th\ \%ile} \times Application\ rate\ (g/ha) \times \%Active\ substance\ in\ sediment}{1000 \times sediment\ density\ (g/cm^3) \times sediment\ height\ (cm)}$$

The application of Chlormequat 34.5% + Mepiquat 11.5% SL is 2 L/ha, corresponding to 2176 g/ha (taking into account a density of 1.088 g/cm^3) for winter wheat. The maximum percentage of Chlormequat in the sediment is 63.3% and the maximum percentage of Mepiquat in the sediment is 56.2%. The height of the sediment was assumed to be 5 cm and the sediment density was assumed to be 1.3 g/cm^3. The resulting maximum instantaneous PEC_{sed} value is presented in the table 8.9-7.

Table 8.9-7: PEC_{sed} for Chlormequat 34.5% + Mepiquat 11.5% SL following single application to winter wheat

Crop	Distance (m)	Drift (%)	Active substance	% in the sediment	Max PEC_{sed} (µg/kg) (based on maximum occurrence)
Winter wheat	1	2.77	Chlormequat	63.3	58.699
			Mepiquat	56.2	52.115

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Table 8.10-1: Summary of atmospheric degradation and behaviour - Chlormequat

Compound	Chlormequat
Direct photolysis in air	Not studies – no data requested
Quantum yield of direct phototransformation	Not studies
Photochemical oxidative degradation in air	DT50 (h): 1.45 days, assuming 12 hours of light per day, derived by the Atkinson model
Volatilisation	No data submitted, non required. Vapour pressure (Pa): 1 x 10^{-7} (worst case)
Metabolites	None determined

The vapour pressure at 20 °C of the active substance Chlormequat is < 10^{-5} Pa. Hence the active substance Chlormequat is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Chlormequat due to volatilization with subsequent deposition should not be considered.

Table 8.10-2: Summary of atmospheric degradation and behaviour - Mepiquat

Compound	Mepiquat
Direct photolysis in air	No data submitted, none required.
Quantum yield of direct phototransformation	No data submitted., none required.
Photochemical oxidative degradation in air	DT50 (h): 4.56 hours derived by the Atkinson model OH (12h) concentration assumed = 1.5 x 10^6 radicals/cm^3
Volatilisation	No data subimtted. Vapour pressure (Pa): < 1.0 x 10^{-8} (at 20 and 25°C) Henry's Law Constant (Pa.m3/mol): < 2.994 x 10^{-12} Pa.m^3.mol^{-1}
Metabolites	None

The vapour pressure at 20 °C of the active substance Mepiquat is < 10^{-5} Pa. Hence the active substance Mepiquat is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Mepiquat due to volatilization with subsequent deposition should not be considered.

zRMS comments

The atmospheric degradation and behaviour for chormequat and mepiquat are in line with EU agreed endpoints.

Appendix 1 Lists of data considered in support of the evaluation
Appendix 2 Detailed evaluation of the new Annex II studies
Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)