

# **FINAL REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: SHA 126000 B**

**Product name: CLARA**

**Chemical active substances:**

**Chlormequat chloride, 720 g/L**

### **Central Zone**

**Zonal Rapporteur Member State: Poland**

**NATIONAL ASSESSMENT Poland**

**(authorization)**

**Applicant: Sharda Cropchem Ltd.**

**Submission date: February 2022**

**MS Finalisation date: June 2023; October 2023**

**February 2024; March 2024**

## Version history

When	What
February	Submission date
June 2023	ZRMs evaluated dRR submitted by Applicant
10/2023	The Final Registration Report
October 2023	Updated by Applicant the data protection request
February 2024	ZRMs made changes in the final version due to reviewed comments from MRiRW
March 2024	Corrected by zRMS

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# PART A

## RISK MANAGEMENT

### 1 Details of the application

#### 1.1 Application background

This application is submitted by SHARDA CROPCHEM LTD.

This application is for approval of CLARA, a soluble concentrate containing 720 g/L of Chlormequat (as chloride) as plant growth regulator on winter wheat.

zRMS: Poland

#### 1.2 Letters of Access

Not application. Letter of access not needed.

#### 1.3 Justification for submission of tests and studies

This dossier relies on new tests and studies, providing data and information specific to the formulation Chlormequat 72% SL as required by EU regulations.

#### 1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

### 2 Details of the authorization decision

#### 2.1 Product identity

Product code	SHA 126000 B
Product name in MS	CLARA
Authorization number	First authorisation
Function	Plant growth regulator
Applicant	Sharda Cropchem Ltd.
Active substances (incl. content)	Chlormequat chloride, 720 g/L
Formulation type	Soluble concentrate [Code: SL]
Packaging	0.25, 0.5, 1, 5, 10 L COEX (HDPE/PA) 0.25, 0.5, 1, 5, 10, 20 L HDPE

Coformulants of concern for national authorizations	-
Restrictions related to identity	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

## 2.2 Conclusion

The evaluation of the application for CLARA resulted in the decision to grant the authorization.

### Efficacy section:

CLARA can be registered in PL against reduction of height winter wheat crops at recommended dose 1,3-2,1 L/ha at BBCH 29-32. Prevention against lodging is accepted **only conditionally** due to **limited** number of trials.

### Mammalian toxicology:

SHA 126000 B / CLARA is classified Acute Tox.4/H302. No unacceptable risks to operators have been identified when the product is used as intended and with appropriate PPE.

**Ecotoxicology:** Accepted. In addition, the chronic study for adult bees and a study effects on honey bee development and other honey bee life stages was submitted by Applicant. The chronic studies were accepted by zRMS in updated RAR. However, the risk assessment based on this studies should be considered when GD for Bees, 2013 is implemented at EU level. Final decision should be taken into account at MSs level.

## 2.3 Substances of concern for national monitoring

Not relevant.

## 2.4 Classification and labelling

### 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Acute Tox. 4 (oral)
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	<b>GHS07</b>
Signal word:	<b>Warning</b>
Hazard statement(s):	<b>H302</b>
Precautionary statement(s):	<b>P264, P270, P280, P301+P312, P330, P501, P273</b>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	-

See Part C for justifications of the classification and labelling proposals.

## 2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
-	-

## 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

-	-
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## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
P280	Wear protective gloves, protective clothing.
Worker protection:	
-	Work wear (arms, body and legs covered)
-	Treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
-	-
Other specific restrictions	
-	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	-

## 2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
-	-	-




## 2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): CLARA / SHA 126000 B  
Active substance 1: Chlormequat chloride  
Active substance 2:  
Safener: -  
Synergist: -  
Applicant: Sharda Cropchem Ltd.  
Zone(s): Central  
Verified by MS: **yes**

Formulation type: SL (Soluble Concentrate)  
Conc. of as 1: 720 g/L  
Conc. of as 2:  
Conc. of safener: -  
Conc. of synergist: -  
Professional use: ☒  
Non professional use: ☐

Field of use: Plant growth regulator

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(i)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	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		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1		Winter wheat	F	Regulation of growth, prevention of lodging	Foliar Spray	BBCH 29-32	a) 1 b) 1	-	a) 1.3-2.1 b) 1.3-2.1	a) 0.936-1.51 b) 0.936-1.51	200- 300		Eff. section: regulation of growth – accepted and prevention of lodging is not accepted conditionally
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3													
4													

Minor uses according to Article 51 (zonal uses)													
5													
6													
Minor uses according to Article 51 (interzonal uses)													
7													
8													

<b>Remarks table heading:</b>	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
<b>Remarks columns:</b>	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	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	10	For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

### **3 Background of authorization decision and risk management**

#### **3.1 Physical and chemical properties (Part B, Section 2)**

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of colourless to light yellow liquid with characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable/has a flash point  $>130^{\circ}\text{C}$ . It has a self ignition temperature of  $345^{\circ}\text{C}$ . In aqueous solution, it has a pH value around 3.8 at  $20^{\circ}\text{C}$ . There is no effect of low and high temperature on the stability of the formulation, since after 7 days at  $0^{\circ}\text{C}$  and 14 days at  $54^{\circ}\text{C}$ , neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in COEX. Its technical characteristics are acceptable for a SL formulation.

The intended concentration of use is 0.43% v/v to 1.05% v/v.

No tank mixes recommended

#### **3.2 Efficacy (Part B, Section 3)**

CLARA (Chlormequat chloride 72% SL is a soluble concentrate (SL) formulation containing 720 g/l chlormequat-chloride, that acts as a growth regulator for the use in winter wheat.

In compliance with the GAP, the following dose rate is applied for registration:

- One application per season (BBCH 29-32) to reduce of height to regulation of growth and prevent lodging in winter wheat, target rate: 1.3-2.1 L/ha

This document serves the registration of Chlormequat chloride 72% SL in the Central zone of the EU. The objective of this document is to prove and support the label claims of the plant growth regulator efficacy and crop safety of Chlormequat chloride 72% SL in the GAP claimed crops.

Comprehensive field trials were conducted in Poland, Lithuania, France, United Kingdom, Germany, Czech Republic, Italy and Hungary in 2016 and 2017. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

#### **3.3 Efficacy data**

##### **Preliminary tests**

No results of the preliminary range-finding tests were submitted by the Applicant, however the active substances of CLARA (product code: SHA 126000 B) –chlormequat chloride is registered and have been commonly used in agricultural practice for many years (over 30). So, preliminary range finding tests are deemed too not be necessary in the opinion of ZRMs.

##### **Minimum effective dose tests**

The trials submitted to support the MED (minimum effective dose) of CLARA (product code: SHA 126000 B) are the same as the efficacy trials described under section efficacy.

To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance with EPPO 1/225 (2).

23 field trials carried out in different growing seasons (2016 and 2017) on winter wheat were established to determine the minimum effective dose of CLARA. Trials were performed in three EPPO zones – N-E in PL (6 trials) and LT (3 trials); MED in FR (2 trials) and IT (2 trials) and MAR in FR (4 trials), UK (2 trials), DE (2 trials) and CZ (2 trials). Three different doses were studied: 1,0 L/ha; 1,3 L/ha and 2,1 L/ha. All results were compared to standard reference products. In the trials, specifically targeted for height reduction, single application was applied at growth stages ranging between BBCH 29 and BBCH 32.

The proposed doses were derived from registered doses of standard reference products with chlormequat chloride as active compound and, product safety parameters and environmental limitations. Such products are used across Europe for many years and their MED (minimum effective dose) is justified. The proposed dose against lodging and growth reduction is 1,3 -2,1 L/ha applied once a season. Detailed results were presented by Applicant in the table: Table 3.3-8.

#### **Minimum effective dose results:**

- **N-E EPPO zone:** During 9 trials effect of reduction of height was observed. Control plants were characterized by average of 84,93 cm height. The most effective was dose 2,1 L/ha (average: 13,76% reduction of height in comparable to control plants). Effect of dose 1,3 L/ha (average: 12,59%) was slightly lower than dose 2,1 L/ha. Dose of 1,0 L/ha was characterized by 11,06% of reduction height of plants in comparable to control. The most effective against reduction of height was range of dose 1,3 -2,1 L/ha and this dose should be recommended for use.

Lodging was observed only in 2 trials on control plants (average: 54,4%). Dose 2,1 L/ha was the most effective in reducing of lodging (average: 10,9%). Dose 1,3 L/ha reduce of lodging (average: 25,0%) with average of efficacy and dose 1,0 L/ha (32,55%) average: was least effective. Applicant submitted too few studies to support anti-lodging action. At least 6 studies should have been submitted. However, even on such little number of trials it can be seen that the most effective against lodging is dose 2.1 L/ha. Also, dose 1.3 L/ha was characterized by good efficiency against lodging.

Trial ID	Country	Assess. Type	Untreated		Clormequat 72% SL 720 g ai/ha		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha	
			Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
110/2016	PL	Height (cm)	85.4	a	74.7	b	72.7	bc	71.9	bc
121/2016	PL	Height (cm)	119.9	a	103.1	b	97.3	c	95.5	c
122/2016	PL	Height (cm)	104.0	a	85.9	ab	86.5	ab	85.8	ab
142/2016	PL	Height (cm)	74.6	a	65.2	b	64.9	b	63.9	b
184 /2017	PL	Height (cm)	93.78	a	86.93	b	85.95	b	85.78	b
185/2017	PL	Height (cm)	85.78	a	77.9	b	77.18	b	76.45	b
LTZI2016PGR-02-01	LT	Height (cm)	55.2	a	53.4	ab	52.5	b	51.1	b
LTZI2016PGR-02-02	LT	Height (cm)	74.9	a	68.4	bc	67.5	bc	66.3	c
LTZI2016PGR-02-03	LT	Height (cm)	70.8	a	64.3	b	63.6	bc	62.4	c

Trial ID	Country	Crop GS at assessment	Assessm. Days after appl.	Assess. Type	Untreated		Clormequat 72% SL 720 g ai/ha		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha	
					Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
110/2016	PL	83	68	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
121/2016	PL	87	60	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
122/2016	PL	87	71	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
142/2016	PL	73	54	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
184 /2017	PL	87	83	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
185/2017	PL	77	77	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
LTZI2016PGR-02-01	LT	75	67	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		89	98	Lodging (0-100)	33.8	a	21.3	bc	22.5	b	11.0	d

100)										
LTZI2016PGR-02-02	LT	75	55	Lodging (0-100)	27.5	a	0.0	a	0.0	a
		89	84	Lodging (0-100)	75.0	a	43.8	b	27.5	bc
LTZI2016PGR-02-03	LT	75	66	Lodging (0-100)	0.0	a	0.0	a	0.0	a
		89	95	Lodging (0-100)	0.0	a	0.0	a	0.0	a

- **Maritime EPPO zone:** During 10 trials effect of reduction of height was observed. Control plants were characterized by average of 89,01 cm height. The most effective was dose 2,1 L/ha (average: 6,3% reduction of height in comparable to control plants). Effect of dose 1,3 l/ha (average: 4,48%) was slightly lower than dose 2,1 L/ha. Dose of 1,0 L/ha was characterized by 3,91% of reduction height of plants in comparable to control. The most effective against reduction of height was dose 2,1 L/ha and this dose should be recommended for use. The dose of 1,3 l/ha as well as the dose of 1,0 had only retardant properties and their effectiveness was lower than 5%. So, cMS form Maritime should consider the acceptance of dose 2,1 L/ha, not range of doses 1,3-2,1 L/ha in the opinion of ZRMs. However, final decision is left to each cMS.

Lodging as LODARE (lodging area) was observed only in 4 trials (average: 16,83%) and as a LODANG (lodging angle) in 1 trial on control plants (average: 40,75%). Dose 2,1 L/ha was the most effective in reducing of lodging. Dose 1,3 L/ha reduce of lodging with average of efficacy and dose 1,0 L/ha average: was least effective. Applicant submitted too few studies to support anti-lodging action. At least 6 studies should have been submitted. cMS should decide if presented trials against lodging can be acceptable.

Trial ID	Country	Crop GS at assessment	Assess. Type	Untreated		Clormequat 72% SL 720 g ai/ha		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha	
				Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
PC 16-05-12-NE1	FR	75	Height (cm)	79.9	a	78.1	a	79.4	a	77.5	a
PC 16-05-12-WE1	FR	75	Height (cm)	95.0	a	92.3	b	91.6	bc	90.8	c
SHA835-16-EFF001-001	UK	75	Height (cm)	91.25	a	85.7	b	86.25	b	85.0	b
SHA835-16-EFF001-002	UK	-	Height (cm)	88.25	a	93.0	a	93.0	a	88.75	a
Sharda16-046	DE	37	Height (cm)	71.6	a	68.3	b	67.0	b	67.4	b
		73	Height (cm)	108.3	a	102.5	b	102.9	b	102.6	b
Sharda16-047	DE	71	Height (cm)	111.0	a	107.0	b	107.0	b	104.0	c
SWEPL-CZE16-CLOR-TRZAW-KUJ32	CZ	85	Height (cm)	79.8	a	75.6	b	74.4	bc	70.9	c
SWEPL-CZE16-CLOR-TRZAW-RYM3	CZ	75	Height (cm)	61.3	a	57.4	a	56.5	c	56.1	c
P17GC01UEN01	FR	31	Height (cm)	45.28	a	44.35	a	42.58	a	42.03	a
		41	Height (cm)	76.6	a	67.3	b	63.7	b	62.38	b
		89	Height (cm)	88.18	a	78.13	b	73.5	b	73.5	b
P17GC01UEN02	FR	59	Height (cm)	84.1	a	82.98	a	83.45	a	82.68	a
		69	Height (cm)	88.48	a	87.35	a	88.55	a	87.8	a
		89	Height (cm)	87.15	a	85.6	a	85.68	a	84.83	a

Trial ID	Country	Crop GS at assessment	Assess. Type	Untreated		Clormequat 72% SL 720 g ai/ha		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha	
				Mean	Stat	%	Stat	%	Stat	%	Stat

try				n		Control		Control		Control	
PC 16-05-12-NE1	FR	61	LODARE (%)	0.0	a	0.0	a	0.0	a	0.0	a
		99	LODARE (%)	7.5	a	1.3	b	2.5	b	0.5	b
PC 16-05-12-WE1	FR	85	LODARE (%)	31.3	a	12.0	b	6.3	b	6.8	b
SHA835-16-EFF001-001	UK	89	LODARE (%)	1.0	a	0.3	b	0.0	a	0.0	a
SHA835-16-EFF001-002	UK	-	LODARE (%)	0.0	a	0.0	a	0.0	a	0.0	a
SWEPL-CZE16-CLOR-TRZAW-RYM3	CZ	77	LODARE (%)	27.5	-	0.0	a	0.0	a	0.0	a
		77	LODARE (%)	27.5	-	0.0	a	0.0	a	0.0	a

				Untreated		Clomequat 72% SL 720 g ai/ha		Clomequat 72% SL 936 g ai/ha		Clomequat 72% SL 1510 g ai/ha	
Trial ID	Country	Crop GS at assessment	Assess. Type	Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
Sharda16-046	DE	83	Lodging (0-100)	40.75	a	30.75	a	31.25	a	30.0	a
Sharda16-047	DE	63	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		71	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		81	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
P17GC01UEN01	FR	30	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		31	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		41	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
P17GC01UEN02	FR	41	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		59	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		69	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a

- **Mediterranean EPPO zone:** During 4 trials effect of reduction of height was observed. Control plants were characterized by average of 94,48 cm height. The most effective was dose 2,1 L/ha (average: 9,4% reduction of height in comparable to control plants). Effect of dose 1,3 l/ha (average: 6,06%) was lower than dose 2,1 L/ha. Dose of 1,0 L/ha was characterized by 2,82% of reduction height of plants in comparable to control. The most effective against reduction of height was range of dose 1,3 -2,1 L/ha and this dose should be recommended for use. However, CMS should decide if limited number of trials can be accepted or consider possibility of usage results from other zones.

Lodging as LODARE (lodging area) was observed only in 2 trials (average: 28,8%) and as a LODANG (lodging angle) in 1 trial on control plants (average: 0,2%). Dose 2,1 L/ha was the most effective in reducing of lodging. Dose 1,3 L/ha reduce of lodging with average of efficacy and dose 1,0 L/ha average: was least effective. Applicant submitted too few studies to support anti-lodging action. At least 6 studies should have been submitted. CMS should decide if presented trials against lodging can be acceptable.

				Untreated		Clomequat 72% SL 720 g ai/ha		Clomequat 72% SL 936 g ai/ha		Clomequat 72% SL 1510 g ai/ha	
Trial ID	Country	Crop GS at assessment	Assess. Type	Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
036.H.SAG16/e	IT	75	Height (cm)	84.08	a	78.18	b	77.4	b	76.48	b
037.H.SAG15/e	IT	83	Height (cm)	68.6	a	65.2	ab	62.7	bc	61.4	bc
PC 16-05-12-SW1	FR	83	Height (cm)	107.8	a	109.1	a	103.7	a	106.3	a
PC 16-05-12-SW2	FR	83	Height (cm)	116.7	a	114.8	ab	111.2	b	102.2	d

				Untreated		Clomequat 72% SL 720 g ai/ha		Clomequat 72% SL 936 g ai/ha		Clomequat 72% SL 1510 g ai/ha	
Trial ID	Country	Crop GS at assessment	Assess. Type	Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
036.H.SAG16/e	IT	89	Lodging (0-100)	0.2	a	0.0	a	0.0	a	0.0	a
037.H.SAG15/e	IT	73	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a

Trial ID	Country	Crop GS at assessment	Assess. Type	Untreated		Clomequat 72% SL 720 g ai/ha		Clomequat 72% SL 936 g ai/ha		Clomequat 72% SL 1510 g ai/ha	
				Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
PC 16-05-12-SW1	FR	63	LODARE (%)	41.3	a	16.3	b	18.3	b	10.3	b
		89	LODARE (%)	80.0	a	75.0	b	72.5	b	65.0	c
PC 16-05-12-SW2	FR	75	LODARE (%)	16.3	a	15.0	a	10.0	a	7.5	a
		89	LODARE (%)	26.3	a	27.5	a	15.0	b	11.3	b

**Summary:** In the opinion of ZRMs, presented results and knowledge about registered doses of standard reference products with chlomequat chloride allow to consider range of dose 1,3 – 2,1 L/ha as the most effective for winter wheat against reduction of height for N-E and MED EPPO zone. cMS from MAR should consider only dose 2,1 L/ha as MED for CLARA.

For lodging Applicant submitted too small number of trials. However, the most effective was dose 1,3 - 2,1 L/ha. **In PL this use can be accepted only conditionally.**

### Efficacy tests and conclusions regarding authorization of intended uses

Lodging in cereals was evaluated in accordance with the EPPO standards PP 1/144(3). Details of experiment are presented in the table above by Applicant. All used methodology is in accordance with GEP rules and EPPO standards, in the exception with EPPO 1/181 (4) for winter wheat in MED EPPO zone (all trials were carried out only in one growing season – 2016). In N-E (2016 and 2017) and MAR (2016 and 2017) – two different growing seasons were studied in line to EPPO.

We are dealing with the active substance used commonly for many years in many countries. On the basis on EPPO standard Applicant should submitted for reduction height and against lodging at least six trials for each EPPO zone. For Poland trials from neighbouring countries are acceptable. Submitted documentations is sufficient in the opinion of Evaluator for winter wheat for MAR (10 trials) and N-E (9 trials) against reduction of height. cMS from MED should decide if limited number of trials (only 4 trials) carried out in one growing season can be acceptable or consider possibility of usage results from other EPPO zones.

Prevention use against lodging can **not** be acceptable in Polish label due to **not-enough limited** number of trials **only conditionally**. cMS from N-E, MAR and MED should consider if it is possible to use results from other chlomequat chloride products due to very limited number of trials against lodging.

- **N-E EPPO zone:** Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging which was assessed.

Trial ID	Country	Crop GS at assessment	Assess. Type	Untreated		Clomequat 72% SL 936 g ai/ha		Clomequat 72% SL 1510 g ai/ha		Clomequat ref. prod. 1125-1500 g ai/ha	
				Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
110/2016	PL	83	Height (cm)	85.4	a	72.7	bc	71.9	bc	70.2	c
121/2016	PL	87	Height (cm)	119.9	a	97.3	c	95.5	c	94.7	d
122/2016	PL	87	Height (cm)	104.0	a	86.5	ab	85.8	ab	84.6	b
142/2016	PL	73	Height (cm)	74.6	a	64.9	b	63.9	b	64.8	b
184 /2017	PL	87	Height (cm)	93.78	a	85.95	b	85.78	b	85.38	b
185/2017	PL	77	Height (cm)	85.78	a	77.18	b	76.45	b	75.53	b
LTZI2016PGR-02-01	LT	39	Height (cm)	55.2	a	52.5	b	51.1	b	52.3	b
		51	Height (cm)	77.6	a	73.2	bc	71.7	c	73.5	bc
		75	Height (cm)	92.6	a	86.9	cd	84.4	e	86.3	d
		89	Height (cm)	89.8	a	83.9	cd	82.4	d	85.2	bc
LTZI2016PGR-02-02	LT	45	Height (cm)	74.9	a	67.5	bc	66.3	c	67.5	bc
		55	Height (cm)	120.7	a	107.4	cd	105.8	d	108.4	bc
		75	Height (cm)	117.5	a	105.6	cd	103.5	d	106.4	bc
		89	Height (cm)	109.7	a	103.3	b	100	c	101.8	bc
LTZI2016PGR-02-03	LT	39	Height (cm)	70.8	a	63.6	bc	62.4	c	63.0	bc
		51	Height (cm)	90.8	a	78.4	bc	75.6	d	77.9	c
		75	Height (cm)	99.4	a	87.1	cd	84.5	e	87.0	cd

89	Height (cm)	99.7 a	86.2 c	84.2 d	86.2 c
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Trial ID	Country	Crop GS at assessment	Assess. Type	Untreated		Clomequat 72% SL 936 g ai/ha		Clomequat 72% SL 1510 g ai/ha		Clomequat ref. prod. 1125-1500 g ai/ha	
				Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
110/2016	PL	83	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
121/2016	PL	87	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
122/2016	PL	87	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
142/2016	PL	73	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
184 /2017	PL	87	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
185/2017	PL	77	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
LTZI2016PGR-02-01	LT	75	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)	33.8	a	22.5	b	11.0	d	13.8	cd
LTZI2016PGR-02-02	LT	75	Lodging (0-100)	27.5	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)	75.0	a	27.5	bc	10.8	c	30.0	bc
LTZI2016PGR-02-03	LT	75	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a

During 9 trials effect of reduction of height was observed. Control plants were characterized by average of 84,93 cm height. The most effective was dose 2,1 L/ha (average: 13,76% reduction of height in comparable to control plants). Effect of dose 1,3 l/ha (average: 12,59%) was slightly lower than dose 2,1 L/ha. The most effective against reduction of height was range of dose 1,3 -2,1 L/ha and this dose should be recommended for use. CLARA at both recommended doses (1,3 and 2,1 L/ha) has better efficacy in reduction of height than standard ref. product (average; 0,97%).

Lodging was observed only in 2 trials on control plants (average: 54,4%). Dose 2,1 L/ha was the most effective in reducing of lodging (average: 10,9%). Dose 1,3 L/ha reduce of lodging (average: 25,0%) with average of efficacy. St. ref. product has lower efficiency in control of lodging (average: 21,9%) than CLARA used at 2,1 L/ha dose and slightly better than CLARA at dose 1,3 L/ha. Applicant submitted too few studies to support anti-lodging action. **At least 6 studies should have been submitted. So, only conditional registration in PL is recommended by ZRMs.**

- **Maritime EPPO zone:** Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging which was assessed.

Trial ID	Country	Crop GS at assessment	Assess. Type	Untreated		Clomequat 72% SL 936 g ai/ha		Clomequat 72% SL 1510 g ai/ha		Clomequat ref. prod 1500-1575 g ai/ha	
				Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
PC 16-05-12-NE1	FR	75	Height (cm)	79.9	a	79.4	a	77.5	a	77.7	a
PC 16-05-12-WE1	FR	75	Height (cm)	95.0	a	91.6	bc	90.8	c	90.9	c
SHA835-16-EFF001-001	UK	75	Height (cm)	91.25	a	86.25	b	85.0	b	85.75	b
SHA835-16-EFF001-002	UK	-	Height (cm)	88.25	a	93.0	a	88.75	a	96.75	a
Sharda16-046	DE	37	Height (cm)	71.6	a	67.0	b	67.4	b	66.6	b
		73	Height (cm)	108.3	a	102.9	b	102.6	b	102.2	b
Sharda16-047	DE	71	Height (cm)	111.0	a	107.0	b	104.0	c	105.0	c
SWEPL-CZE16-CLOR-TRZAW-	CZ	85	Height	79.8	a	74.4	bc	70.9	c	71.1	c



KUJ32			(cm)								
SWEPL-CZE16-CLOR-TRZAW-RYM3	CZ	75	Height (cm)	61.3	a	56.5	c	56.1	c	55.8	c
P17GC01UEN01	FR	31	Height (cm)	45.2	a	42.58	a	42.03	a	42.8	a
		41	Height (cm)	76.6	a	63.7	b	62.38	b	62.35	b
		89	Height (cm)	88.1	a	73.5	b	73.5	b	72.6	b
P17GC01UEN02	FR	59	Height (cm)	84.1	a	83.45	a	82.68	a	82.0	a
		69	Height (cm)	88.4	a	88.55	a	87.8	a	87.55	a
		89	Height (cm)	87.1	a	85.68	a	84.83	a	84.93	a

Trial ID	Country	Crop GS at assessment	Assess. Type	Untreated		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha		Clormequat ref. prod. 1500-1575 g ai/ha	
				Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
PC 16-05-12-NE1	FR	61	LODARE (%)	0.0	a	0.0	a	0.0	a	0.0	a
		99	LODARE (%)	7.5	a	2.5	b	0.5	b	1.0	b
PC 16-05-12-WE1	FR	85	LODARE (%)	31.3	a	6.3	b	6.8	b	5.3	b
SHA835-16-EFF001-001	UK	89	LODARE (%)	1.0	a	0.0	a	0.0	a	0.0	b
SHA835-16-EFF001-002	UK	-	LODARE (%)	0.0	a	0.0	a	0.0	a	0.0	a
SWEPL-...-TRZAW-RYM3	CZ	77	LODARE (%)	27.5	-	0.0	a	0.0	a	0.0	a
		77	LODARE (%)	27.5	-	0.0	a	0.0	a	0.0	a

Trial ID	Country	Crop GS at assessment	Assess. Type	Untreated		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha		Clormequat ref. prod. 1500-1575 g ai/ha	
				Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
Sharda16-046	DE	83	Lodging (0-100)	40.75	a	31.25	a	30.0	a	25.8	a
Sharda16-047	DE	63	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		71	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		81	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
P17GC01UEN01	FR	30	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		31	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		41	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
P17GC01UEN02	FR	41	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		59	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		69	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a
		89	Lodging (0-100)	0.0	a	0.0	a	0.0	a	0.0	a

During 10 trials effect of reduction of height was observed. Control plants were characterized by average of 89,01 cm height. The most effective was dose 2,1 L/ha (average: 6,3% reduction of height in comparable to control plants). Effect of dose 1,3 l/ha (average: 4,48%) was slightly lower than dose 2,1 L/ha. The most effective against reduction of height was dose 2,1 L/ha and this dose should be recommended for use. The dose of 1,3 l/ha had only retardant properties and their effectiveness was lower than 5%. CLARA at recommended dose 2,1 L/ha has better efficacy and at dose 1,3 L/has slightly lower (average: 4,48%) in reduction of height than standard ref. product (average; 5,32%). Final decision about accepted dose is left to each cMs.

Lodging as LODARE (lodging area) was observed only in 4 trials (average: 16,83%) and as a LODANG (lodging angle) in 1 trial on control plants (average: 40,75%). Dose 2,1 L/ha was the most effective in

reducing of lodging. Dose 1,3 L/ha reduce of lodging with average of efficacy was less effective than dose 2,1 L/ha. Results were similar to st. ref. product. Applicant submitted too few studies to support anti-lodging action. At least 6 studies should have been submitted. cMS should decide if presented trials against lodging can be acceptable.

- **Mediterranean EPPO zone:** Below, ZRMs presented detailed results from all trials separately for reduction of growth and lodging which was assessed.

Trial ID	Country	Crop GS at assessment	Assess. Type	Untreated		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha		Clormequat ref. prod. 1515-1575 g ai/ha	
				Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
036.H.SAG16/e	IT	75	Height (cm)	84.08	a	77.4	b	76.48	b	75.58	b
037.H.SAG15/e	IT	83	Height (cm)	68.6	a	62.7	bc	61.4	bc	62.9	bc
PC 16-05-12-SW1	FR	83	Height (cm)	107.8	a	103.7	a	106.3	a	106.5	a
PC 16-05-12-SW2	FR	83	Height (cm)	116.7	a	111.2	b	102.2	d	101.9	d

Trial ID	Country	Crop GS at appl. BBCH	Crop GS at assessment	Assess. Type	Untreated		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha		Clormequat ref. prod. 1515 g ai/ha	
					Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
036.H.SAG16/e	IT	29	89	Lodging (0-100)	0.2	a	0.0		0.0	a	0.0	a
037.H.SAG15/e	IT	31 (29-31)	73	Lodging (0-100)	0.0	a	0.0		0.0	a	0.0	a
			89	Lodging (0-100)	0.0	a	0.0		0.0	a	0.0	a

Trial ID	Country	Crop GS at assessment	Assess. Type	Untreated		Clormequat 72% SL 936 g ai/ha		Clormequat 72% SL 1510 g ai/ha		Clormequat ref. prod. 1575 g ai/ha	
				Mean	Stat.	% Control	Stat.	% Control	Stat.	% Control	Stat.
PC 16-05-12-SW1	FR	63	LODARE (%)	41.3	a	18.3	b	10.3	b	10.8	b
		89	LODARE (%)	80.0	a	72.5	b	65.0	c	66.3	c
PC 16-05-12-SW2	FR	75	LODARE (%)	16.3	a	10.0	a	7.5	a	2.5	a
		89	LODARE (%)	26.3	a	15.0	b	11.3	b	7.8	b

During 4 trials effect of reduction of height was observed. Control plants were characterized by average of 94,48 cm height. The most effective was dose 2,1 L/ha (average: 9,4% reduction of height in comparable to control plants). Effect of dose 1,3 l/ha (average: 6,06%) was lower than dose 2,1 L/ha. The most effective against reduction of height was range of dose 1,3 -2,1 L/ha and this dose should be recommended for use. CLARA at recommended dose 2,1 L/ha has better efficacy and at dose 1,3 L/has lower (average: 4,48%) in reduction of height than standard ref. product (average: 8,21%). However, cMS should decide if limited number of trials can be accepted or consider possibility of usage results from other zones.

Lodging as LODARE (lodging area) was observed only in 2 trials (average: 28,8%) and as a LODANG (lodging angle) in 1 trial on control plants (average: 0,2%). Dose 2,1 L/ha was the most effective in reducing of lodging. Results were comparable to st. ref. product. Dose 1,3 L/ha reduce of lodging with average of efficacy. Applicant submitted too few studies to support anti-lodging action. At least 6 studies should have been submitted. cMS should decide if presented trials against lodging can be acceptable.

Regarding comment about number of results for each use (lodging and reduction of growth) it would be like to indicate that according to the EPPO standard PP 1/226: the full number of trials is needed particularly for plant protection products or active substances which have not been on the market in the region in which authorization is sought, or for intended uses for which no extrapolation of any aspect of efficacy from other uses is possible. Chlormequat chloride is well known, as it has been marketed for many years

for use in a broad number of crops to act as a regulation of growth. In addition, comparability of performance of the tested product with the reference is proved. So, cMS should decide if CLARA (product code: SHA 126000 B) can be accepted by them only on the basis on extrapolation results from N-E EPPO, MED EPPO zone and/or Maritime EPPO zone.

According to EPPO PP 1/144 Reduction of lodging in cereals, an assessment of lodging and height was done during efficacy trials. The crop height reduction led to a reduction of lodging in trials where lodging was observed. The target dose reached the highest efficacy. CLARA (product code: SHA 126000 B) provided an acceptable level of reduction in crop height as well as control of lodging in the GAP claimed crop with the recommended dose rate in winter wheat.

In summary, ZRMs consents to the registration of the product in Poland against reduction of height (13 trials: PL-6, LT-3, CZ-2, DE-2) in winter wheat in the range of dose 1,3 -2,1 L/ha. Due to not enough number of trials (4 trials: LT-2, CZ-1, DE-1), lodging in PL ~~cannot~~ can be accepted only conditionally. ~~At least 6 valid trials carried out in N-E EPPO zone or neighbouring country to PL from another zone~~ Considering the fact that the retardant action is intended to contribute to the limitation of lodging and, as confirmed in many years of practice, such an effect of products containing CCC, it would be advisable to consider conditional registration of the substance (without limitations in the description/scope of action on its label). Within two years of registration, the Applicant should submit at least two studies from the North-Eastern EPPO zone on the efficacy of the registered substance in limiting/preventing lodging.

It is left to the Member States to decide on the acceptability of the results presented in this dRR and to consider registration of CLARA on the basis on submitted documentation.

### **3.3.1 Information on the occurrence or possible occurrence of the development of resistance**

Since Chlormequat chloride 72% SL is a plant growth regulator, the crop is the target of the application and not any pests as such. It is therefore not applicable to describe the possible development of resistance or cross-resistance of the crop towards Chlormequat chloride.

### **3.3.2 Adverse effects on treated crops**

#### **Phytotoxicity to host crop**

The phytotoxicity trials about tested plant protection product (plant growth regulator) have been carried out in accordance with EPPO Guidelines (1/181 (4)). The conduct of the field work is principally compliant with “Good Agricultural Practice” and in accordance with EPPO Guidelines PP 1/135.

The trials were performed with the use of different agricultural practice in North-East EPPO zone, Mediterranean EPPO zone, South-East EPPO zone and Maritime EPPO zone.

All presented trials were performed with the use of cultivars, differing in growth strength as well as soil and water requirements. The appropriate experimental design was applied. In all trials studied product was compared to the standard reference products. Statistical analysis of the data was performed. Also, quality of yield was evaluated in submitted trials.

Both EU Directive 91/414 (EU, 1991) and EPPO PP 1/226 (3) – Number of efficacy trials requires testing phytotoxicity at normal (N) and double (2N) recommended dose. However, EPPO 1/135 (3) – Phytotoxicity assessment states: ‘EPPO Standards on fungicides, insecticides and plant growth regulators or seed treatments, on the other hand, include only a relatively simple special section on phytotoxicity assessment, because, for these types of plant protection products, phytotoxic effects will be less frequent’. Selectivity trials and studied dose 2N were not required, which is in accordance with EPPO 1/135 (3). However, Applicant submitted 22 trials in which dose N and 2 N was studied. Those selectivity trials were carried out in MAR 10 (FR-4, UK-2, DE-2, CZ-2), MED 4 (FR-2, IT-2); S-E 2 (HU) and N-E 6 (PL-4, LT-2).

Also, Applicant submitted in total 23 efficacy trials in which phytotoxicity assessment was carried out on winter wheat. Those trials were carried out in MAR 10 (FR-4, UK-2, DE-2, CZ-2), MED 4 (FR-2, IT-2) and N-E 9 (PL-6, LT-3). Lack of trials for S-E EPPO zone. Trials were performed during different growing season. The evaluation of phytotoxicity effects was done according to EPPO Standard 1/135 (4) of plant growth regulators applied on crops of winter wheat was performed visually by comparing the condition of the plants in the plots treated with PPP – CLARA in comparison to untreated plots (no PPP). The intensity of damage to the plant was expressed as a percentage (0%-no symptoms of phytotoxic effects of PPP, 100% - total destruction).

**Assessment for Poland:** Research should be conducted in the Poland or/and in other countries from the North-East EPPO zone or neighbouring countries not belonging to the zone. According to the Polish guidelines for well-known active substance should be submitted at least 4-5 phytotoxicity studies performed in two growing seasons on 3-4 varieties. Also, Applicant can use CIRCA for the assessment, but into account must be taken issues related to data protection. Alternatively, Applicant can use the data from the records of other / neighbouring countries – but the justification for using this part by Applicant must be submitted.

In the opinion of Evaluator, the Applicant submitted enough phytotoxicity and selectivity trials for winter wheat. **On the basis on presented results it can be concluded that tested product is safe for winter wheat.** No negative effects are expected at recommended dose (1,3 L/ha and 2,1 L/ha).

#### **Assessment for cMS:**

- *N-E EPPO zone:* No adverse effects in regard to phytotoxicity were observed in any of the 9 efficacy trials as well as no adverse effects were observed in the 6 selectivity trials conducted in the North-east EPPO zone.
- *MAR EPPO zone:* No adverse effects in regard to phytotoxicity were observed in any of the 10 efficacy trials as well as no adverse effects were observed in the 10 selectivity trials conducted in the Maritime EPPO zone.
- *S-E EPPO zone:* No adverse effects in regard to phytotoxicity, or lodging were observed in any of the two selectivity trials.
- *MED EPPO zone:* No adverse effects in regard to phytotoxicity were observed in three of the 4 efficacy trials as well as no adverse effects were observed in three of the 4 selectivity trials conducted in the Mediterranean EPPO zone. In one efficacy trial and in one selectivity trial, conducted on the variety Arkeos and the variety Palesio, minor phytotoxicity was observed as reduction of vigor in the plots treated with Chlormequat chloride 72% SL. Comparable phytotoxicity was also observed in the plots treated with the standard Chlormequat chloride reference product.

In the opinion, of Evaluator submitted documentation is sufficient for N-E, MED and MAR EPPO zone. cMS from S-E should decide if limited trials in number of 2 can be acceptable or/and consider possibility of use results from other zones.

#### **Effects on yield and quality**

According to EPPO 1/144 - For the purposes of quantitative and qualitative recording of yields, the yield should be collected only from the experimental plot without shelterbelts. In the case of cereals, the following should be recorded the following data:

- (a) grain yield in kg ha<sup>-1</sup> adjusted to the established moisture content (according to the national standard);
- (b) moisture content;
- (c) weight of grain in hectoliters (optional);
- (d) weight of 1,000 grains (optional);
- (e) grain size assessment (optional);
- (f) protein content (optional).

Yield and quality trials presented were designed and conducted to test the recommended dose rate of CLARA in winter wheat.

CLARA is recommended applied in wheat at 1,3 -2,1 L/ha. **No negative impact on yield was recorded during trials.** CLARA applied at the recommended range of dose did not significantly affect the yield. Applicant submitted in total 45 trials: MED – 8 (ES-4, FR-4), MAR – 20 (FR-8, UK-4, DE-4, CZ-4); S-E -2 (HU) and N-E – 15 (PL-10, LT-5). In the opinion, of Evaluator submitted documentation is sufficient for N-E, MED and MAR EPPO zone. cMS from S-E should decide if limited trials in number of 2 can be acceptable or/and consider possibility of use results from other zones.

#### Effect on transformation processes

~~Chlormequat-chloride 72% SL is composed of Chlormequat-chloride which has been widely used for several years on cereals without identifying any quality problems on the treated crops.~~

~~Chlormequat-chloride 72% SL is recommended applied on cereal crops from BBCH 29 to BBCH 32, i.e. post-emergence, but before inflorescence emergence and heading. Therefore, it is not expected that the active ingredient is transferred to the grains.~~

The impact of chlormequat chloride on grain processing processes can encompass several aspects:

- **Rheological Properties:** chlormequat chloride can influence the rheological properties of grain dough. It may affect viscosity, elasticity, and other parameters, which can have consequences for baking processes, dough formation, etc.
- **Flour Quality:** The application of chlormequat chloride can affect the properties of flour obtained from processed grains. This can be significant for the quality of bakery products.
- **Dough Stability:** Chlormequat chloride may impact the stability of dough, which can be crucial during processing processes such as kneading or bread shaping.
- **Effect on Plant Structure:** By controlling plant growth, chlormequat chloride can influence the structure of the plant itself, which may have implications for yield and ease of processing during harvest.

Based on long term use of chlormequat chloride without any problems and low residues in grain, the above-mentioned argumentation can lack of studies can be accepted. No negative impact on processing is to be expected in the opinion of Evaluator. According to EPPO 1/243 in the case of low or lack of residues in grain, it can be concluded that if the applicant can demonstrate that the residues of plant protection products are trace amounts or that they will not impact yeast, supported by arguments, a case-by-case basis may be sufficient to meet these requirements. Data from preliminary screening of biological activity can provide valuable evidence of no impact on yeast or lactic acid bacteria. However, their absence seems acceptable given that chlormequat chloride has been used for many years on cereals, and market-available product labels do not contain warnings that the product may affect processing processes.

ZRMs agree with Applicant that: “Chlormequat chloride 72% SL is recommended applied on cereal crops from BBCH 29 to BBCH 32, i.e. post-emergence, but before inflorescence emergence and heading. Therefore, it is not expected that the active ingredient is transferred to the grains.”

It is important to note that the impact of chlormequat chloride may depend on various factors, such as the substance dosage, type of grains, and specific cultivation conditions. It is always crucial to adhere to recommendations regarding the use of plant protection products and to meticulously follow the instructions provided on product labels.

CLARA seems to be safe for transformation processes. However, this assessment was made only on the basis on argumentations. In the opinion of ZRMs, entry in label about no negative effect on transformation processes should not been put in label. Such provisions should be primarily considered based on research findings.

#### Impact on treated plants or plant products to be used for propagations

~~Special tests to investigate this purpose are not required~~

No data were submitted by Applicant. Also, lack of Applicant's argumentation about effect on propagat-

ing. The applicant generally wishes to cite the original registrant's data on chlormequat chloride now out of protection. Therefore, the evaluators should consider such data and label restrictions/warnings regarding propagating on standard chlormequat chloride products. According to Polish rules we cannot use data from other PPPs label. The assessment should be done on the basis on trials or expert's judgement.

Negative effects of the active ingredient on parts of plant used for propagating purposes can be excluded due to the growth of regulator nature of the product. GERMIN was studied during 7 trials: 5 carried out in NE and 2 trials carried out in Maritime EPPO zone. No reduction in winter wheat grain germination rate recorded in treated compare to untreated plots during those trials. According to EPPO 1/135 (4) in table 2 – for PGRs PPP including desiccants the studies about germination are needed. So, on the basis on data from selectivity trials about GERMIN and lack of phytotoxicity effects observed during trials, it can be concluded that CLARA can be considered as a safe PPP for propagation purposes of cereals accepted in GAP table and label project. Due to the fact that in labels containing chlormequat chloride as the active substance, no information was found regarding its impact or lack thereof on processing processes. It seems to us that in the case of CLARA as well, such information does not need to be included on the label. The absence of such information simultaneously implies that negative impacts on processing processes are not expected.

### 3.4 Observations on other undesirable or unintended side-effects

No significant residue levels are to be expected in rotational crops following application of Chlormequat chloride according to the proposed GAP.

The applicant advises that the use of Chlormequat-chloride 720g/L does not pose any risk of adverse effects on succeeding crops. There is no need to restrict the range of possible succeeding crop species or to provide for minimum waiting periods or other precautions. This includes situations of potential emergency replanting. The submitted information's and a review of available literature as well as the lack of phytotoxicity symptoms recorded during the field trials suggest that product application in accordance with label recommendation has no negative impact on succeeding crops

#### Impact on other plants including adjacent crops

Risk assessments were conducted according to EPPO Guideline PP1/256 and the results confirm that no further testing is necessary and that no negative impact on adjacent crops is expected.

No negative effects of applications of chlormequat chloride containing products on adjacent crops are known, neither from field trials nor from long term agricultural use when the products were applied according to the use instructions. Drift onto adjacent crops should be generally avoided. However, due to the good safety of CLARA on plants, there is no risk for adjacent crop to become injured, even in case of improper applications.

#### Effects on beneficial and other non-target organisms

From the experimentation carried out with Chlormequat chloride 72% SL in 2016 and 2017, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

For more information, see the results of the standard ecotoxicological tests being presented in dRR Part B section 6.

### 3.5 Methods of analysis (Part B, Section 5)

Analytical method for Chlormequat in food and feed of plant and animal origin, soil, water and air and in the formulation Chlormequat 72% SL are available.

### 3.5.1 Analytical method for the formulation

#### Active substance Chlormequat chloride in plant protection product

	Chlormequat chloride
Author(s), year	M. Urbani, 2018
Principle of method	HPLC
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	5 points 26.20 ng/mL to 78.60 ng/mL 33% w/w to 90% w/w $y = 8607x + 48970$ $R^2 = 0.99355$
Precision – Repeatability Mean n = 6 (%RSD)	63.4 % w/w %RSD = 1.01 %RSD <sub>r</sub> = 1.44 Hr = $0.70 \leq 1$
Accuracy n = 6 for each level (% Total Recovery)	Low level at 50% w/w – 99.2% Medium level at 60% w/w – 98.5% High level at 80% w/w – 98.2% Total mean recovery: 98.6%
Interference/ Specificity	No interference: The method is specific

According to SANCO3030/99 rev. 5 the method was successfully validated and is suitable for determination of active substance Chlormequat chloride in the test item Chlormequat chloride 72% SL.

#### Relevant impurities of Chlormequat chloride in plant protection product

	1,2-dichloroethane	Chloroethene (vinyl chloride)
Author(s), year	M. Urbani, 2018	
Principle of method	GC-FID	
Linearity (linear between mg/L) (correlation coefficient, expressed as r)	5 points, 0.05 µg/mL – 5.14 µg/mL 0.01 g/kg – 1 g/kg $y = 461353x + 24895$ $R^2 = 0.99812$	5 points, 1.02 µg/mL – 20.37 µg/mL 0.1 mg/kg - 2.00 mg/kg $y = 42837x + 6831$ $R^2 = 0.99953$
Precision – Repeatability Mean n = 6 for each level (%RSD)	Low level (0.013 g/kg): %RSD = 6.61 %RSD <sub>r</sub> = 7.29 Hr = $0.91 \leq 1$  High level (0.13 g/kg): %RSD = 3.56 %RSD <sub>r</sub> = 5.15 Hr = $0.69 \leq 1$	Low level (0.15 mg/kg): %RSD = 7.42 %RSD <sub>r</sub> = 14.26 Hr = $0.52 \leq 1$  High level (1.02 mg/kg): %RSD = 4.94 %RSD <sub>r</sub> = 10.69 Hr = $0.46 \leq 1$
Accuracy n = 6 for each level (% Total Recovery)	Low level (0.013 g/kg): 95.6% High level (0.13 g/kg): 98.4%	Low level (0.15 mg/kg): 96.6% High level (1.02 mg/kg): 89.5%
Interference/ Specificity	No interference, the method is specific	No interference, the method is specific

	1,2-dichloroethane	Chloroethene (vinyl chloride)
<b>LOQ</b>	0.014 g/kg	0.15 mg/kg

According to SANCO3030/99 rev. 5 the method was successfully validated and is suitable for determination of relevant impurities 1,2-dichloroethane and chloroethene (vinyl chloride) in the test item Chlomequat chloride 72% SL.

### 3.5.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Noticed data gaps are:

- Data gap (minor): ILV method for water. This data gap can be supplemented after registration.

Commodity/crop	Supported/ Not supported
High starch content (Winter wheat )	Supported

## 3.6 Mammalian toxicology (Part B, Section 6)

The assessment of acute toxicological properties (acute oral toxicity, acute inhalation toxicity, skin irritation, eye irritation and skin sensitisation) of Chlomequat chloride 72% SL are derived from the classification of the active compounds and co-formulants.

Acute dermal toxicity study of CLARA was not evaluated as part of the EU review of Chlomequat chloride. All relevant data were provided and are considered adequate. Acute dermal toxicological study has been performed.

### 3.6.1 Acute toxicity

Classification for Chlomequat chloride 72% SL was calculated based on classification of active substance and co-formulants, except for acute dermal toxicity. Based on those calculations for formulation, Chlomequat chloride 72% SL is classified as Acute Tox. 4 (oral).

The toxicological classification of Chlomequat chloride 72% SL is derived from experimental data with the formulation for acute dermal toxicity. Chlomequat chloride 72% SL is not toxic by dermal route.

**Classification:** Acute Tox., 4 (oral), H302

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	XXXXXXX 2018

### 3.6.2 Operator exposure

Operator exposure to CLARA was not evaluated as part of the EU review of Chlomequat chloride for



this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate.

Estimations of potential operator exposure have been undertaken for Chlormequat chloride using the AOEM.

### Conclusion

According to the EFSA AOEM Model, it can be concluded that the risk for operator is acceptable, using CLARA with tractor mounted spray application in winter wheat, with use of adequate work clothing and gloves during mixing and loading.

**Implication for labelling:** P280: Wear protective gloves, protective clothing.

### 3.6.3 Worker exposure

Worker exposure to CLARA was not evaluated as part of the EU review of Chlormequat chloride.

Estimations of potential worker exposure have been undertaken for Chlormequat chloride using the AOEM.

### Conclusion

According to the EFSA AOEM Model, it can be concluded there is no unacceptable risk anticipated for the worker wearing adequate work clothing without gloves for inspection/irrigation activities for re-entering winter wheat treated with CLARA.

**Implication for labelling:** P280: Wear protective clothing

### 3.6.4 Bystander and resident exposure

Bystander and resident exposures to CLARA was not evaluated as part of the EU review of Chlormequat chloride.

Therefore, all relevant data and risk assessments have been provided and are considered adequate. Calculations were made using the AOEM model.

### Conclusion

According to the EFSA AOEM Model, it can be concluded that there is no undue risk to any bystander after accidental short-term exposure nor to any resident exposure to CLARA.

**Implication for labelling:** None

## 3.7 Residues and consumer exposure (Part B, Section 7)

The preparation Chlormequat 72% SL is composed of Chlormequat chloride.

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

Unprotected data were sufficient to support all the uses of Chlormequat 34.5% + Mepiquat 11.5% SL.

An acceptable chronic risk for the consumer is expected after the use of Chlormequat 72% SL accordingly to the intended GAP.

### 3.7.1 Residues

#### Chlormequat chloride

##### Stability of Residues

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

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

##### Metabolism in plants and animals

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

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

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

The intended uses are covered by the established residue definitions.

No additional studies are required.

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

##### Magnitude of residues in plants

Proposed uses:

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

Applicant refers to new trials and to EU unprotected data.

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

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

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

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

Use is accepted.

##### Magnitude of residues in livestock

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

No exceedance of the current EU-MRL is expected.

### Magnitude of residues in processed commodities

Available EU data are sufficient to cover the proposed use.

### Magnitude of residues in representative succeeding crops

EFSA Journal 2020;18(1):5982:

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

Field rotational crop studies are not required.

Restrictions for succeeding crops are not required.

EFSA Journal 2020;18(1):5982:

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

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

### Other / special studies

Wheat have not melliferous capacity. Studies are not required.

### Estimation of exposure through diet and other means

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

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

## 3.7.2 Consumer exposure

### 3.7.2.1 Chlormequat chloride

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

IEDI (% ADI) according to EFSA PRIMo rev.3.1	80% NL toodler (highest contributor: milk cattle)
IESTI (% ARfD) according to EFSA PRIMo rev.3.1	<b>Unprocessed commodities:</b> <u>Results for children:</u> Wheat: 5%  <u>Results for adults:</u> Wheat: 3%

	<p><b>Processed commodities:</b></p> <p><u>Results for children:</u> Wheat/ milling (flour): 4% Wheat/ milling (wholemeal)-baking: 4%</p> <p><u>Results for adults:</u> Wheat/ bread/ pizza: 1% Wheat/ pasta: 1% Wheat/ bread (wholemeal): 1%</p>
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The proposed uses of Chlormequat chloride in the formulation Chlormequat 72% SL do not represent unacceptable acute and chronic risks for the consumer.

### 3.8 Environmental fate and behaviour (Part B, Section 8)

Concentration of Chlormequat in various environmental compartments are predicted according to the proposed use pattern. The predicted environmental concentrations (PEC values) in soil, surface water, sediment and ground water are provided.

#### 3.8.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)

PEC<sub>soil</sub> calculations have been conducted with Chlormequat using the EU agreed endpoints (EFSA Scientific Report (2008) 179, 1-77).

Maximum PEC<sub>soil</sub> value for Chlormequat was 1.611 mg/kg following the highest application rate of 1510 g Chlormequat/ha.

#### 3.8.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)

PEC<sub>gw</sub> have been calculated for Chlormequat.

The PEC<sub>gw</sub> value for Chlormequat was <0.1 µg/L in scenarios.

#### 3.8.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)

The PEC<sub>sw/sed</sub> of Chlormequat have been assessed with the model FOCUS Steps 1-2. Please refer to Part B, Section 8, Point 8.9 for more details about the results obtained.

#### 3.8.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)

The vapour pressure at 20 °C of the active substance Chlormequat is < 10<sup>-5</sup> 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.

### 3.9 Ecotoxicology (Part B, Section 9)

#### 3.9.1 Effects on terrestrial vertebrates

- Birds:

According to the screening and first tier risk assessment for cereals, the TERA and TERIt values for Chlormequat chloride are lower than the Annex VI trigger of 10 and 5, respectively for the large herbivorous bird “goose”, indicating that CLARA (Chlormequat chloride 72% SL) presents unacceptable acute and long-term risk to birds according to the intended use in cereals. A refinement of the risk was done and the TERA and TERIt were above the triggers showing no risk

- **Mammals:**

According to the first-tier risk assessment for cereals, the TERA values for the active substance Chlormequat chloride are lower than the Annex VI trigger of 10 for small omnivorous mammal ‘mouse’, indicating that CLARA (Chlormequat chloride 72% SL) presents an unacceptable acute risk to mammals. A refinement of the risk was done and the TERA were above the trigger showing no risk. The TERIt values for Chlormequat chloride are greater than the Annex VI trigger of 5 indicating that CLARA presents no unacceptable long-term risk to mammals.

### 3.9.2 Effects on aquatic species

#### **Chlormequat chloride:**

For the intended uses on winter wheat, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for invertebrate prolonged as characterised by a NOEC for *Daphnia magna* of 2.4 mg/L in connection with an assessment factor of 10) in all FOCUS Steps 1-2 scenarios. Therefore, no further assessment is necessary.

#### **CLARA:**

For the intended uses winter wheat, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for invertebrate acute as characterised by an EC<sub>50</sub> for *Daphnia magna* of 88.49 mg/L in connection with an assessment factor of 100) in all FOCUS Step 1 scenarios. Therefore, no further assessment is necessary.

### 3.9.3 Effects on bees

The risk assessment for bees was conducted in accordance with SANCO/10329/2002 rev. 2 final. The acute oral and contact toxicity data are available for the formulation **CLARA**. Based on the first-tier assessment results, the risk is acceptable (HQ values exceeded 50) for the product. In addition, the chronic study for adult bees and a study effects on honey bee development and other honey bee life stages was submitted by Applicant. The chronic studies were accepted by zRMS in updated RAR. The risk assessment based on this studies should be considered when GD for Bees, 2013 is implemented at EU level. Final decision should be taken into account at MSs level.

### 3.9.4 Effects on other arthropod species other than bees

Studies on the toxicity to arthropods show that the active substance chlormequat chloride and the formulated product CLARA for *A.rhopalosiphi* pose no in-field and off-field risk for non-target arthropods, since HQ values were below 2 and the PERin-field and the corr. PERoff-field were below the rate with ≤ 50 % effect. Therefore, an application of CLARA in respect of the GAP does not present an unacceptable risk for arthropods other than bees.

Study on the toxicity to *T.pyri* for formulated product CLARA was also provided by Applicant. In general, the study was accepted as its validity criteria were met. However, RMS decided not to use the results of this study for risk assessment due to study limitations such as: 1. No clear dose-response for test concentrations for mortality and reproduction parameters. 2. For the dose of 2.069 L/ha, the LR<sub>50</sub> value was determined. Therefore, an analysis of the effect of CLARA on reproduction at a dose of 2.069 L/ha

should be performed. In this case, risk assessment for *T.pyri* was based on toxicity endpoints for substance active – chlormequat chloride.

RMS considered that a low risk from the formulation **CLARA** (containing 1 active substance) can be concluded, due to the margin of safety based on the exposure assessment for the active substance - chlormequat chloride for *A.rhopalosiphi* and *T.pyri* is sufficient.

Acceptable risk assessment for arthropods other than bees for **CLARA** could be conclude.

### 3.9.5 Effects on soil organisms

- **Earthworms and other non-target soil organisms:**

The acute and chronic TER for Chlormequat chloride is above the Annex VI trigger of 10 and 5, respectively. Therefore, it is concluded that Chlormequat chloride do not poses acute and long-term risk to earthworms.

Earthworms:

The study on the effects of **CLARA** on earthworms was not provided by Applicant. In this case, the Applicant used the available data for substance active chlormequat chloride to indicate acceptable risk for earthworms. In opinion RMS this approach should be accepted for PL. It was acknowledged that the active substance chlormequat chloride did not show a high toxicity to earthworms. The RMS noted that the risk assessment for chlormequat chloride indicated a very high margin of safety based on the currently available exposure assessment. In this case, the toxicity of the plant protection product **CLARA** can be predicted on the basis of the data for the active substance. Acceptable risk assessment could be conclude.

Non-target soil macro-organisms:

In accordance with the data requirements of the (EU) Regulation 284/2013 data on *Folsomia candida* and *Hypoaspis aculeifer* should be submitted. No toxicity data are available for the PPP **CLARA**. However, the Applicant provided a justification indicating that the data requirements indicate that an assessment is not triggered since it is of low risk to NTAs. This approach was accepted by RMS.

**Justification:**

As stated in Commission Regulation EU No 284/2013 of 1 March 2013, “For plant protection products applied as a foliar spray, data on the relevant two non-target arthropod species might be taken into account for a preliminary risk assessment. If effects do occur on either species, testing on *Folsomia candida* and *Hypoaspis aculeifer* shall be required.” The formulated product **CLARA** is applied as a foliar spray treatment. Acceptable risks are expected towards the earthworms and a low in-field and off-field risk is demonstrated for non-target arthropods - such as - *Typhlodromus pyri*, *Aphidius rhopalosiphi* (standard laboratory studies).

- **Soil microorganisms:**

Risk assessments conducted with relevant  $PEC_{soil}$  for Chlormequat chloride in **CLARA** (Chlormequat chloride 72% SL) formulation indicate a low risk to soil microorganisms when applied according to the proposed use rates.

### 3.9.6 Effects on non-target terrestrial plants

Risk assessment conducted with relevant toxicity data on non-target terrestrial plants for **CLARA** (Chlormequat chloride 72% SL) shows that Annex VI trigger of 5 is not exceeded, indicating that **CLARA** poses a low risk to non-target plants when applied according to the proposed use rates.

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SAN-CO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop

plants located outside the treated area.

The study on the effects of **CLARA** on non-target terrestrial plants for the vegetative vigour test (OECD 227 "Terrestrial Plant Test: Vegetative Vigour Test) and the study on the effects of MEPCY (SHA 126085 A) on non-target terrestrial plants in terms of seedling emergence and seedling growth test (OECD Guideline for the Testing of Chemicals No. 208 "Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test") were provided by Applicant. In this case, the Applicant used also the available data for substance active to indicate acceptable risk for non-target plants. The RMS noted that the risk assessment for chlormequat chloride and formulation **CLARA** indicated a very high margin of safety based on the currently available exposure assessment.

Overall, the RMS considered that a low risk from the substance active such as chlormequat chloride and formulation **CLARA** can be concluded. No mitigation measures is needed.

### **3.9.7 Effects on other terrestrial organisms (Flora and Fauna)**

Not relevant.

### **3.10 Relevance of metabolites (Part B, Section 10)**

Not relevant, there are no Chlormequat metabolites in soil.

## **4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)**

Not relevant. CLARA contains the active substance Chlormequat which is not candidate for substitution.

## **5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization**

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

## **Appendix 1    Copy of the product authorization**

MS assessor to insert details of the product authorization for MS country.
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## Appendix 2 Copy of the product label

### Sekcja skuteczności:

~~Nie-zaakceptowano środka do stosowania przeciw wyleganiu, dlatego zostało ono wykreślone z projektu etykiety.~~ Zastosowanie w regulacji wzrostu- zaakceptowano. **Działanie przeciwdziałaniu wyleganiu zaakceptowano warunkowo. Niezbędne będzie przedstawienie co najmniej 2 badań wykonanych w strefie pln.-wsch. na pszenicy w celu wykazania działania przeciwdziałającemu wyleganiu.** Reszta zapisów z etykiety zaakceptowana bez konieczności wprowadzania zmian. Z uwagi na rodzaj sów nie wymagana strategia przeciwdziałania rozwojowi odporności, następstwa roślin oraz wpływu na rośliny sąsiadujące.

### Sekcja toksykologii:

W części: ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH wprowadzono zmiany.

### Sekcja metabolizm i pozostałości:

Proponowany zapis w etykiecie:

Nie stosować słomy z pszenicy traktowanej chloromekwatem jako ogrodniczego podłoża wzrostowego w uprawie grzybów.

**Sekcja los i zachowanie w środowisku:** bez uwag.

**Sekcja ekotoksykologii:** bez uwag.

Załącznik do zezwolenia MRiRW nr R-...../2022 z dnia .....2022 r.

Posiadacz zezwolenia: Sharda Cropchem Limited z siedzibą Prime Business Park Dashrathlal Joshi Road, Vile Parle (West), Mumbai – 400 056, Indie, Tel. xxx


Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin: (.....).

## CLARA

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:  
**chlórek chloromekwatu – 720 g/l**

**Zezwolenie MRiRW nr R -..../2022 z dnia ..... 2022 r.**

	
<b>Uwaga</b>	
H302	Działa szkodliwie po połknięciu.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.

P264	Dokładnie umyć ręce po użyciu.
P280	Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy.
P270	Nie jeść, nie pić ani nie palić podczas używania produktu.
P301+P312	W PRZYPADKU POŁKNIECIA: W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem/
P330	Wypłukać usta.
P501	Zawartość/pojemnik usuwać zgodnie z przepisami krajowymi.
P273	Unikać uwolnienia do środowiska.

## OPIS DZIAŁANIA

REGULATOR WZROSTU I ROZWOJU ROŚLIN w formie koncentratu rozpuszczalnego w wodzie (SL) przeznaczony do stosowania w celu zapobiegania nadmiernemu wyrastaniu roślin i ich wyleganiu. Środek zawiera substancję czynną chlorek chloromekwatu (związek z grupy czwartorzędowej soli amoniowej). Chlorek chloromekwatu hamuje wzrost, skraca i usztynnia źdźbło pszenicy, w rezultacie zapobiegając wyleganiu.

Działanie środka powoduje ograniczanie wzrostu międzywęźli i uzyskanie roślin o bardziej zwartym pokroju, poprawia się kwitnienie i zawiązywanie nasion.

## STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych..

### Pszenica ozima

*regulacja wzrostu, przeciwdziałanie wyleganiu*

Termin stosowania: środek stosować wiosną, w fazie wzrostu pędu głównego do fazy widocznych dwóch kolanek(BBCH 29-32).

Środek stosować zapobiegawczo, w celu skrócenia oraz wzmocnienia pędów roślin (zapobieganie wyleganiu).

Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,3-2,1 l/ha

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zalecana ilość wody: 200 - 300 l/ha

Ilość wody dostosować do wielkości roślin i ich zagęszczenia.

Zalecane opryskiwanie: średniokropliste.

## ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

~~Pszenica ozima nie dotyczy~~

Środka nie stosować:

- na glebach o niskiej zasobności, w warunkach niskiego nawożenia azotowego
- w temperaturze powietrza poniżej 10°C i powyżej 25°C
- podczas wiatru stwarzającego możliwość znoszenia cieczy użytkowej na sąsiednie pola
- na rośliny mokre

Podczas stosowania nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,

- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach

### **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Zawartość opakowania przed użyciem wstrząsnąć.

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

### **POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY**

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

- po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

### **ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas stosowania środka.

~~Unikać wdychania rozpylonej cieczy.~~

Stosować rękawice ochronne, odzież roboczą (kombinezon) ~~oraz ochronę oczu~~ w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Dokładnie umyć ręce po użyciu.

### **ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

~~W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.~~

~~W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.~~

**OKRES KARENCJI** (okres od dnia ostatniego zabiegu do dnia zbioru i przeznaczenia do konsumpcji)

**NIE DOTYCZY**

**OKRES PREWENNCJI DLA LUDZI, ZWIERZĄT** (okres zapobiegający zatruciu)

**NIE DOTYCZY**

**Uwaga:** Nie stosować słomy z pszenicy traktowanej chloromekwatem jako ogrodniczego podłoża wzrostowego w uprawie grzybów.

## **WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 5°C – 30°C,
- w suchym i dobrze wentylowanym miejscu.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

## **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku narażenia lub styczości: zasięgnąć porady/ zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji - .....

Zawartość netto - .....

Nr partii - .....

### **Appendix 3 Letter of Access**

No letter of access is required.

## Appendix 4 Lists of data considered for national authorization

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 KCP 2.3.1 KCP 2.3.2 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.4 KCP 2.8.2 KCP 2.8.4	Urbani M.	2018	Chlormequat chloride 72% SL: Two Years Storage Stability and Corrosion Characteristic Report No CH-1026/2017 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.2.1 KCP 2.2.2	Mena Artero B.,	2022	Chlormequat 72% SL Determination of the oxidizing properties and explosive properties Report No. SCE-047/2022 Sharda Cropchem España S.L. Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.7.1 KCP 2.7.3	Urbani M.	2018	Chlormequat chloride 72% SL: Determination of the Accelerated Storage Stability and Corrosion Characteristics Report No CH-1030/2017 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.7.6	Urbani M.	2020	Chlormequat chloride 72% SL: Two Years Storage Stability and Corrosion Characteristic Report No CH-1031/2017 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.11	Urbani M.	2018	Chlormequat chloride 72% SL: Washing efficacy after application Report No CH-1069/2017 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-01 Also cited in: 3.2.3 3.4.1	Sara Desogus	2016	Efficacy and selectivity of CHLORMEQUAT 72 % SL applied on winter wheat as growth regulator, Italy 2016 Testing facility: SAGEA, IT CRO Trial number: 036.H.SAG16/e Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-02 Also cited in: 3.2.3 3.4.1	Sara Desogus	2016	Efficacy and selectivity of CHLORMEQUAT 72 % SL applied on winter wheat as growth regulator, Italy 2016 Testing facility: SAGEA, IT CRO Trial number: 037.H.SAG15/e Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-03 Also cited in: 3.2.3 3.4.1	Krystyna Snarska	2016	Study the effectiveness of growth regulator Clormequat 72 % SL in winter wheat . Testing facility: INSTITUTE OF PLANT PROTECTION - NATIONAL RESEARCH INSTITUTE, PL CRO Trial number: 110/2016 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.2.2-04 Also cited in: 3.2.3 3.4.1	Ewa Jakubiak	2016	Efficacy evaluation of growth regulator Clormequat 72% SL applied in winter wheat Testing facility: INSTITUTE OF PLANT PROTECTION - NATIONAL RESEARCH INSTITUTE, PL CRO Trial number: 121/2016 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-05 Also cited in: 3.2.3 3.4.1	Ewa Jakubiak	2016	Efficacy evaluation of growth regulator Clormequat 72% SL applied in winter wheat Testing facility: INSTITUTE OF PLANT PROTECTION - NATIONAL RESEARCH INSTITUTE, PL CRO Trial number: 122/2016 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-06 Also cited in: 3.2.3 3.4.1	Dr. Wojciech Miziniak	2016	Efficacy evaluation of growth regulator Clormequat 72% SL applied in winter wheat Testing facility: INSTITUTE OF PLANT PROTECTION - NATIONAL RESEARCH INSTITUTE, PL CRO Trial number: 142/2016 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-07 Also cited in: 3.2.3 3.4.1	Adrian Luboinski	2017	Efficacy evaluation of growth regulator Clormequat 72% SL applied in winter wheat Testing facility: INSTITUTE OF PLANT PROTECTION - NATIONAL RESEARCH INSTITUTE, PL CRO Trial number: 184/2017 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited



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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.2.2-08 Also cited in: 3.2.3 3.4.1	Adrian Luboinski	2017	Efficacy evaluation of growth regulator Clormequat 72% SL applied in winter wheat Testing facility: INSTITUTE OF PLANT PROTECTION - NATIONAL RESEARCH INSTITUTE, PL CRO Trial number: 185/2017 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-09 Also cited in: 3.2.3 3.4.1	Ona Auškalnienė	2016	REPORT ON THE EFFICACY EVALUATION PGR CHLORMEQUAT 72 % SL EFFICACY IN WINTER WHEAT AND COMPARE IT TO STANDARD PGR STABILAN 750 SL Testing facility: INSTITUTE OF AGRICULTURE, LITHUANIAN RESEARCH CENTRE FOR AGRICULTURE AND FORESTRY, LT CRO Trial number: LTZI2016PGR-02-01 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-10 Also cited in: 3.2.3 3.4.1	Ona Auškalnienė	2016	REPORT ON THE EFFICACY EVALUATION PGR CHLORMEQUAT 72 % SL EFFICACY IN WINTER WHEAT AND COMPARE IT TO STANDARD PGR STABILAN 750 SL Testing facility: INSTITUTE OF AGRICULTURE, LITHUANIAN RESEARCH CENTRE FOR AGRICULTURE AND FORESTRY, LT CRO Trial number: LTZI2016PGR-02-02 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.2.2-11 Also cited in: 3.2.3 3.4.1	Ona Auškalnienė	2016	REPORT ON THE EFFICACY EVALUATION PGR CHLORMEQUAT 72 % SL EFFICACY IN WINTER WHEAT AND COMPARE IT TO STANDARD PGR STABILAN 750 SL Testing facility: INSTITUTE OF AGRICULTURE, LITHUANIAN RESEARCH CENTRE FOR AGRICULTURE AND FORESTRY, LT CRO Trial number: LTZI2016PGR-02-03 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-12 Also cited in: 3.2.3 3.4.1	Nicolas Lehning	2016	Efficacy winter wheat Testing facility: Agrostation, FR CRO Trial number: PC 16-05-12-NE1 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-13 Also cited in: 3.2.3 3.4.1	Nicolas Lehning	2016	Efficacy winter wheat Testing facility: Agrostation, FR CRO Trial number: PC 16-05-12-SW1 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-14 Also cited in: 3.2.3 3.4.1	Nicolas Lehning	2016	Efficacy winter wheat Testing facility: Agrostation, FR CRO Trial number: PC 16-05-12-SW2 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-15 Also cited in: 3.2.3 3.4.1	Nicolas Lehning	2016	Efficacy winter wheat Testing facility: Agrostation, FR CRO Trial number: PC 16-05-12-WE1 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.2.2-16 Also cited in: 3.2.3 3.4.1	Abi Croshaw	2016	PGR activity of Chlormequat 72% SL in winter wheat Testing facility: SGS GROUP, UK CRO Trial number: SHA835-16-EFF001-001 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-17 Also cited in: 3.2.3 3.4.1	Abi Croshaw	2016	PGR activity of Chlormequat 72% SL in winter wheat Testing facility: SGS GROUP, UK CRO Trial number: SHA835-16-EFF001-002 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-18 Also cited in: 3.2.3 3.4.1	Andreas Hetterich	2017	Evaluation of the efficacy of Clormequat 72% in winter wheat - GERMANY 2016 Testing facility: Hetterich Fieldwork GbR, DE CRO Trial number: Sharda16-046 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-19 Also cited in: 3.2.3 3.4.1	Andreas Hetterich	2017	Evaluation of the efficacy of Clormequat 72% in winter wheat - GERMANY 2016 Testing facility: Hetterich Fieldwork GbR, DE CRO Trial number: Sharda16-047 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-20 Also cited in: 3.2.3 3.4.1	Pavel Tóth	2016	The postemergence efficacy of chlormequat 72% SL in winter wheat in the Czech Republic 2016. Testing facility: Zemědělská zkušební stanice Kujavy, s.r.o., CZ CRO Trial number: SWEPL-CZE16-CLOR-TRZAW-KUJ32 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.2.2-21 Also cited in: 3.2.3 3.4.1	Jana Konvalinková	2016	PGR efficacy of Chlormequat 72% SL in winter wheat. Testing facility: Zkušební stanice Rýmařov, s.r.o., CZ CRO Trial number: SWEPL-CZE16-CLOR-TRZAW-RYM3 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-22 Also cited in: 3.2.3 3.4.1	DALLE Fabien	2017	Plant growth regulator efficacy of Chlormequat 72 % SL on wheat in France in 2017 Testing facility: SARL Cotesia, FR CRO Trial number: P17GC01UEN01 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.2.2-23 Also cited in: 3.2.3 3.4.1	DALLE Fabien	2017	Plant growth regulator efficacy of Chlormequat 72 % SL on wheat in France in 2017 Testing facility: SARL Cotesia, FR CRO Trial number: P17GC01UEN02 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-01 Also cited in: 3.4.2 3.4.3	Sara Desogus	2016	Selectivity of CHLORMEQUAT 72 % SL applied on winter wheat as growth regulator, Italy 2016 Testing facility: SAGEA, IT CRO Trial number: 038.S.SAG16/e Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-02 Also cited in: 3.4.2 3.4.3	xxx	2016	Selectivity of CHLORMEQUAT 72 % SL applied on winter wheat xxxx CRO Trial number: 039.S.SAG16/e Sharda Reference no.: - GEP, Unpublished	Y	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.4.1-03 Also cited in: 3.4.2 3.4.3	Ewa Jakubiak	2016	Phytoxicity evaluation of plant growth regulator Clomequat 72% SL applied in winter wheat. <b>Testing facility:</b> INSTITUTE OF PLANT PROTECTION - NATIONAL RESEARCH INSTITUTE, PL <b>CRO Trial number:</b> 123/2016 <b>Sharda Reference no.:</b> - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-04 Also cited in: 3.4.2 3.4.3	Ewa Jakubiak	2016	Phytoxicity evaluation of plant growth regulator Clomequat 72% SL applied in winter wheat. <b>Testing facility:</b> INSTITUTE OF PLANT PROTECTION - NATIONAL RESEARCH INSTITUTE, PL <b>CRO Trial number:</b> 124/2016 <b>Sharda Reference no.:</b> - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-05 Also cited in: 3.4.2 3.4.3 3.4.5	Adrian Luboinski	2017	Phytoxicity evaluation of growth regulator Clomequat 72% SL applied in winter wheat <b>Testing facility:</b> INSTITUTE OF PLANT PROTECTION - NATIONAL RESEARCH INSTITUTE, PL <b>CRO Trial number:</b> 185/2017 <b>Sharda Reference no.:</b> - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-06 Also cited in: 3.4.2 3.4.3 3.4.5	Adrian Luboinski	2017	Phytoxicity evaluation of growth regulator Clomequat 72% SL applied in winter wheat <b>Testing facility:</b> INSTITUTE OF PLANT PROTECTION - NATIONAL RESEARCH INSTITUTE, PL <b>CRO Trial number:</b> 186/2017 <b>Sharda Reference no.:</b> - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.4.1-07 Also cited in: 3.4.2 3.4.3	Ona Auškalnienė	2016	REPORT ON THE SELECTIVITY EVALUATION PGR CHLORMEQUAT 72 % SL IN WINTER WHEAT AND COMPARE IT TO STANDARD PGR STABILAN 750 SL Testing facility: INSTITUTE OF AGRICULTURE, LITHUANIAN RESEARCH CENTRE FOR AGRICULTURE AND FORESTRY, LT CRO Trial number: LTZIPGR2016-01-01 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-08 Also cited in: 3.4.2 3.4.3	Ona Auškalnienė	2016	REPORT ON THE SELECTIVITY EVALUATION PGR CHLORMEQUAT 72 % SL IN WINTER WHEAT AND COMPARE IT TO STANDARD PGR STABILAN 750 SL Testing facility: INSTITUTE OF AGRICULTURE, LITHUANIAN RESEARCH CENTRE FOR AGRICULTURE AND FORESTRY, LT CRO Trial number: LTZIPGR2016-01-02 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-09 Also cited in: 3.4.2 3.4.3 3.4.5	Nicolas Lehning	2016	PROTOCOL POST APPLICATION - CROP SAFETY PGR winter wheat Testing facility: Agrostation, FR CRO Trial number: PC 16-05-13-NE1 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-10 Also cited in: 3.4.2 3.4.3	Nicolas Lehning	2016	PROTOCOL POST APPLICATION - CROP SAFETY PGR winter wheat Testing facility: Agrostation, FR CRO Trial number: PC 16-05-13-NO1 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.4.1-11 Also cited in: 3.4.2 3.4.3	Nicolas Lehning	2016	PROTOCOL POST APPLICATION - CROP SAFETY PGR winter wheat Testing facility: Agrostation, FR CRO Trial number: PC 16-05-13-SW1 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-12 Also cited in: 3.4.2 3.4.3	Nicolas Lehning	2016	PROTOCOL POST APPLICATION - CROP SAFETY PGR winter wheat Testing facility: Agrostation, FR CRO Trial number: PC 16-05-13-SW2 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-13 Also cited in: 3.4.2 3.4.3 3.4.5	Abi Croshaw	2016	Crop safety of Chlormequat 72% SL in winter wheat Testing facility: SGS GROUP, UK CRO Trial number: SHA835-15-SEL001-001 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-14 Also cited in: 3.4.2 3.4.3 3.4.5	Abi Croshaw	2016	Crop safety of Chlormequat 72% SL in winter wheat Testing facility: SGS GROUP, UK CRO Trial number: SHA835-15-SEL001-002 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-15 Also cited in: 3.4.2 3.4.3	Andreas Hetterich	2017	Evaluation of the selectivity of Clormequat 72% SL in winter wheat - Germany 2016 Testing facility: Hetterich Fieldwork GbR, DE CRO Trial number: Sharda16-048 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.4.1-16 Also cited in: 3.4.2 3.4.3	Andreas Hetterich	2017	Evaluation of the selectivity of Clormequat 72% SL in winter wheat - Germany 2016 Testing facility: Het terich Fieldwork GbR, DE CRO Trial number: Sharda16-049 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-17 Also cited in: 3.4.2 3.4.3	Pavel Tóth	2016	The selectivity of postemergence application of chlormequat 72 % SL in TRZAW in the Czech Republic 2016. Testing facility: Zemědělská zkušební stanice Kujavy, s.r.o., CZ CRO Trial number: SWEPL-CZE16-CLOR-TRZAW-KUJ33 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-18 Also cited in: 3.4.2 3.4.3	Jana Konvalinková	2016	PGR efficacy of Chlormequat 72% SL in winter wheat Testing facility: Zkušební stanice Rýmařov, s.r.o., CZ CRO Trial number: SWEPL-CZE16-CLOR-TRZAW-RYM4 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-19 Also cited in: 3.4.2 3.4.3 3.4.5	Balázs LANG	2016	Selectivity of Chlormequat 72% SL in winter wheat in Hungary 2016. Testing facility: Plant-Art Research Kft, HU CRO Trial number: 151542671 Sharda Reference no.: SWEPL-HU16-CLOR-TRZAW-PLA25 GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited



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KCP 3.4.1-20 Also cited in: 3.4.2 3.4.3 3.4.5	Balázs LANG	2016	Selectivity of Chlormequat 72% SL in winter wheat in Hungary 2016. Testing facility: Plant-Art Research Kft, HU CRO Trial number: 151542671 Sharda Reference no.: SWEPL-HU16-CLOR-TRZAW-PLA26 GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-21 Also cited in: 3.4.2 3.4.3 3.4.5	DALLE Fabien	2017	Selectivity of plant growth regulator Chlormequat 72% SL on soft wheat in France in 2017 Testing facility: SARL Cotesia, FR CRO Trial number: P17GC02UEN01 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 3.4.1-22 Also cited in: 3.4.2 3.4.3	DALLE Fabien	2017	Selectivity of plant growth regulator Chlormequat 72% SL on soft wheat in France in 2017 Testing facility: SARL Cotesia, FR CRO Trial number: P17GC02UEN02 Sharda Reference no.: - GEP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 5.1.1-02	M. Urbani	2018	Chlormequat chloride 72% SL: Validation of the Analytical Method for the Determination of Vinyl chloride Relevant Impurity Content Report No. CH – 1029/2017 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 5.1.1-03	M. Urbani	2018	Chlormequat chloride 72% SL: Validation of the Analytical Method for the Determination of 1,2-Dichloroethane (1,2-DCE) Relevant Impurity Content Report No. CH – 1028/2017 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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KCP 5.1.2	D. Gąsczyk	2021	Validation of method for determination of Chlormequat chloride by Liquid Chromatography (LC-MS/MS), Report No.: PW-2021-05 and amendment No. 1 Fertico Sp z o.o. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.0-001	Anonymous	2022	Biological Assessment Dossier: Chlormequat chloride 72% SL (720 g/L Chlormequat chloride) – EU Central zone Sharda Cropchem España -, - Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 7.1.2	xxxxxxx	2018	Acute dermal toxicity study of Chlormequat chloride 72% SL in rat xxx GLP Unpublished	Y	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 8.3.1.1	D. Gąsczyk	2021	Quantitative analysis of Chlormequat chloride residues in winter wheat in field conditions (Raw Agricultural Commodity) after one application of a formulated product Chlormequat chloride 720 SL – two harvest and two decline trials in Northern Europe – Poland, 2020, Report No.: PB-2021-35 Fertice Sp z o.o. – Laboratorium GLP Unpublished	N	Y	Data/study report never submitted before to Spain	SHARDA Cropchem Limited
KCP 8.3.1.2	D. Gąsczyk	2021	Quantitative analysis of Chlormequat chloride residues in winter wheat in field conditions (Raw Agricultural Commodity) after one application of a formulated product Chlormequat chloride 720 SL – two harvest and two decline trials in Northern Europe – Hungary, 2020, Report No.: PB-2021-31 Fertice Sp z o.o. – Laboratorium GLP Unpublished	N	Y	Data/study report never submitted before to Spain	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.1.1-2	Michał Taranus	2022	Magnitude of the residue of chlormequat chloride in winter wheat (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product Chlormequat chloride 720 SL – two harvest and two decline curve trials in Northern Europe – Poland, 2020. Report No.: D-2020-27 Fertico Sp. z o.o. Agricultural Research Service GLP Unpublished	N	Y	Data/study report never submitted before to Spain	SHARDA Cropchem Limited
KCP 8.3.1.2-2	Gábor Wágner	2022	Determination of the residues of chlormequat chloride in/on winter wheat after one application of chlormequat chloride 720 SL in Northern Europe - Hungary in 2020. Report No.: 065CPRHU20R28 CPR Europe Kft. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-01	XXXXXXX	2018	Chlormequat chloride 72% SL, Rainbow trout Acute toxicity test. Report No. W/132/17. XXXXXXX GLP Unpublished	Y	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-02	Nierzędska, E.	2019	Chlormequat chloride 72% SL <i>Raphidocelis subcapitata</i> (formerly <i>Pseudokirchneriella subcapitata</i> ) SAG 61.81. Growth inhibition test. Report No. W/133/17. Institute of Industrial Organic Chemistry, Branch Pszczyna. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-03	Nierzędska, E.	2019	Chlormequat chloride 72% SL <i>Daphnia magna</i> , Acute immobilisation test. Report No. W/134/17. Institute of Industrial Organic Chemistry, Branch Pszczyna. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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KCP 10.2.1-04	Nierzędska, E.	2019	Chlormequat chloride 72% SL <i>Lemna gibba</i> CPCC 310, Growth inhibition test. Report No. W/135/17. Institute of Industrial Organic Chemistry, Branch Pszczyna. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.1.1	Glanas, A.	2017	Chlormequat chloride 72% SL Honeybees ( <i>Apis mellifera</i> L.), Acute Oral Toxicity Test. Report No. B/100/16. Institute of Industrial Organic Chemistry, Branch Pszczyna. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.1.2	Glanas, A.	2017	Chlormequat chloride 72% SL Honeybees ( <i>Apis mellifera</i> L.), Acute Contact Toxicity Test. Report No. B/101/16. Institute of Industrial Organic Chemistry, Branch Pszczyna. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.2	M Mohanraj	2023	Chronic Oral Toxicity Study of Chlormequat chloride 72% SL on honey bee ( <i>Apis mellifera</i> ). Report No. 12354/2023, Bioscience Research Foundation. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.3	M Mohanraj	2023	Effect of Chlormequat chloride 72% SL on larvae of honey bee, <i>Apis mellifera</i> (L.) following repeated exposure. Report No. 12355/2023, Bioscience Research Foundation. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.2.2-01	Lemańska, N.	2018	An extended laboratory test for evaluating the effects of Chlormequat chloride 72% SL on the parasitic wasp, <i>Aphidius rhopalosiphii</i> (De Stefani-Perez). Report No. B/102/16. Institute of Industrial Organic Chemistry Branch Pszczyna. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.5-01	Gierbuszewska, A.	2020	Chlormequat chloride 72% SL Soil Microorganisms: Nitrogen Transformation Test. Report No. G/195/17 Institute of Industrial Organic Chemistry Branch Pszczyna. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.5-02	Gierbuszewska, A.	2020	Chlormequat chloride 72% SL Soil Microorganisms: Carbon Transformation Test. Report No. G/194/17, Institute of Industrial Organic Chemistry Branch Pszczyna. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.6.2-01	Gierbuszewska, A.	2020	Chlormequat Chloride 72% SL Terrestrial Plant Test: Vegetative Vigour Test. Report No. G/200/17. Institute of Industrial Organic Chemistry Branch Pszczyna. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.6.2-02	Gierbuszewska, A.	2020	Chlormequat Chloride 72% SL Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test. Report No. G/199/17. Institute of Industrial Organic Chemistry Branch Pszczyna. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

**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	Data protection claimed Y/N	Justification if data protection is claimed	Owner

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Zietz E.	2004	Determination of the storage stability of chlormequat chloride in cereal (grain and straw) and selected processed fractions of wheat and barley. Institut Fresenius, Project no. IF-101/23411-00 GLP, Unpublished	N	CCC Task Force
	Zenide D.	2002	Freezer storage stability of Chlormequat-Chloride in milk, eggs and edible tissues. Battelle, Project no. A-51-01-01 GLP, Unpublished	N	CCC Task Force
	Keller E.	1990	Radioactive residues and studies on the metabolism of <sup>14</sup> C-chlormequat chloride (ccc, BAS 062W in spring wheat. BASF AG, Report no. BASF 90/0299 GLP, Unpublished	N	CCC Task Force
	Veit P.	2003	Confined Rotational Crop study with <sup>14</sup> C-Chlormequatchloride. BASF AG, Report no. doc. 2003/1004686 GLP, Unpublished	N	CCC Task Force
	Hofmann M.	1992	Rotational-Crop-Studie mit <sup>14</sup> C-Chlormequat-chlorid. BASF AG, Report no. doc. 92/10223 GLP, Unpublished	N	BASF AG
	Adam D.	2004	<sup>14</sup> C-Chlormequat-chloride: simulated processing, RCC Ltd. Report no. 854870 GLP, Unpublished	N	Nufarm
	Phillips M., McCombe W.S., Gedik L.	2003a	Report Amendment 1: The distribution and metabolism of [ <sup>14</sup> C]-Chlormequat Chloride in the lactating goat. Report No.: 20589 GLP, Unpublished	N	CCC Task Force
	Phillips M., McCombe W.S., Gedik L.	2004	Report Amendment 1: The distribution and metabolism of [ <sup>14</sup> C]-Chlormequat Chloride in the lactating goat. Report No.: 200554	N	CCC Task Force

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			GLP, Unpublished				
	Phillips M., McCombe W.S., Gedik L.	2003a	The distribution and metabolism of [14C]-Chlormequat Chloride in the laying hen. Report No.: 20357 GLP, Unpublished			N	CCC Task Force
	Raunft E., Mackenroth C.	2005	Study on the residue behaviour of chlormequat-chlorid in wheat after application of BAS 062 00 W and BAS 062 03 W under field conditions in Germany, France (N&S) and the United Kingdom, 2004 (study code 176257). BASF AG, Report no. 2005/1014176 Trial ref: ACK/03/04 Trial ref: FAN/03/04 Trial ref: OAT/01/04 GLP, Unpublished			N	CCC Task Force
	Schulz H.	2005	Study on the residue behaviour of BAS 062 W in cereals after application of BAS 062 24 W and BAS 062 03 W under field conditions in France (S and N), Germany and United Kingdom, 2003 (study code 161200). BASF AG, DocID 2004/1015956 Trial ref: DU2/07/03 GLP, Unpublished			N	CCC Task Force
	Zietz E., Klimmek S.	2004	Determination of the residues of chlormequat chloride in wheat and in the processed fractions bran, flour, whole-meal and bread following one treatment under field conditions in Germany Season 2001. Institut Fresenius, Report no. IF-101/11753-00 GLP, Unpublished			N	Nufarm

The following tables are to be completed by MS

**List of data submitted by the applicant and not relied on**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Data protection claimed</b> <b>Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>

**List of data relied on and not submitted by the applicant but necessary for evaluation**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Data protection claimed</b> <b>Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>