

# FINAL REGISTRATION REPORT

## Part B

### Section 1: Identity

### Section 2: Physical and chemical properties

### Section 4: Further information

Detailed summary of the risk assessment

Product code: SHA 6821 A

Product name(s): PRIORITY

Chemical active substances:

Dimethomorph, 150 g/kg

Dithianon, 350 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: April 2019

Update date: February 2022; June 2023

MS Finalisation date: 03.2022; 06.2023; 01.2024

## Version history

When	What
03.2022	RMS Assessment
02.2022	Applicant's update
06.2023	Applicant updated (new packaging)
06.2023	zRMS correction after new packaging proposal
01.2024	The final Registration Report

## Table of Contents

<b>1</b>	<b>Section 1: Identity of the plant protection product.....</b>	<b>4</b>
1.1	Applicant (KCP 1.1) .....	4
1.2	Producer of the plant protection product and of the active substances (KCP 1.2) .....	4
1.2.1	Producer(s) of the preparation .....	4
1.2.2	Producer(s) of the active substance(s) .....	4
1.2.3	Statement of purity (and detailed information on impurities) of the active substance(s).....	4
1.2.3.1	Dimethomorph .....	4
1.2.3.2	Dithianon.....	4
1.3	Trade names and producer's development code numbers for the preparation (KCP 1.3).....	5
1.4	Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4) .....	5
1.4.1	Composition of the plant protection product (KCP 1.4.1).....	5
1.4.2	Information on the active substance(s) (KCP 1.4.2).....	5
1.4.3	Information on safeners, synergists and co-formulants (KCP 1.4.3).....	6
1.5	Type and code of the plant protection product (KCP 1.5).....	6
1.6	Function (KCP 1.6) .....	6
<b>2</b>	<b>Section 2: Physical, chemical and technical properties of the plant protection product .....</b>	<b>7</b>
<b>3</b>	<b>Section 3 is presented as a separate document .....</b>	<b>17</b>
<b>4</b>	<b>Section 4: Further information on the plant protection product .....</b>	<b>18</b>
<b>Appendix 1</b>	<b>Lists of data considered in support of the evaluation .....</b>	<b>22</b>
<b>Appendix 2</b>	<b>Additional data on the physical, chemical and technical properties of the active substance.....</b>	<b>25</b>
A 2.1	Dimethomorph .....	25
A 2.2	Dithianon.....	25

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substances.

Noticed data gaps are:

- none

## **1 Section 1: Identity of the plant protection product**

### **1.1 Applicant (KCP 1.1)**

Name: Sharda Cropchem España S.L.  
Address: Edificio Atalayas Business Center,  
Carril Condomina nº 3, 12th Floor,  
30006 Murcia, Spain  
Phone: +34868127589  
FAX: +34868127588

### **1.2 Producer of the plant protection product and of the active substances (KCP 1.2)**

#### **1.2.1 Producer(s) of the preparation**

Confidential information or data are provided separately (Part C).

#### **1.2.2 Producer(s) of the active substance(s)**

Confidential information or data are provided separately (Part C).

#### **1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)**

##### **1.2.3.1 Dimethomorph**

Dimethomorph	min. 985 g/kg (Sharda source)
Dimethomorph	min. 965 g/kg (E/Z isomer ratio 44/56) (SANCO/10040/06 – rev. 3)

##### **1.2.3.2 Dithianon**

Dithianon	min. 975 , 980 g/kg (Sharda sources)
Dithianon	min. 930 g/kg (SANCO/10349/2011 final)

### 1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Please refer to Registration Report Part A for the relevant country (or)

Trade name: PRIORITY

Company code number: SHA 6821 A

### 1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

#### 1.4.1 Composition of the plant protection product (KCP 1.4.1)

**Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)**

Active substance / variant	Declared content of the pure active substance / variant (g/kg)	FAO Limits (min – max)	Technical content (g/kg)	Technical content (%w/w)
Dimethomorph	150	141 – 159 ( $\pm 6$ % of the declared content)	152.3	15.23
Dithianon	350	332.5 – 367.5 ( $\pm 5$ % of the declared content)	357.1	35.71

#### 1.4.2 Information on the active substance(s) (KCP 1.4.2)

**Table 1.4-2: Information on Dimethomorph**

Type	Name/Code Number
ISO common name	Dimethomorph
CAS No.	110488-70-5
EC No.	404-200-2
CIPAC No.	483

**Table 1.4-32: Information on Dithianon**

Type	Name/Code Number
ISO common name	Dithianon
CAS No.	3347-22-6
EC No.	222-098-6
CIPAC No.	153

### **1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)**

CONFIDENTIAL information is provided separately (Part C).

### **1.5 Type and code of the plant protection product (KCP 1.5)**

Type: Water dispersible granules

[Code: WG]

### **1.6 Function (KCP 1.6)**

Fungicide.

## **2 Section 2: Physical, chemical and technical properties of the plant protection product**

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 dark brown granules with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self ignition temperature of 360 °C. In aqueous solution, it has a pH value around 4.91 at 20±1 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. ~~A shelf life of at least 2 years at ambient temperature is on-going and the final report will be provided as soon as available.~~

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in *PP packaging material*.

Its technical characteristics are acceptable for a water dispersible granule formulation.

The intended concentration of use is 1.5 kg/ha (max 1.9g/L, min 1.5 g/L)

According to the GAP provided, the minimal intended concentration is 1.5 g/L and the maximal is 1.9 g/L. The differences to the values used in the study - 1.2 g lowest. It is very low probability that they could influence the final results, so the concentration proposed is accepted.

### **Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only**

Neither classification nor labelling is relevant for this section.

### **Notifier Proposals for Risk and Safety Phrases (KCP 12)**

No risk and safety phrases are relevant for this section

### **Compliance with FAO specifications:**

The product PRIORITY complies with FAO specifications.

### **Formulation used for tests**

The product used in the tests has the same composition as the one cited in Part C, PRIORITY (Dimethomorph 15% + Dithianon 35% WG / SHA 6821 A).

**Table 2-1: Physical, chemical and technical properties of the plant protection product**

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual inspection	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	Dark brown granules of characteristic odour	Y	Al Amin, I., 2017 Report no.:BF-108/16	Accepted
Explosive properties (KCP 2.2.1)	EEC A.14	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	Dimethomorph 15% + Dithianon 35% WG does not have explosive properties according to the criteria of EEC A.14 method.	Y	Buczowski, D., 2017 Report no.:BW-21/17	Accepted RMS Comments: The product does not have an explosive properties
Oxidizing properties (KCP 2.2.2)	EEC A.17	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	Dimethomorph 15% + Dithianon 35% WG does not have the oxidizing properties in accordance with test A.17 criteria.	Y	Flasinska, P., 2017 Report no.:BC-39/17	Accepted RMS Comments: The product does not have an oxidizing properties
Flash point (KCP 2.3.1)	-	-	Not relevant for a WG formulation	-	-	Statement accepted
Flammability (KCP 2.3.2)	ECC A.10	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	Dimethomorph 15% + Dithianon 35% WG is not highly flammable in accordance with test A.10. criteria.	Y	Flasinska, P., 2017 Report no.:BC-39/17	Accepted RMS Comments: The product is not highly flammable
Self-heating (KCP 2.3.3)	EEC A.16	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	Dimethomorph 15% + Dithianon 35% WG have got the relative self-ignition temperature: 360 °C in accordance with test A.16 criteria.	Y	Flasinska, P., 2017 Report no.:BC-39/17	Accepted
Acidity or alkalinity and pH			Not required.			Statement accepted



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																		
(KCP 2.4.1)																								
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	pH 4.91 at 20°C	Y	Al Amin, I., 2017 Report no.:BF-108/16	Accepted																		
Viscosity (KCP 2.5.1)	-	-	Not relevant for a WG formulation	-	-	Statement accepted																		
Surface tension (KCP 2.5.2)	-	-	Not relevant for a WG formulation	-	-	Statement accepted																		
Relative density (KCP 2.6.1)	-	-	Not relevant for a WG formulation	-	-	Statement accepted																		
Bulk density (KCP 2.6.2)	CIPAC MT 186	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	Pour density – 0.65 g/mL, Tap density – 0.69 g/mL	Y	Al Amin, I., 2017 Report no.:BF-108/16	Accepted																		
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3.2	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	<table><tr><td>Test</td><td>Initial tested material After accelerated storage</td><td>Initial tested material After accelerated storage</td></tr><tr><td>Appearance</td><td>Dark brown granules of characteristic odour</td><td>Dark brown granules of characteristic odour</td></tr><tr><td>pH of 1% water suspension</td><td>4.91</td><td>4.91</td></tr><tr><td>Wet sieve test</td><td>1 s Residue in 75 µm sieve 0.50%</td><td>1 s Residue in 75 µm sieve 0.30%</td></tr><tr><td>Wettability</td><td>1 s</td><td>1 s</td></tr><tr><td>Suspension stability</td><td>1.2 g/l: 82.66 1.95 g/l: 82.22</td><td>1.2 g/l: 81.75 1.95 g/l: 83.00</td></tr></table>	Test	Initial tested material After accelerated storage	Initial tested material After accelerated storage	Appearance	Dark brown granules of characteristic odour	Dark brown granules of characteristic odour	pH of 1% water suspension	4.91	4.91	Wet sieve test	1 s Residue in 75 µm sieve 0.50%	1 s Residue in 75 µm sieve 0.30%	Wettability	1 s	1 s	Suspension stability	1.2 g/l: 82.66 1.95 g/l: 82.22	1.2 g/l: 81.75 1.95 g/l: 83.00	Y	Al Amin, I., 2017 Report no.:BF-108/16	Accepted  RMS Comment: All results are accepted.  Product is stable after accelerated storage test which was stored glass.  All validation parameters for a.s. meet the requirements of the guidance document SAN-CO/3030/99 rev. 4. and accepted. (Test was done in 2017)
Test	Initial tested material After accelerated storage	Initial tested material After accelerated storage																						
Appearance	Dark brown granules of characteristic odour	Dark brown granules of characteristic odour																						
pH of 1% water suspension	4.91	4.91																						
Wet sieve test	1 s Residue in 75 µm sieve 0.50%	1 s Residue in 75 µm sieve 0.30%																						
Wettability	1 s	1 s																						
Suspension stability	1.2 g/l: 82.66 1.95 g/l: 82.22	1.2 g/l: 81.75 1.95 g/l: 83.00																						

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			Dispersion spontaneity	95.86%	95.66%			
			Granule size	fraction > 3350 µm 0.65%	fraction > 3350 µm 0.49%			
				fraction 2000 - 3350 µm 0.15%	fraction 2000 - 3350 µm 0.93%			
				fraction 1000 - 2000 µm 30.51%	fraction 1000 - 2000 µm 24.12%			
				fraction 500 - 1000 µm 66.81%	fraction 500 - 1000 µm 73.17%			
				fraction 250 - 500 µm 1.14%	fraction 250 - 500 µm 0.65%			
				fraction 125 - 250 µm 0.23%	fraction 125 - 250 µm 0.16%			
				fraction 75 - 125 µm 0.31%	fraction 75 - 125 µm 0.14%			
				fraction < 75 µm 0.21%	fraction < 75 µm 0.21%			
			Attrition resistance	99.70%	99.77%			
			Dustiness	1.50 mg (0.00%)	1.6 mg (0.00%)			
			Flowability	100% after accelerated storage				
			Particle size	d10 = 0.42 µm d50 = 1.87µm d90 = 7.67 µm *Average d4,3 = 3.07 µm SD = 0.069µm, RSD = 2.25%	d10 = 0.43 µm d50 = 1.92µm d90 = 8.54 µm *Average d4,3 = 3.31 µm SD = 0.063µm, RSD = 1.90			

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments																				
			<table><tr><td rowspan="2">Active ingredients</td><td>Dimethomorph – 14.63%</td><td>Dimethomorph – 14.75%</td></tr><tr><td>Dithianon 35.50%</td><td>Dithianon 34.49%</td></tr></table>				Active ingredients	Dimethomorph – 14.63%	Dimethomorph – 14.75%	Dithianon 35.50%	Dithianon 34.49%																		
Active ingredients	Dimethomorph – 14.63%	Dimethomorph – 14.75%																											
	Dithianon 35.50%	Dithianon 34.49%																											
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not relevant for a WG formulation				-	-	Statement accepted																				
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Not relevant for a WG formulation				-	-	Statement accepted																				
Effect of low temperatures on stability (KCP 2.7.4)	-	-	Not relevant for a WG formulation				-	-	Statement accepted																				
Ambient temperature shelf life (KCP 2.7.5)	GIFAP n 17, Visual inspection, CIPAC MT 75.3 CIPAC MT 185 CIPAC MT 53.3 CIPAC MT 184 CIPAC MT 174 CIPAC MT 170 CIPAC MT 178.2 CIPAC MT 187 HPLC validated method	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	<table><tr><th>Test</th><th>Initial tested material</th><th>After the first year storage</th><th>After the second year storage</th></tr><tr><td>Appearance</td><td>Dark brown granules of characteristic odour</td><td>Dark brown granules of characteristic odour</td><td>Dark brown granules of characteristic odour</td></tr><tr><td>pH of 1% water suspension</td><td>4.91</td><td>5.01</td><td>5.05</td></tr><tr><td>Wettability</td><td>1 s</td><td>2 s</td><td>2 s</td></tr><tr><td>Wet sieve test</td><td>Residue in 75 µm sieve 0.50%</td><td>Residue in 75 µm sieve 0.50%</td><td>Residue in 75 µm sieve 0.70%</td></tr></table>				Test	Initial tested material	After the first year storage	After the second year storage	Appearance	Dark brown granules of characteristic odour	Dark brown granules of characteristic odour	Dark brown granules of characteristic odour	pH of 1% water suspension	4.91	5.01	5.05	Wettability	1 s	2 s	2 s	Wet sieve test	Residue in 75 µm sieve 0.50%	Residue in 75 µm sieve 0.50%	Residue in 75 µm sieve 0.70%	Y	Arévalo E., 2019, Report No.:BF-108/16	Accepted  RMS Comment: All results are accepted.  Product is stable after storage test which was stored in PP packaging.  All validation parameters for a.s. meet the requirements of the guidance document SAN-CO/3030/99 rev. 4. and accepted. (Test was done in 03.2017-03.2019)
Test	Initial tested material	After the first year storage	After the second year storage																										
Appearance	Dark brown granules of characteristic odour	Dark brown granules of characteristic odour	Dark brown granules of characteristic odour																										
pH of 1% water suspension	4.91	5.01	5.05																										
Wettability	1 s	2 s	2 s																										
Wet sieve test	Residue in 75 µm sieve 0.50%	Residue in 75 µm sieve 0.50%	Residue in 75 µm sieve 0.70%																										

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
			<div>Suspension stability</div>	<div>1.2 g/ l: 82.66%</div> <div>1.95 g/l: 82.22%</div>	<div>1.2 g/ l: 84.10%</div> <div>Dithianon – 85.21%</div> <div>1.95 g/l: 80.70%</div> <div>Dithianon – 84.28%</div>	<div>1.2 g/ l: 89.94%</div> <div>Dithianon – 88.78%</div> <div>1.95 g/l: 68.71%</div> <div>Dithianon – 72.41%</div>			
			<div>Dispersion spontaneity</div>	<div>95.86%</div>	<div>97.45%</div>	<div>98.22%</div>			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			Granule size	fraction > 3350 µm 0.65% fraction 2000 - 3350 µm 0.15% fraction 1000 - 2000 µm 30.51% fraction 500 - 1000 µm 66.81% fraction 250 - 500 µm 1.14% fraction 125 - 250 µm 0.23% fraction 75 - 125 µm 0.31% fraction < 75 µm 0.21%	fraction > 3350 µm 0.11% fraction 2000 - 3350 µm 0.16% fraction 1000 - 2000 µm 32.36% fraction 500 - 1000 µm 64.62% fraction 250 - 500 µm 1.57% fraction 125 - 250 µm 0.64% fraction 75 - 125 µm 0.24% fraction < 75 µm 0.31%	fraction > 3350 µm 0.01% fraction 2000 - 3350 µm 0.02% fraction 1000 - 2000 µm 32.28% fraction 500 - 1000 µm 64.49% fraction 250 - 500 µm 2.14% fraction 125 - 250 µm 0.6% fraction 75 - 125 µm 0.25% fraction < 75 µm 0.23%		
			Attrition resistance	99.70%	99.75%	99.83%		
			Dustiness	1.50 mg (0.00%)	0.2 mg (0.00%)	0.3 mg (0.00%)		
			Particle size	d10 = 0.42 µm d50 = 1.87µm d90 = 7.67 µm *Average d4,3 = 3.07 µm SD = 0.069µm, RSD = 2.25%	d10 = 0.42 µm d50 = 2.15µm d90 = 10.99 µm *Average d4,3 = 4.32 µm SD = 0.128µm, RSD = 2.965%	d10 = 0.40 µm d50 = 1.93µm d90 = 8.92 µm *Average d4,3 = 3.357 µm SD = 0.078µm, RSD = 2.18%		

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments								
			<table><tr><td>Active ingredients</td><td>Dimethomorph – 14.63% Dithianon 35.50%</td><td>Dimethomorph – 14.54% Dithianon 34.90%</td><td>Dimethomorph – 14.85% Dithianon 34.40%</td></tr><tr><td>Package evaluation</td><td>1 kg PP</td><td>Stable</td><td>Stable</td></tr></table>				Active ingredients	Dimethomorph – 14.63% Dithianon 35.50%	Dimethomorph – 14.54% Dithianon 34.90%	Dimethomorph – 14.85% Dithianon 34.40%	Package evaluation	1 kg PP	Stable	Stable			
Active ingredients	Dimethomorph – 14.63% Dithianon 35.50%	Dimethomorph – 14.54% Dithianon 34.90%	Dimethomorph – 14.85% Dithianon 34.40%														
Package evaluation	1 kg PP	Stable	Stable														
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not relevant for a WG formulation				-	-	Statement accepted								
Wettability (KCP 2.8.1)	CIPAC MT 53.3	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	1 s				Y	Al Amin, I., 2017 Report no.:BF-108/16	Accepted								
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	1.2 g/l: 20 ml after 1 min and 12 ml after 12 min. 1.95 g/l: 29 ml after 1 min and 20 ml after 12 min.				Y	Al Amin, I., 2017 Report no.:BF-108/16	Accepted								
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	1.2 g/l: 82.66 1.95 g/l: 82.22				Y	Al Amin, I., 2017 Report no.:BF-108/16	Accepted								
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 174	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	95.86% After 1 minutes of stirring.				Y	Al Amin, I., 2017 Report no.:BF-108/16	Accepted								
Dispersion stability (KCP 2.8.3.3)	-	-	Not relevant for a WG formulation				-	-	Statement accepted								

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not relevant for a WG formulation	-	-	Statement accepted
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 170  CIPAC MT 187	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	Granule size fraction > 3350 µm 0.65% fraction 2000 - 3350 µm 0.15% fraction 1000 - 2000 µm 30.51% fraction 500 - 1000 µm 66.81% fraction 250 - 500 µm 1.14% fraction 125 - 250 µm 0.23% fraction 75 - 125 µm 0.31% fraction < 75 µm 0.21%  Particle size d10 = 0.42 µm d50 = 1.87 µm d90 = 7.67 µm *Average d4,3 = 3.07 µm SD = 0.069 µm, RSD = 2.25%	Y	Al Amin, I., 2017 Report no.:BF-108/16	Accepted  Accepted
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	Residue in 75 µm sieve 0.50%	Y	Al Amin, I., 2017 Report no.:BF-108/16	Accepted
Dust content (KCP 2.8.5.2.1)	CIPAC MT 171	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	1.50 mg (0.00%)	Y	Al Amin, I., 2017 Report no.:BF-108/16	Accepted
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant for a WG formulation	-	-	Statement accepted
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	Dimethomorph 15% +	99.70%	Y	Al Amin, I., 2017 Report no.:BF-	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Dithianon 35% WG Batch no.: SLC - 20561			108/16	
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant for a WG formulation	-	-	Statement accepted
Emulsifiability (KCP 2.8.6.1)	-	-	Not relevant for a WG formulation	-	-	Statement accepted
Emulsion stability (KCP 2.8.6.2)	-	-	Not relevant for a WG formulation	-	-	Statement accepted
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not relevant for a WG formulation	-	-	Statement accepted
Flowability (KCP 2.8.7.1)	CIPAC MT 172	Dimethomorph 15% + Dithianon 35% WG Batch no.: SLC - 20561	100% flow through the sieve after accelerated storage	Y	Al Amin, I., 2017 Report no.:BF- 108/16	Accepted
Pourability (KCP 2.8.7.2)	-	-	Not relevant for a WG formulation	-	-	Statement accepted
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not relevant for a WG formulation	-	-	Statement accepted
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant	-	-	Statement accepted
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant	-	-	Statement accepted
Adhesion to seeds (KCP 2.10.1)	-	-	Not relevant	-	-	Statement accepted



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Distribution to seed (KCP 2.10.2)	-	-	Not relevant	-	-	Statement accepted
Other/special studies (KCP 2.11)	-	-	Not relevant	-	-	Statement accepted

### **3            Section 3 is presented as a separate document**

Please refer to the separate file “dRR Part B3”.

## 4 Section 4: Further information on the plant protection product

**zRMS comment:** 2-years storage was performed in PP rigid packaging, which remained stable. Extrapolation to other rigid packaging types is possible, therefore HDPE bottles (Tables 4.1-9 – 4.1-13) are acceptable. According to the polish Ministry of Agriculture and Rural Development guidelines, extrapolation from rigid to elastic packaging is not acceptable for solid preparations and for that reason all bags (Tables 4.1-1 – 4.1-8) have been crossed out.

The bags used for packaging 100, 200, 250, 500, 750 and 1000 grams are obtained from a coil, and the material of these bags consists in PE\* multifilm with the next layers:

Material 1:	OPP	Thickness: 20.0 mc
Material 2:	PET met	Thickness: 12.0 mc
Material 3:	PEBD TR	Thickness: 70.0 mc

The specifications of size for these bags are in the next tables:

**Table 1.6-1: Packaging information for 100 grams**

Type	Description
Material:	PE*
Shape/size:	bag / approx. 195 mm x 130 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 1.6-2: Packaging information for 200 grams**

Type	Description
Material:	PE*
Shape/size:	bag / approx. 190 mm x 170 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 1.6-3: Packaging information for 250 grams**

Type	Description
Material:	PE*
Shape/size:	bag / approx. 190 mm x 170 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 1.6-4: Packaging information for 500 grams**

Type	Description
Material:	PE*
Shape/size:	bag / approx. 190 mm x 210 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 1.6-5: Packaging information for 750 grams**

Type	Description
Material:	PE*
Shape/size:	bag / approx. 190 mm x 260 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 1.6-6: Packaging information for 1 kg**

Type	Description
Material:	PE*
Shape/size:	bag / approx. 190 mm x 260 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 1.6-7: Packaging information for 5 kg and 10 kg**

Type	Description
Material:	PE
Shape/size:	<p>Sac / approx. 380 mm (width) x 570 mm (length) x 100 mm (bottom)</p> <p>Layers of sac:</p> <ol style="list-style-type: none"> <li>1. Semi-stretchable white (70 g/m<sup>2</sup>)</li> <li>2. Straight (70 g/m<sup>2</sup>)</li> <li>3. Straight (70 g/m<sup>2</sup>)</li> </ol> <p>Inner bag: approx. 390 mm (width) x 680 mm (length) [thickness: 45 µm]</p>
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 1.6-8: Packaging information for 20 kg and 25 kg**

Type	Description
Material:	PE
Shape/size:	Sac / approx. 550 mm (width) x 810 mm (length) x 130 mm (bottom) Layers of sac: 1. Semi-stretchable white (70 g/m <sup>2</sup> ) 2. Semi-stretchable (70 g/m <sup>2</sup> ) 3. Semi-stretchable (70 g/m <sup>2</sup> )  Inner bag: approx. 560 mm (width) x 910 mm (length) [thickness: 37 µm]
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 1.6-9: Packaging information for 500 grams (1 litter bottle)**

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 95 mm diameter x 166 mm
Opening:	80 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 1.6-10: Packaging information for 1000 grams (2 litter bottle)**

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 117 mm diameter x 227 mm
Opening:	80 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 1.6-11: Packaging information for 3000 grams (5 litter bottle)**

Type	Description
Material:	HDPE
Shape/size:	jerry can / 195 mm x 130 mm x 310.5 mm
Opening:	53 mm inner diameter

Type	Description
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 1.6-12: Packaging information for 5000 grams (10 litter bottle)**

Type	Description
Material:	HDPE
Shape/size:	jerrycan / approx. 192 mm x 232 mm x 313 mm
Opening:	47 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 1.6-13: Packaging information for 10000 grams (20 litter bottle)**

Type	Description
Material:	HDPE
Shape/size:	jerrycan / approx. 240.0 mm x 285.0 mm x 387.5 mm
Opening:	47.0 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**RMS Comments:**

Extrapolation is possible between all containers types.

Recommended packaging are accepted.

;

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1, KCP 2.4.2, KCP 2.6.2, KCP 2.7.5, KCP 2.8.1, KCP 2.8.2, KCP 2.8.3.1, KCP 2.8.3.2, KCP 2.8.5.1.1, KCP 2.8.5.1.2, KCP 2.8.5.2.2, KCP 2.8.5.3, KCP 2.8.7.1,	Idris Al Amin	2017	Dimethomorph 15% + Dithianon 35% WG: Part I: Evaluation of physiochemical properties of the initial preparation and after accelerated storage Study code no. BF-108/16 Institute of Industrial Organic Chemistry GLP Unpublished	N	Sharda
KCP 2.2.1	Daniel Buczkowski	2017	Dimethomorph 15% + Dithianon 35% WG: Determination of explosive properties Study code: BW-21/17 Institute of Industrial Organic Chemistry GLP Unpublished	N	Sharda
KCP 2.2.2, KCP 2.3.2, KCP 2.3.3	Paulina Flasińska	2017	Dimethomorph 15% + Dithianon 35% WG: Determination of flammability, relative self-ignition temperature and oxidizing properties. Study No.: BC-39/17 Institute of Industrial Organic Chemistry GLP	N	Sharda

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
			Unpublished		
KCP 2.7.5	Enzo Arévalo	2019	Dimethomorph 15% + Dithianon 35% WG: Part III: Evaluation of physiochemical properties after the second year storage Study code no. BF-108/16 Institute of Industrial Organic Chemistry GLP Unpublished	N	Sharda

**List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

The following tables are to be completed by MS.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner



## **Appendix 2    Additional data on the physical, chemical and technical properties of the active substance**

### **A 2.1                    Dimethomorph**

No additional data was submitted on the physical chemical and technical properties on the active substance.

### **A 2.2                    Dithianon**

No additional data was submitted on the physical chemical and technical properties on the active substance.