FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

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: 06.2021, 02.2022

Version history

When	What
02. 2021	Submission dRR by Applicant
06. 2021	Draft asessment to commenting
February 2022	Final version of RR

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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/ syner-gist 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, winter barley, spring barley**	F	Reduction of crop height	Foliar Spray	BBCH 31-39	a) 1 b) 1	-	a) 0.75 b) 0.75	a) 0.0285(mepiquat-Cl) b) 0.0285(mepiquat-Cl)	200-400		0.0285g/ha mepiquat-Cl corresponds with 37.5 g/ha mepi-quat-Cl chloride	A
2	CEU	**Winter Oilseed rape**	F	Reduction of crop height	Foliar Spray	BBCH 31-39	a) 1 b) 1	-	a) 0.75 b) 0.75	a) 0.0285(mepiquat-Cl) b) 0.0285(mepiquat-Cl)	200-400		0285g/ha mepiquat-Cl corresponds with 37.5 g/ha mepi-quat-Cl chloride	A

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

** 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 Mepiquat-Cl 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 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		
1	Belgium, Denmark, Finland, France, Ireland, Luxembourg, Sweden, UK	**Cereals**	F	Stem stabilisation	SP	BBCH 31-49	a) 1 b) 1	NA	-	a) 0.7625 mepiquat-Cl chlorid + 0.3875 etephon b) 0.7625 mepiquat-Cl chlorid + 0.3875 etephon	150-600	[2]	[1]

* 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] 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 consumers 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.

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 Mepiquat -Cl and its metabolites

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

Mepiquat- Cl, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (r^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Neuhofen	Loamy sand	6.8*	20	40	31	102	23	0.92	SFO, non-linear regression	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** (Q10 = 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 Mepiquat-Cl

In laboratory anaerobic metabolism studies and soil photodegradation studies Mepiquat-Cl-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 Mepiquat-Cl and its metabolites

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 Mepiquat-Cl

For the same reason of relatively rapid laboratory degradation, no soil residue testing or soil accumulation testing was required or performed (DAR Mepiquat-Cl-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 Mepiquat-Cl and its metabolites

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

Mepiquat-Cl							
Soil name	**Soil type**	**OC (%)**	**pH (H_2O)**	**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	Sandy 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	

Mepiquat-Cl							
Soil name	**Soil type**	**OC (%)**	**pH (H_2O)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
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	
Geometric mean (n=12)					**702.02**	-	
Arithmetic mean (n=12)					-	**0.968**	
pH-dependency					No		

***pH determined in KCl**

8.5.2 Column leaching (KCP 9.1.2.1)

Mepiquat-Cl	Column leaching: No data submitted – none required. Aged residues leaching: Guideline: BBA IV: 4-2, 1996 and SETAC 1995 Aged for (d): 30 d Time period (d): 2 d Precipitation (mm): 200 mm Leachate: 0.1% total radioactivity in leachate All radioactivity presents as active substance >60% total radioactivity retained in top 24 cm

8.5.3 Lysimeter studies (KCP 9.1.2.2)

Mepiquat-Cl	No data submitted – none required.

8.5.4 Field leaching studies (KCP 9.1.2.3)

Mepiquat-Cl	Please refer to point 8.5.4.

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 Mepiquat-Cl and its metabolites

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

Mepiquat-Cl Distribution (max. in sediment 56.2% after 14 days)											
Water/sediment system	**pH wa-ter/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**St. (r^2)**	**DissT50 -90 wa-ter (d)**	**St. (r^2)**	**DissT50 sed. (d)**	**DissT90 sed. (d)**	**St. (r^2)**	**Method of calc.**	**Evaluat-ed on EU level y/n/ Reference**
Kellmetschweiher, Germany	8.45/ 5.8	32	107	0.99	Nd*		25	83	0.94	SFO, non-linear regression	EFSA Scientific report (2008) 146, 1-73
Ranschgraben, Garmeny	7.80/ 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)

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	2
Crop	**Winter cereals**	**Winter oilseed rape**
Application rate (g as/ha)	**28.5** (which corresponds 37.5 g/ha mepiquat-Cl chloride)	
Number of applications/interval	1/-	
Crop interception (%)	80	
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. occurrence (%)**	**DT50 (days)**	**Value in accord-ance to EU end-point y/n/ Reference**
Mepiquat-Cl	149.7	-	40 d (longest DT_{50} from laboratory studies)	EFSA Scientific Report (2008) 143, 1-73

8.7.2.1 Mepiquat-Cl and its metabolites

Table 8.7-3: PEC_{soil} for Mepiquat on crop

PEC_{soil} (mg/kg)		Winter cereals and winter oilseed rape	
		Single application	
		Actual	TWA
Initial		0.008	-
Short term	24h	0.007	0.008
	2d	0.007	0.007
	4d	0.007	0.007
Long term	7d	0.007	0.007
	14d	0.006	0.007
	21d	0.005	0.006
	28d	0.005	0.006
	50d	0.003	0.005
	100d	0.001	0.004
Plateau concentration (20 cm) after year		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

8.7.2.2 PEC_{soil} of MEPISHA

Since MEPISHA 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:

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

Table 8.7-4: PEC_{soil} for MEPISHA on winter cereals and winter oilseed rape

Active substance(s)/Preparation	Application rate (g/ha)	Crop interception (%)	PEC_{act} (mg/kg)
MEPISHA	764.7*	80	0.2039

***Based on density value of 1.0196 g/mL.**

zRMS comments:
PECsoil calculations has been accepted for the active substance mepiquat for single application.
The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific Report (2008) 146, 1-73. Interception is appropriate to the proposed BBCH of crops (guidance 2014).

However, according to EFSA (2008) 146, 1-73 the PECs calculations should be performed for mepiquat chloride (1 x 37.5 g/ha).
The PECs calculations performed by zRMS for mepiquat-Cl chloride are included in Table below.

PEC_{soil} (mg/kg) **Mepiquat-Cl chloride**		**Winter cereals and winter oilseed rape**	
		Single application	
		Actual	TWA
Initial		0.010	-
Short term	24h	0.010	0.010
	2d	0.010	0.010
	4d	0.009	0.010
Long term	7d	0.009	0.009
	14d	0.008	0.009
	21d	0.007	0.007
	28d	0.006	0.008
	50d	0.004	0.007
	100d	0.002	0.002
Plateau concentration (20 cm) after year		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

The calculations cover proposed uses in GAP.

PECs mepiquat = 0.008 mg/kg

PECs mepiquat-Cl chloride = 0.010 mg/kg

The submitted values of PEC_S for mepiquat-Cl chloride should be used in further risk assessment.

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

8.8.1 Justification for new endpoints

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

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

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

Use No.	1	2
Crop	**Winter, spring cereals**	**Winter oilseed rape**
Application rate (g as/ha)	28.5 (which corresponds 37.5 g/ha mepiquat-Cl chloride)	
Number of applications/interval (d)	1/-	

Crop interception (%)	80
Frequency of application	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3

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 5.7 g Mepiquat/ha.

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

Scenario	Application dates (absolute)*	
	Winter cereals	Winter oilseed rape
Châteaudun	17/04	13/03
Hamburg	05/05	19/04
Jokioinen	15/05	-
Kremsmünster	25/04	16/04
Okehampton	22/04	10/04
Piacenza	21/03	09/03
Porto	02/02	04/01
Sevilla	07/01	-
Thiva	20/01	-

***According to AppDate v 3.06 -28 June 2019).**

8.8.2.1 Mepiquat-Cl and its metabolites

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

Compound	Mepiquat-Cl	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 x 10^{-8} at 20°C	
DT_{50} in soil (d)	13.2 (geomean of lab. data, n=6, normalisation to 10 kPa or pF2, 20°C with Q_{10} of 2.2)	
K_{foc} (mL/g)/K_{fom}	702.02/407.20 (geomean, n=12)	
1/n	0.968 (arithmetic mean, n=12)*	
Plant uptake factor	0	

***For calculations, as not K_f specific site will be used, 1 instead of 0.968 has been used according to the EFSA conclusions as worst case**

Table 8.8-4: PEC_{gw} for Mepiquat-Cl on winter cereals (with FOCUS PEARL 4.4.4 and PELMO 5.5.3)

Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)	
	PEARL	PELMO
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

Table 8.8-5: PEC_{gw} for Mepiquat-Cl on winter oilseed rape (with FOCUS PEARL 4.4.4 and PELMO 5.5.3)

Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)	
	PEARL	PELMO
Châteaudun	< 0.001	< 0.001
Hamburg	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001
Okehampton	< 0.001	< 0.001
Piacenza	< 0.001	< 0.001
Porto	< 0.001	< 0.001

zRMS comments:

PECgw calculations has been accepted for the active substance mepiquat-Cl for single application.
The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific Report (2008) 146, 1-73. Interception is appropriate to the proposed BBCH of crops (guidance 2014).
The calculations cover proposed uses in GAP.
The PEC_{GW} 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.

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

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

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	MEPISHA	
Use No.	1	2
Crop	**Winter cereals**	**Winter oilseed rape**
Application rate (kg as/ha)	28.5 (which corresponds 37.5 mepiquat-Cl chloride g/ha)	
Number of applications/interval (d)	1/-	
Application window	March-May (full canopy)	
Application method	Foliar spray	
CAM (Chemical application method)	CAM 2	
Soil depth (cm)	4 cm	
Models used for calculation	FOCUS STEPS 1-2 v3.2	

8.9.2.1 Mepiquat-Cl and its metabolites

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

Compound	**Mepiquat-Cl**	**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 x 10^{-8} at 20 °C	
Water solubility (mg/L)	> 500000	
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)	

Compound	**Mepiquat-Cl**	**Value in accordance to EU endpoint y/n/ Reference**
$DT_{50,water}$ (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 8.9-3: FOCUS Step 1-2 PEC_{sw} and PEC_{sed} for Mepiquat following single application of MEPISHA to winter cereals

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	---	5.17	Drainage/runoff	4.08	34.66
Step 2					
Northern Europe	March-May	0.40	Drainage/runoff	0.33	2.52
Southern Europe	March-May	0.63		0.54	4.15

Table 8.9-2: FOCUS Step 1-2 PEC_{sw} and PEC_{sed} for Mepiquat following single application of MEPISHA to winter oilseed rape

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	---	5.17	Drainage/runoff	4.08	34.66
Step 2					
Northern Europe	March-May	0.36	Drainage/runoff	0.29	2.24
Southern Europe	March-May	0.55		0.47	3.60

8.9.2.2 $PEC_{sw/sed}$ of MEPISHA

The PEC_{SW} for MEPISHA 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 MEPISHA is 0.75 L/ha, corresponding to 764.7 g/ha (taking into account a density of 1.0196 g/cm^3) for winter cereals and winter oilseed rape. 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 8.9-5.

Table 8.9-5: PEC_{sw} for MEPISHA following single application to winter cereals and winter oilseed rape

Crop	Distance (m)	Drift (%)	Max PEC_{sw} (µg/L)
Winter cereals and winter oilseed rape	1	2.77	7.061

The PEC_{sed} for MEPISHA 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 MEPISHA is 0.75 L/ha, corresponding to 764.7 g/ha (taking into account a density of 1.0196 g/cm^3) for winter cereals and winter oilseed rape. The maximum percentage of Mepiquat-Cl 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 8.9-6.

Table 8.9-6: PEC_{sw} for MEPISHA following single application to winter cereals and winter oilseed rape

Crop	Distance (m)	Drift (%)	Active substance	% in the sediment	Max PEC_{sed} (µg/kg) (based on maximum occurrence)
Winter cereals and winter oilseed rape	1	2.77	Mepiquat-Cl	56.2	18.314

zRMS comments:

PECsw/sed calculations has been accepted for the active substance mepiquat-Cl for single application. The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific Report (2008) 146, 1-73. Interception was appropriate to the proposed BBCH of crops (guidance 2014).
However, according to EFSA (2008) 146, 1-73. the PECsw calculations should be performed for mepiquat-Cl chloride (1 x 37.5 g/ha).
The PECsw/sed calculations performed by zRMS for mepiquat-Cl chloride are included in Tables below:

FOCUS Step 1-2 PEC_{sw} and PEC_{sed} for <u>Mepiquat-Cl chloride</u> following single application of MEPISHA to winter, spring cereals

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	---	6.81	Drainage/runoff	5.37	45.33
Step 2					
Northern Europe	March-May	0.77	Drainage/runoff	0.65	5.00
Southern Europe	March-May	1.33		1.14	8.84

FOCUS Step 1-2 PEC_{sw} and PEC_{sed} for <u>Mepiquat-Cl chloride</u> following single application of MEPISHA to winter oilseed rape

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	---	6.80	Drainage/runoff	4.27	45.33
Step 2					
Northern Europe	March-May	0.77	Drainage/runoff	0.98	7.69
Southern Europe	March-May	0.88		0.74	5.77

The calculations cover proposed uses in GAP.

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

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

Table 8.10-1 Summary of atmospheric degradation and behaviour - Mepiquat-Cl

Compound	Mepiquat-Cl
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 on the basis of the assumption of 1.5 x 10^6 OH radicals/cm^3. This equates to 0.38 days assuming a 12 hr light day (derived by the Atkinson method of calculation)
Volatilisation	Vapour pressure (Pa): 1 x 10^{-8} at 20°C Henry's Law Constant (Pa.m3/mol): < 2.994 x 10^{-12}
Metabolites	None

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

zRMS comments

The atmospheric degradation and behaviour for mepiquat-Cl is in line with EU agreed endpoints.

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

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 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 new Annex II studies

No additional information was provided.

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

No additional information was provided.