

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: SHA 6821 A

Product name: PRIORITY

Chemical active substances:

Dimethomorph, 150 g/kg

Dithianon, 350 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

Applicant: Sharda Cropchem España S.L.

Submission date: April 2019

**MS Finalisation date: 03.2022; corr. 24.02.2023, 06.2023;
01.2024; 02/2024**

Version history

When	What
03/2022	Initial assessment by zRMS for commenting
02/2023	Corrected ecotoxicology by zRMS
06/2023	zRMS correction after new packaging proposal
01/2024	The final Registration Report
02/2024	Updated toxicology by expert

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by SHARDA CROPChem ESPAÑA S.L.

The application is for approval of PRIORITY, a water dispersible granules formulation containing 150 g/L and 350 g/L of Dimethomorph and Dithianon respectively, as a fungicide on grapevine.
zRMS: Poland

1.2 Letters of Access

Not applicable. Letter of access not needed.

1.3 Justification for submission of tests and studies

This dossier relies on new test and studies providing data and information specific to the formulation PRIORITY as required by the 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 3.

2 Details of the authorization decision

2.1 Product identity

Product code	SHA 6821 A
Product name in MS	PRIORITY
Authorization number	First registration
Function	Fungicide
Applicant	Sharda Cropchem España S.L.
Active substance(s) (incl. content)	Dimethomorph; 150 g/kg Dithianon; 350 g/kg
Formulation type	Water dispersible granules [Code: WG]
Packaging	100 g, 200 g, 250 g, 500 g, 750 g, 1 kg, 5 kg, 10 kg, 20 kg, 25 kg PE 500 g, 1 kg, 3 kg, 5 kg and 10 kg (1, 2, 5, 10 and 20 L bottle, accordingly); 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 product name resulted in the decision to grant the authorization.

Efficacy section:

PRIORITY can be registered in Poland to protect grapevine against *Plasmopara viticola*.

Metabolism and residues section:

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

Toxicology section:

According to the toxicological property classification and labelling of product under Regulation (EC) No 1272/2008: Acute Tox.4/H302, Skin Sens.1B/H317, Eye Irrit.2/H319, Repr.2 1B /H360F

According to the AOEM model, calculations, it can be concluded that the risk for the operator using PRIORITY is acceptable with the use of gloves and working clothing (long sleeved shirt and trousers) during mixing/loading and application. It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves), for maintenance activities when for re-entering grapes treated with PRIORITY a time period of 15 day after application is respected or without gloves when a time period of 22 days after application is respected. It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves), for maintenance activities when for re-entering grapes treated with PRIORITY a time period of 15 day after application is respected or without gloves when a time period of 22 days after application is respected. It can be concluded that there is no undue risk to any bystander after.

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)/H302
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	Eye Irrit. 2;/H319 Skin Sens. 1B/H317 Repr,1B, H3060F Aquatic Acute 1; Aquatic Chronic 1;
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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:	GH07, GH09, GHS08
Signal word:	Warning
Hazard statement(s):	H302, H317, H319, H360F, H400, H410
Precautionary statement(s):	P264, P280, P301+P312, P305+P351+P338, P302+P352, P310, P391, P501
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).
SPe3	To protect aquatic organisms respect an unsprayed buffer zone of 20 m to surface water bodies with 50% of nozzles reduction. To protect aquatic organisms respect an unsprayed buffer zone of 50 m to surface water bodies with 90% of nozzles reduction

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) - time period of 22days after application Work wear (arms, body and legs covered) and gloves - time period of 15 days after application
Integrated pest management (IPM)/sustainable use:	
respective code if available	-
Environmental protection	
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).
SPe3	To protect aquatic organisms respect an unsprayed buffer zone of 20 m to surface water bodies with 50% of nozzles reduction. <i>To protect aquatic organisms respect an unsprayed buffer zone of 50 m to surface water bodies with 90% of nozzles reduction</i>
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

Not relevant.

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code):	PRIORITY	Formulation type:	GAP rev. 0, date: 2016-November-28 th Water dispersible granules (WG) ^(a, b)
Active substance 1:	Dimethomorph	Conc. of as 1:	150 g/kg ^(c)
Active substance 2:	Dithianon	Conc. of as 2:	350 g/kg ^(c)
Safener:	-	Conc. of safener:	- ^(c)
Synergist:	-	Conc. of synergist:	- ^(c)
Applicant:	Sharda Cropchem España S.L.	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Central ^(d)	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes/no		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	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 ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	CEU	Grapevine	F	<i>Plasmopara viticola</i>	Foliar Spray	BBCH 55-79	a) 3 b) 3	10-12	a) 1.5 b) 4.5	a) 0.225 dime- thomorph + 0.525 dithianon b) 0.675 dime- thomorph + 1.575 dithianon	800- 1000	42	

Remarks table heading:	<ul style="list-style-type: none"> (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008 (c) g/kg or g/l 	<ul style="list-style-type: none"> (d) Select relevant (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1 (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.
Remarks columns:	<ul style="list-style-type: none"> 1 Numeration necessary to allow references 2 Use official codes/nomenclatures of EU Member States 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure) 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 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. 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated. 	<ul style="list-style-type: none"> 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 8 The maximum number of application possible under practical conditions of use must be provided. 9 Minimum interval (in days) between applications of the same product 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. 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha). 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind". 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 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.

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.

3.2 Efficacy (Part B, Section 3)

PRIORITY is a Water Dispersible Granular (WG) formulation containing 350 grams per kilogram (g/kg) dithianon and 150 grams per kilogram (g/kg) dimethomorph for use in grapevine. It is used protectively to control downy mildew, caused by *Plasmopara viticola*, in grapevine.

In compliance with the GAP the following dose rates are applied for registration:

- Up to three applications in grapevine to control Downy mildew (*Plasmopara viticola*), target rate: 1.5 kg/ha

This document serves the registration of PRIORITY in the Central zone of the EU. The objective of this biological assessment dossier is to prove and support the label claims of the fungicidal efficacy and crop safety of PRIORITY in grapevine.

Comprehensive field trials were conducted in Spain, Italy, Greece, France, the Czech Republic and Hungary in 2016, 2020 and 2021. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

The data demonstrate that the disease control and safety to the crop of PRIORITY is equivalent to that of the dithianon + dimethomorph co-formulated standard reference product to which it was compared. Furthermore, the efficacy data also demonstrated that PRIORITY is equivalent to slightly more effective, but still as selective to the GAP claimed crops as the dithianon straight reference products and the dimethomorph straight reference products to which the test product was also compared. The applicant therefore wishes to cite the data on dithianon and dimethomorph containing products now out of protection in additional support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal and national evaluators extrapolate from those data.

3.3 Efficacy data

Preliminary tests

The activity of dithianon as well as dimethomorph are both well known; both actives have been marketed by BASF for the use in fruits, vegetables and/or other crops to control a wide range of fungal pests for a number of years, i.e. dithianon has been used since approx. 1965 and Dimethomorph has been marketed since 1993. Based on the knowledge about the active substances (+50 years and +25 years, respectively) and the experiences with the actives in the label claimed crops at the proposed dose rates, the necessary application rates to obtain sufficient control of the pest organism are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

The benefits obtained with the mixture of dithianon and dimethomorph was demonstrated by comparing the control obtained with PRIORITY with the control obtained with dithianon straight or dimethomorph straight at the same assessments. The co-formulation of dithianon with dimethomorph is not new and has been registered for several years with the same ratio of active substances in markets of Europe.

Minimum effective dose tests

PRIORITY was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with PRIORITY applied at different dose rates was evaluated in 21 grapevine trials. In the 21 grapevine trials, PRIORITY was applied at 0.75, 1.0 and 1.5 kg/ha for the control of *Plasmopara viticola* (PLASVI). The dose rates tested reflects 50% to 100% of the recommended rate of PRIORITY, in accordance with the EPPO guideline PP 1/225(2) "Minimum effective dose". The dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy is tested under a range of environmental conditions to fully challenge the product. Data are presented from trials conducted in the Mediterranean EPPO zone (i.e. Spain, Italy, Greece and France), the Maritime EPPO zone (i.e. N-France and Czech Republic) and the South-east EPPO zone (i.e. Hungary).

Control of *Plasmopara viticola* in grapevine: To prove and to support the proposed dose rate of 1.5 kg/ha PRIORITY [525 g dithianon + 225 g dimethomorph per hectare, per application] for the control of Downy mildew (*Plasmopara viticola* (PLASVI)) in Grapevines, the assessment results of twenty-one efficacy trials performed in the Mediterranean EPPO zone (9), the Maritime EPPO zone (7) and the South-east EPPO zone (5) in 2016, 2020 and 2021 are reported. PRIORITY was included in these trials at 1.5 kg/ha to demonstrate the recommended dose rate as well as at two lower dose rates (0.75 kg/ha and 1.0 kg/ha [262.5 g dithianon + 112.5 g dimethomorph per hectare, per application and 350 g dithianon + 150 g dimethomorph per hectare, per application]). In the trials, specifically targeted for this pathogen, three (18) or four (3) applications were applied in the late spring/summer (May-July) at growth stages ranging between BBCH 14 and BBCH 79.

The data from the 21 trials proves that the minimum effective dose rate of PRIORITY to control *Plasmopara viticola* in grapevine is 1.5 kg/ha, with up to three applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Conclusion: According to the presented results, the dose of 1.5 kg/ha per application for downy mildew in grapevine provided the optimal overall control and should be considered as effective against the disease, for which activity of PRIORITY is claimed. As diseases often occur as complexes of several pathogens throughout a season, up to three applications of PRIORITY at the proposed rate should be used to efficiently control the pathogen claimed on the label.

This document clearly demonstrates – as will be demonstrated in the following sections – that the efficacy and crop safety of PRIORITY is equivalent to the standard dithianon + dimethomorph co-formulated reference products to which it was compared. The applicant therefore wishes to cite the data on dithianon and dimethomorph now out of protection in additional support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal and national evaluators extrapolate from those data.

Efficacy tests and conclusions regarding authorization of intended uses

Details of experiment are presented above by Applicant. All used methodology is in accordance with GEP rules.

Applicant submitted in total 21 efficacy trials carried out on grapevines in three different EPPO zones: Maritime (7 trials), Mediterranean (9 trials) and South-east (5 trials). The number of trials is accepted for Maritime and MED EPPO zone. CMS from S-E EPPO zone should decide if 5 trials carried out in two growing seasons (2016 and 2020) can be accepted. Lack of trials for N-E EPPO zone.

For example, grapevines are minor crops in Poland. So, each CMS should decide if presented number of trials is sufficient according to their national rules. Usually, for minor crops it is enough to submit only 2-3 efficacy tests. In Poland we can use trials from neighboring countries, so 6 trials from CZ are accepted for registration PRIORITY in Poland.

During MED EPPO and Maritime EPPO zone 3 application per season were studied during efficacy trials, in S-E EPPO zone – 4 trials (however, efficacy was evaluated after 2, 3 and 4 appl.). Time between application in Maritime EPPO trials was 12-13 days, S-E EPPO zone: 11-14 days and MED EPPO zone: 11-14 days.

Applicant carried out studies in one growing season (2016) in MED EPPO zone, which is not in line with EPPO 1/181 (4). No explanation was provided by Applicant regarding the limitation of the study to one season only. In the opinion of Evaluator, each CMS should decide whether this exception is acceptable to them. In Maritime and S-E EPPO zone two different growing seasons were studied.

- **North-East EPPO zone:**

Lack of efficacy trials for North-East EPPO zone. For Poland we can use only trials from Czech Republic (Maritime EPPO zone) as neighboring country to Poland. There are six field trials from Czech Republic performed in 2016 and 2021. It is worth emphasizing that in Poland (according to the register of plant protection products) so far, no plant protection product containing the same substances (dithianon and dimethomorph) as the evaluated product has been registered. In accordance with the Polish harmonization arrangements for a new mixture of substances for minor crops, the Applicant should submit at least 6 field trials carried out in 2 growing seasons. In the opinion of ZRMs, Applicant submitted enough number of trials for registration PRIORITY in Poland. The individual trial results show that Dithianon 35% + Dimethomorph 15% WG gave moderate to excellent control of *Plasmopara viticola*, equivalent to that achieved by the dithianon + dimethomorph co-formulated reference product.

- **Maritime EPPO zone:**

Applicant submitted 7 efficacy trials (1 performed in France and 6 in Czech Republic) during two growing seasons (2016 and 2021). The number of tests should be sufficient. The individual trial results show that Dithianon 35% + Dimethomorph 15% WG gave moderate to excellent control of *Plasmopara viticola*, equivalent to that achieved by the dithianon + dimethomorph co-formulated reference product.

- **Mediterranean EPPO zone:**

Applicant submitted in total 9 efficacy trials (France – 3 trials, Greece – 2 trials, Spain – 2 trials, Italy – 2 trials). In the opinion of Evaluator, number of trials is sufficient for major crops, according to EPPO rules. The individual trial results show that Dithianon 35% + Dimethomorph 15% WG gave moderate to excellent control of *Plasmopara viticola*, equivalent to that achieved by Forum Gold (the dithianon + dimethomorph co-formulated reference product) and superior to that achieved with Forum (the dimethomorph straight reference product).

- **South-East EPPO zone:**

Applicant submitted in total 5 efficacy trials performed in Hungary. Only in case, if grapevine is a minor crop the number of trials will be sufficient. For major crops at least 6 efficacy trials are required. So, in the opinion of evaluator each CMS should decide if presented documentation is sufficient. The individual trial results show that Dithianon 35% + Dimethomorph 15% WG gave moderate to good

control of *Plasmopara viticola*, equivalent to that achieved by reference product.

The relevance of extrapolations should be confirmed at the national level with respect to national conventions. Concerned Member States will need to consider the relevance of the submitted formulation comparability data in relation to the current authorized uses for the standard product in their own Member State.

EFFECTIVENESS ACCORDING TO LWA APPROACH:

According to EPPO PP 1/239, the application rate should be calculated per treated leaf wall area unit (LWA) and results of the test product should be presented and interpreted according to LWA by the applicant. The applicant did not submit any data and results related to LWA score combined with reference to ha ground area. From efficacy's point of view, the reference to ha ground area is not sufficient anymore (EPPO PP 1/239). Therefore, the Applicant calculated the LWA for PRIORITY, using the treated canopy height as well as the row distance between the rows from the single trial reports (where these parameters were available).

Conversion of the application dose in kg/ha LWA

According to the EPPO guideline PP 1/239(2) "great efforts are being made to obtain optimum efficacy from the applied product and to avoid unnecessary emission of products into the environment and residues in feed and food" and "the best way to achieve this is to adapt dose rate to the area where the treatment is needed (e.g., crop canopy) and its structure.

An easy way to establish correct application dose in three-dimensional crops is to use dose per treated leaf area unit (LWA)

To calculate LWA is needed to know distance between rows and between plants in the row, treated foliage height, number of sides per row.

- Distance between rows
- Distance between plants in the row
- Treated foliage height
- Number of sides per row = 2 side

Calculation of LWA

Number of trees on 1 ha soil surface:

$$\text{Number of trees per hectare} \times m \text{ in row} \times m \text{ crop height} \times \text{number of sides} = \text{LWA (m}^2\text{)}$$

Below LWA is calculated for each report:

Trial report	Tree distance between rows x distance within row (m)	Number of trees per Hectare	Crop height (m) (average)	LWA (m ²)
F-111312016 (HU)	2,1 x 1,0	no data	no data	no data
F -1 1 1 1 12016 (HU)	2,7 x 1,38	no data	no data	no data
FU/PD/HU/2016/026 (HU)	2,4 x 1,0	4166	1,78	14790
FU-PD-HU-20S6-a2-6-PAR (HU)	2,1 x 1,0	4762	no data	no data
F-134-PLASVI-2020-PLA (HU)	2,7 x 1,0	no data	no data	no data
56216-EVIF.S1 025E16S (SP)	3,0 x 1,5	2222	1,57	10444
56216-EVIF.S1 026E16S (SP)	3,0 x 1,5	2222	0,99	6600
055.F.SAG16/e (IT)	2,5 x 0,9	4444	2,3	18398
56.F.SAG16/e (IT)	2,8 x 0,8	4464	no data	no data
TSTF2016061A (GR)	2,2 x 1,1	4132	1,72	15606
TSTF2016062A (GR)	2,2 x 1,1	4132	1,72	15606

FR161006AP103 (FR)	2,0 x 1,0	5000	0,68	6834
FR161006AS105 (FR)	2,0 x 1,0	5000	1,7	17000
FR161006MH110 (FR)	2,7 x 1,1,	3367	1,4	10370
SWEPL-CZE16-DIDI-VITVI-PPT13 (CZ)	2,5 x 1,0	4000	1,7	13600
SWEPL-CZE16-DIDI-VITVI-PPT14 (CZ)	3,0 x 1,0	3333	1,67	11110
CZOR-SWE21-VITVI-008PPT (CZ)	3,0 x 1,0	3333	1,50	10000
CZOR-SWE21-VITVI-008PPT (CZ)	2,4 x 0,9	3750	1,3	10833
CZOR-SWE21-VITVI-009PPT (CZ)	3,0 x 1,0	3333	1,4	9333
CZOR-SWE21-VITVI-010PPT (CZ)	2,4 x 0,9	4630	1,2	10000
FR161006DP104 (FR)	1,4 x 1,0	6000	1,4	16800

As can be observed, range of LWA vary between 6600 and 18398 what indicates that the ratio to calculate application per LWA should be between 0,82 and 2,27 kg/ha LWA.

- **Maritime EPPO zone:** range of LWA vary between 9333 and 16800 what indicates that the ratio to calculate application per LWA should be between 0,89 and 1,60 kg/ha LWA. On the basis on the average LWA (11668) the proposed dose LWA should be: 1,29 kg/ha LWA.
- **Mediterranean EPPO zone:** range of LWA vary between 6600 and 18398 what indicates that the ratio to calculate application per LWA should be between 0,82 and 2,27 kg/ha LWA. On the basis on the average LWA (12607) the proposed dose LWA should be: 1,19 kg/ha LWA
- **South-East EPPO zone:** LWA vary 14790 what indicates that the ratio to calculate application per LWA should be 1,01 kg/ha LWA.
- **Poland (N-E):** lack of trials carried out in Poland. On the basis on results from Czech Republic and average LWA (10813), the proposed dose LWA for Poland should be: 1,39 kg/ha LWA.

The final decision to accept this approach and to accept the data is left to cMS

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

Since dithianon is a non-systemic multi-site inhibitor, the risk of disease developing resistance to dithianon is very small. Dithianon has given reliable disease control for many years. Dithianon is widely used in tank-mix or in sequence with systemic fungicides to prolong the activity of the systemic fungicides and to avoid the development of resistance of the disease to the systemic fungicides.

Considering that dimethomorph has now been on the market since 1993/1994, there is enough data to support the original statement that the resistance risk for dimethomorph is moderate.

Common strategies of mixtures with other fungicides, alternation spray program and limitation to the number of spray applications are recommended in order to avoid the development of resistance.

However, since PRIORITY is a fungicide that combines the action of dithianon and dimethomorph, that are two active substance with different mode of action, the possible development of resistance related to the single actives can be considered reduced.

It is therefore expected that the application of PRIORITY, when applied in accordance with good agricultural practices, including label recommendations.

The Registration of PRIORITY is endorsed.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

Phytotoxicity was assessed in 21 efficacy trials which were conducted in the Mediterranean EPPO zone (9; i.e. Spain (2), Italy (2), Greece (2) and S-France (3)), the Maritime EPPO zone (7; i.e. N-France (1) and Czech Republic (6)) and the South-east EPPO zone (5; i.e. Hungary) in 2016, 2020 and 2021.

PRIORITY applied at the recommended dose rate did not cause phytotoxicity in any of the trials conducted on grapevine when applied as recommended.

As the data on grapevine show, the crop safety of PRIORITY is equivalent to that of the dithianon straight reference product, the dimethomorph straight reference product as well as the dithianon + dimethomorph co-formulated reference product tested in the trials. As comparability between the formulations has been demonstrated, the applicant therefore wishes to cite the original registrant's data on dithianon and dimethomorph now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Effects on yield and quality

Four efficacy trials conducted in grapevine were harvested. The trials harvested were conducted in the Mediterranean EPPO zone (2; i.e. Spain) and the Maritime EPPO zone (6; i.e. the Czech Republic) in 2016 and 2021 to evaluate the effect of PRIORITY on yield and/or quality of yield in the GAP claimed crops. In the trials, PRIORITY was applied at three applications at growth stages relevant to the proposed GAP.

Yield (t/ha) as well as assessments on the potential impact of treatment on quality parameters, like sugar content and acidity content was assessed in the grapevine efficacy trials.

PRIORITY applied at the proposed dose rate, at a range of growth stages within or occasionally beyond the label recommended range, in grapevine did not affect crop yield nor the quality of the crop yield significantly in any of the 8 trials harvested. Furthermore, the data obtained in trials harvested demonstrate that PRIORITY is as safe as the reference products (dithianon + dimethomorph mixtures) used in the trials.

For recommendations on the label not sufficiently supported with trials harvested, the applicant wishes to bridge to the trials conducted in grapevine where harvest data demonstrated the safe use following application of PRIORITY as recommended. Furthermore, the data presented in this document also clearly demonstrates that the efficacy and crop safety of PRIORITY is equivalent to the standard dithianon + dimethomorph mixtures products to which it was compared. The applicant therefore wishes to cite the original registrant's data on dithianon and dimethomorph now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

3.3.3 Observations on other undesirable or unintended side-effects

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

PRIORITY is composed of dithianon and dimethomorph, which both have been widely used for several years on e.g. grapevine, without identifying any issues in regards to the ability of treated plant part to be used for propagating purposes.

Thus, negative effects of the two active ingredients on parts of plant used for propagating purposes can be excluded due to the fungicidal nature of the product. Furthermore, phytotoxicity assessments in the performed trials demonstrated the complete crop safety of the product and the absence of any negative effect on the plants or plant products

Impact on succeeding crops.

According to Monograph of Dithianon and Dimethomorph, the EU agreed endpoints have been used in the risk assessment.

The value of NOAER derived for plant weight from seedling emergence study submitted in the Monograph of the active substance have been used as surrogate for the risk assessment for Dithianon.

Regarding Dimethomorph, effects on non-target plants were tested by means of seedling emergence study following soil surface or foliar application of the formulation.

The calculated TER values are higher than trigger of 1 for both active substances. Therefore there are no impact on succeeding crops and no waiting period is necessary.

Impact on other plants including adjacent crops

During the conduct of efficacy trials and phytotoxicity trials no observations about negative or positive effects on other plants or neighbouring crops were reported.

Effects are not to be expected due to the fungicidal nature of the product. Furthermore, the active ingredients contained in PRIORITY have been used for decades on several crops without problem.

Studies presented demonstrated that the calculated TER values are higher than trigger of 1 for grapevines. Therefore no risk mitigation measures are required.

Effects on beneficial and other non-target organisms

There were no adverse effects on beneficial and other non-target organisms observed in any of the efficacy trials conducted.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

	Dimethomorph	Dithianon
Author(s), year	Małgorzata Wołoszynowska, 2017.	Małgorzata Wołoszynowska, 2017.
Principle of method	HPLC with UV/Vis detector	HPLC with UV/Vis detector
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	0.1625 mg/mL to 0.4225 mg/mL	0.3928 mg/mL to 0.8681 mg/mL
Precision – Repeatability Mean n = 6 (%RSD)	0.86	0.53
Accuracy n = 6 (% Recovery)	99.50	101.03
Interference/ Specificity	No interferece	
Comment	Presented method is accepted. The validation parameters are within the acceptance range according to SANCO/3030/99	

	Dimethomorph	Dithianon
	rev.4. because the test was started in 04.2017	

3.4.2 Analytical methods for residues

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

Noticed data gaps are:

- none

MRLs for grapevine was set at 3.0 mg/kg for dimethomorph (Reg. (EU) 2020/1633) and for dithianon (Reg. (EC) 839/2008). Available analytical methods are sufficient to determine analytes for MRL compliance.

Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
High water content	Component of residue definition: Dimethomorph			
	Primary	0.2 mg/kg	GC-PND	EU agreed
	Component of residue definition: Dithianon			
	Primary	0.01 mg/kg	LC-MS/MS	EU agreed
	ILV	0.01 mg/kg	LC-MS/MS	EU agreed
High acid content	Component of residue definition: Dimethomorph			
	Primary	0.02 mg/kg	GC-PND	EU agreed
	Confirmatory	0.05 mg/kg	GC-PND LC-MS/MS	EU agreed
	Component of residue definition: Dithianon			
	Primary	0.01 mg/kg	LC-MS/MS	EU agreed
	ILV	0.01 mg/kg	LC-MS/MS	EU agreed
High oil content	Component of residue definition: Dimethomorph			
	Primary	0.02 mg/kg	GC-PND	EU agreed
	Component of residue definition: Dithianon			
	Primary	0.01 mg/kg	LC-MS/MS	EU agreed
	ILV	0.01 mg/kg	LC-MS/MS	EU agreed
High protein/high starch content (dry)	Component of residue definition: Dimethomorph			
	Primary	0.02 mg/kg	GC-PND	EU agreed
	Confirmatory	0.05 mg/kg	GC-PND LC-MS/MS	EU agreed
		0.01 mg/kg	HPLC-UV	
Component of residue definition: Dithianon				

	Primary	0.01 mg/kg	LC-MS/MS	EU agreed
	ILV	0.01 mg/kg	LC-MS/MS	EU agreed
Difficult	Component of residue definition: Dimethomorph			
	Primary	0.2 mg/kg	GC-PND	EU agreed
	Component of residue definition: Dithianon			
	Primary	1.0 mg/kg	LC-MS/MS	EU agreed
	ILV	1.0 mg/kg	LC-MS/MS	EU agreed
Milk	Component of residue definition: Dimethomorph			
	Primary	0.01 mg/kg	GC-PND	EU agreed
	Component of residue definition: Dithianon			
	Primary	0.01 mg/kg	HPLC-ECD	EU agreed
		0.01 mg/kg	LC-MS/MS	EU agreed
	ILV	0.01 mg/kg	HPLC-ECD	EU agreed
Confirmatory	0.01 mg/kg	LC-MS	EU agreed	
Eggs	Component of residue definition: Dimethomorph			
	Primary	0.01 mg/kg	GC-PND	EU agreed
	Component of residue definition: Dithianon			
	Primary	0.01 mg/kg	HPLC-ECD	EU agreed
	ILV	0.01 mg/kg	HPLC-ECD	EU agreed
	Confirmatory	0.01 mg/kg	LC-MS	EU agreed
Muscle	Component of residue definition: Dimethomorph			
	Primary	0.01 mg/kg	GC-PND	EU agreed
	Component of residue definition: Dithianon			
	Primary	0.01 mg/kg	HPLC-ECD	EU agreed
	ILV	0.01 mg/kg	HPLC-ECD	EU agreed
	Confirmatory	0.01 mg/kg	LC-MS	EU agreed
Fat	Component of residue definition: Dimethomorph			
	Primary	0.01 mg/kg	GC-PND	EU agreed
	Component of residue definition: Dithianon			
	Primary	0.01 mg/kg	HPLC-ECD	EU agreed
		0.01 mg/kg	LC-MS/MS	EU agreed
	ILV	0.01 mg/kg	HPLC-ECD	EU agreed
Confirmatory	0.01 mg/kg	LC-MS	EU agreed	
Kidney, liver	Component of residue definition: Dithianon			
	Primary	0.01 mg/kg	LC-MS/MS	EU agreed
Soil	Component of residue definition: Dimethomorph			

	Primary	0.01 mg/kg	GC-PND GC-MS LC-MS/MS	EU agreed
	Component of residue definition: Dithianon			
	Primary	0.01 mg/kg 0.01 mg/kg	LC-MS LC-MS/MS	EU agreed EU agreed
Water (drinking and surface water)	Component of residue definition: Dimethomorph			
	Primary	0.05 µg/L	HPLC-UV LC-MS/MS	EU agreed
	Component of residue definition: Dithianon			
	Primary	0.05 µg/L	LC-MS/MS	EU agreed
Air	Component of residue definition: Dimethomorph			
	Primary	10 µg/m ³	GC-PND	EU agreed
	Component of residue definition: Dithianon			
	Primary	0.001 mg/m ³	HPLC-UV	EU agreed
Body fluids and tissues	Component of residue definition: Dithianon			
	Primary	0.05 mg/L for human urine and blood	LC-MS/MS	EU agreed

3.5 Mammalian toxicology (Part B, Section 6)

Acute toxicity studies for PRIORITY were not evaluated as part of the EU review of Dimethomorph and Dithianon. Therefore, all relevant data were provided and are considered adequate. All toxicological studies have been performed.

Classification: **H302** **Harmful if swallowed**
 H317 **May cause an allergic skin reaction**
 H319 **Causes serious eye irritation**
 H360F **May damage fertility**

3.5.1 Acute toxicity

Acute toxicity studies for PRIORITY were not evaluated as part of the EU review of Dimethomorph and Dithianon. Therefore, all relevant data were provided and are considered adequate. The results are summarised in the table below:

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat (OECD 423)	500 mg/kg bw	Yes	Acute Tox.4 H302	C.S. Ghogale 2018
LD ₅₀ dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	C.S. Ghogale 2018

LC ₅₀ inhalation, rat (OECD 403)	Non	Yes	None	-
Skin irritation, rabbit (OECD 404)	Non-Irritant	Yes	None	C.S. Ghogale 2018
Eye irritation, rabbit (OECD 405)	Damage	Yes	Eye Irrit..2/ H319	C.S. Ghogale 2018
Skin sensitisation, guinea pig (OECD 406)	Moderate	Yes	Skin Sens. 1B/H317	C.S. Ghogale 2018
Supplementary studies for combinations of plant protection products	No data – not required			

3.5.2 Operator exposure

Operator exposure to PRIORITY was not evaluated as part of the EU review of Dimethomorph and Dithianon. Therefore, all relevant data and risk assessments are provided here and are considered adequate. Estimations of potential operator exposure have been undertaken for both Dimethomorph and Dithianon using the EFSA AOEM model.

Conclusion:

According to the AOEM model, calculations, it can be concluded that the risk for the operator using PRIORITY is acceptable with the use of gloves and working clothing (long sleeved shirt and trousers) during mixing/loading and application. - Work wear (arms, body and legs covered) M/L and A + gloves M/L and A + hood - Application with tractor mounted or Work wear (arms, body and legs covered) M/L and A + gloves M/L and A – Application with closed cab traktor, Work wear (arms, body and legs covered) M/L and A + gloves M/L and A -Application with Manual-Hand held

Implication for labelling: P280: Wear protective gloves, protective clothing/eye protection/face protection

3.5.3 Worker exposure

Worker exposure to PRIORITY was not evaluated as part of the EU review of Dimethomorph and Dithianon. Calculations were made using dermal absorption value and the EFSA model.

Conclusion

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves), for maintenance activities when for re-entering grapes treated with PRIORITY a time period of 15 15 day after application is respected or without gloves when a time period of 22 26 days after application is respected.

3.5.4 Bystander and resident exposure

Bystander and resident exposures to PRIORITY was not evaluated as part of the EU review of Dimethomorph and Dithianon. Therefore, all relevant data and risk assessments have been provided and are considered adequate. Calculations were made using the 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 PRIORITY.

NOTE: Entrance into treated crop prohibited for children.

3.6 Residues and consumer exposure (Part B, Section 7)

The preparation PRIORITY is composed of Dimethomorph and Dithianon.

Toxicological reference values for the dietary risk assessment of Dimethomorph and Dithianon

Reference value	Source	Year	Value	Study relied upon	Safety factor
Dimethomorph - Parent compound					
ADI	EFSA Scientific Report (2006) 82, 1-69	2006	0.005 mg/kg bw/day	1-year dog study	100
ARfD			0.6 mg/kg bw	Developmental toxicity study in rats	100
Dithianon - Parent compound					
ADI	EFSA Journal 2010;8(11):1904	2010	0.01 mg/kg bw/day	Long-term toxicity / carcinogenicity study in the rat	100
ARfD			0.12 mg/kg bw	7-day and 28-day oral toxicity in the rat (mechanistic studies)	100

Residue trials were sufficient to support the uses of PRIORITY. No unacceptable risk for the consumer is expected after the use of PRIORITY according to the intended GAP.

3.6.1 Residues

Storage stability

Dimethomorph

According to EU agreed data (EFSA, 2006 and EFSA, 2011) the available stability of residues data can cover the intended uses on grapevines (matrix with high acid content).

Grapes	24 months	EFSA, 2006
Grape juice	16 months	RMS, 2004
Grape waste	16 months	RMS, 2004
Raisins	14 months	RMS, 2004

Dithianon

According to the EU agreed data (EFSA, 2011 and 2015) the available stability of residues data can cover the uses on grapevines (matrix with high acid content).

Grape	14 months	Greece, 2007, 2010, 2014, EFSA, 2010, 2015
Grape juice	18 months	Greece, 2007, 2010, 2014, EFSA, 2010, 2015
Grape pomace	6 months	Greece, 2007, 2010, 2014, EFSA, 2010, 2015

EU data gap in light of confirmatory data (EFSA Journal 2020;18(9):6189): *storage stability data on dithianon residues in grape wine and covering the maximum storage time interval of the samples from the processing residue trials.*

This study/information should be provided when renewing the product.

Metabolism in plants and animals

The data evaluated during the Annex I inclusion of the active substances are sufficient to describe the behaviour of the formulated product, and no further studies are required.

Dimethomorph

Plant metabolism studies: Plant groups covered Fruit (grapes, tomato); tuber (potato); leafy (lettuce)
 Plant residue definition for monitoring and risk assessment: Dimethomorph (sum of isomers)
 Animals covered: lactating goats and laying hens.
 Animal residue definition for monitoring and risk assessment: Dimethomorph (sum of isomers)

Dithianon

Metabolism studies: Plant groups covered: fruits (apples, oranges), leafy crop (spinach), wheat (cereals) via foliar treatment.
 Plant residue definition for monitoring and risk assessment: Dithianon (open for processed commodities)
 Animals covered: lactating goats and laying hens.
 Animal residue definition for monitoring and risk assessment: Dithianon

Magnitude of residues in plants

Grapevine

Proposed GAP:

BBCH 55-79 3 applications, interval between applications: 10-12 days, 0.225 kg as/ha dimethomorph + 0.525 kg as/ha dithianon, PHI: 42 days

Dimethomorph

The number of trials is sufficient as to support the use of dimethomorph in grapevine according to the proposed GAP in Central Zone.

The residues arising from the proposed use will not exceed the MRLs for grapevine set at 3.0 mg/kg (Reg. (EU) 2020/1633).

EU GAP supported by available unprotected data is presented below. Proposed GAP is within the EU GAP. The proposed use is less critical than those assessed in the EU only in terms of the number of treatments (5 versus 3). Application rate per treatment is within 25% of that assessed in the EU.

List of endpoints (2005)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g as/h L min max	water L/ha min max	g as/ha min max	
Grapevines	North-ern and South-ern Europe	Fo-rum	F	<i>Plasmo-para viticola</i>	DC	150 g/L	Tractor mount- ed spray	BBC H 53 - 79 May - end of Au- gust	5	10 days	30 - 75	400 - 100 0	ma x 300	28

Dithianon

The number of trials is sufficient as to support the use of dithianon in grapevine according to the proposed GAP in Central Zone.

The residues arising from the proposed use will not exceed the MRLs for grapevine set at 3.0 mg/kg (Reg. (EC) 839/2008).

EU GAP supported by available unprotected data is presented below. Proposed GAP is within the EU GAP.

Crop and/or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Formulation	Application	Application rate per treatment	PHI (days)
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(a)			(b)	(c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	g as/ha min max	(l)
Grapevines	Northern and Southern Europe	Delan 70 WG (BAS 216 03F)	F	<i>Plasmo-para viticola</i>	WG	700 g/L	High volume spraying	BBC H 10 – 79	1-8	7-12 days	0.04 7 - 0.14 0	400 – 120 0	0.56 0	42

Magnitude of residues in livestock

The requested uses are not present in EU animal diets.

Processing studies

Dimethomorph

Data/information on processing studies was reviewed during the approval of active substances and were considered acceptable.

Further processing studies are not required because they are not expected to affect the outcome of the risk assessment.

Dithianon

Data/information on processing studies was reviewed during the approval of active substances and were considered acceptable.

Data gap: The magnitude of residues of the metabolites Reg. No. 4107273, Reg. No. 31062, Reg. No. 4005234 (Phthalic acid) and Reg. No. 4110933 in apple and grapes processed commodities is required (EFSA Journal 2015;13(11):4278). Plant residue definition is open for processed commodities.

EU data gap in light of confirmatory data (EFSA Journal 2020;18(9):6189): *storage stability data on dithianon residues in grape wine and covering the maximum storage time interval of the samples from the processing residue trials.*

This study/information should be provided when renewing the product.

Magnitude of residues in representative succeeding crops

Since the intended use in grapevine concern permanent crops, study is not required.

Conclusion:

According to the available data, the intended use on grapevine is considered acceptable.

3.6.2 Consumer exposure

Consumer exposure regarding Dimethomorph

TMDI (% ADI) according to EFSA PRIMo rev.3.1	75 % (based on FR toddler)
IESTI (% ARfD) according to EFSA PRIMo* rev.3.1	<p>Unprocessed commodities</p> <p>Results for children</p> <p>Wine grapes: 5 %</p> <p>Results for adults/general population</p> <p>Wine grapes: 12 %</p> <p>Processed commodities</p>

	Results for children Wine grapes / juice: 22 % Results for adults/general population Wine grapes/juice: 10 % Wine grapes/wine: 5 %
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The proposed uses of Dimethomorph in the formulation PRIORITY do not represent unacceptable acute and chronic risks for the consumer

Consumer exposure regarding Dithianon

TMDI (% ADI) according to EFSA PRIMo rev.3.1	585 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo rev.3.1	194 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo based on specific intended uses (only wine grapes) rev.3.1	25 % (based on PT general)
IESTI (% ARfD) according to EFSA PRIMo * rev.3.1	Unprocessed commodities Results for children Wine grapes: 24 % Results for adults Wine grapes: 59 % Processed commodities Results for children Wine grapes/juice: 109 % Results for adults Wine grapes/juice: 52 % Wine grapes/wine: 24 %
IESTI (% ARfD) according to EFSA PRIMo (based on STMR/HR) rev.3.1	Unprocessed commodities Results for children Wine grapes: 21 % Results for adults Wine grapes: 54 % Processed commodities Results for children Wine grapes/juice: 37 % Results for adults Wine grapes/wine: 21 % Wine grapes/juice: 18 %

The proposed uses of Dithianon in the formulation PRIORITY do not represent unacceptable acute and chronic risks for the consumer.

It can be concluded that the use of PRIORITY do not represent an unacceptable acute and chronic risks for the consumer.

Acute consumer risk assessment for combined exposure

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo)
Wine grapes	Dimethomorph	0.12

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo)
	Dithianon	0.54
	Cumulative risk for grapevine (HI)	0.64
	Wine grapes / juice	Dimethomorph
	Dithianon	0.37
	Cumulative risk for grapevine (HI)	0.59
	Wine grapes / wine	Dimethomorph
	Dithianon	0.21
	Cumulative risk for grapevine (HI)	0.31

The Hazard Index is <1. Thus combined exposure to all active substances in PRIORITY is not expected to present a consumer risk. No further refinement of the assessment is required.

Conclusion

The proposed use of Dimethomorph and Dithianon in the formulation SHA 6821 A do not represent unacceptable acute and chronic risks for the consumer.

Combined exposure active substances in SHA 6821 A is not expected to present a consumer risk.

3.7 Environmental fate and behaviour (Part B, Section 8)

Concentrations of PRIORITY in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentrations (PEC values) in soil, surface water, sediment, ground water and air are provided.

Intended use pattern of PRIORITY

Crop	Application rate (kg ai/ha)	Application method	Max. number of applications	Minimum application interval (days)	Application timing
Grapevine	Dimethomorph: 0.225 Dithianon: 0.525	Foliar spray	3	10	BBCH 55 - 79

The impact of formulants is limited to short-term effects such as formation of stable spray dispersions to facilitate uptake by target organisms, while their influence on long-term processes, such as degradation and distribution is negligible. Therefore, for the purposes of this risk assessment, it is assumed that formulants do not influence the fate and behaviour of the active substance in the environment and are not further considered.

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

PEC_{soil} calculations have been conducted with Dimethomorph using the endpoints in the EFSA conclusions of Dimethomorph (EFSA Scientific Report (2006) 82, 1-69 of 23 June 2006), and with Dithianon

and its relevant metabolite Phthalic acid using the endpoints of the EFSA conclusions (EFSA Journal 2010;8(11):1904 of 25 November 2010).

Maximum PEC_{soil} value for Dimethomorph was 0.335 mg/kg following the highest application rate of 225 g Dimethomorph/ha.

Maximum PEC_{soil} value for Dithianon was 0.707 mg/kg, and 0.025 mg/kg for Phthalic acid, following the highest application rate of 525 g of Dithianon/ha.

The results for PEC soil for the active substances and the metabolites were used for the eco-toxicological risk assessment.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The PEC_{gw} (Predicted Environmental Concentrations in Ground Water) of Dimethomorph, Dithianon and its relevant metabolite Phthalic acid have been assessed with standard FOCUS scenarios to obtain outputs from FOCUS PELMO 5.5.3 and PEARL 4.4.4 models, and the Koc values established in the EU reviews. Seven realistic worst-case standard weather, soil and crop scenarios that collectively represent major agricultural areas for grapevines in the European Union were used as recommended by FOCUS (2000, 2009). Modelling was done for multiple applications of 3 x 1.5 kg product/ha (equivalent to 3 x 0.225 kg Dimethomorph /ha and 3 x 0.525 kg Dithianon/ha) to grapevines. It should be noted that as recommended in the Generic Guidance for Tier 1 FOCUS Ground Water Assessments (FOCUS 2011), a corrected application rate is calculated taking into account the interception by the crop canopy. Therefore, the substance is applied directly to the ground in the models, thus avoiding the internal interception routines in the models. The corrected application rates are 90 g Dimethomorph/ha and 210 g Dithianon/ha in grapevine. Absolute application dates, calculated according to AppDate v3.03 (31 January 2019), were used for modelling.

PEC_{gw} values were all below 0.1 µg/L for both active ingredients Dimethomorph and Dithianon, and for its relevant metabolite Phthalic acid.

It can be concluded, that Dimethomorph and Dithianon and its metabolite will not leach to groundwater to any environmentally hazardous extent under environmentally relevant conditions in Poland.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The PEC_{sw} (Predicted Environmental Concentrations in Surface Water) of Dimethomorph and Dithianon and its relevant metabolites CL 1017911, Phthalic acid, Phthalaldehyde and 1,2-benzenedimethanol have been assessed with the FOCUS SW and the DT50 water/sediment values established in the EU reviews.

Since the aquatic organisms risk assessments using Step 2 PEC_{sw} values still show unacceptable risks for the active substances Dimethomorph and Dithianon and Dithianon's metabolite Phthalaldehyde, further calculations were conducted at Step 3 using the models FOCUS SWASH v5.3, FOCUS PRZM v 4.3.1, FOCUS MACRO v5.5.4 and FOCUS TOXWA v5.5.3. However, Step 3 refinements were not sufficient to show acceptable risk for the active substance Dithianon. Therefore, in order to refine the aquatic risk assessment, further calculations were conducted at Step 4 to quantify the risk mitigation measures such as no spray buffer zones and drift reduction nozzles. The simulations were performed using the SWAN 5.0.0 model.

The results for PEC surface water (Step 1 to 4) for the active substance and its metabolites were used for the eco-toxicological risk assessment.

According to Polish national requirements scenarios D3, D4 and R1 in Step 3 and 4 are required.

FOCUS does not provide for D3 and D4 scenarios for use in vines. Therefore, calculations for these scenarios were performed for substitute crop (pone/stone fruit).

3.7.4 Predicted environmental concentrations in air (PEC_{air})

Dimethomorph and Dithianon are considered as non-volatile substances. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Dithianon due to volatilization with subsequent deposition was not taken into account.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

- Birds

In the Tier I risk assessment, the TERA values were greater than the Annex VI trigger of 10, indicating that PRIORITY presents no unacceptable acute risk to birds according to the intended uses. However, the TER_{lt} value for small insectivorous species “Redstart” in grapevine was below the trigger of 5 for Dithianon. A further refinement of the long-term risk was needed. A refinement of the risk was done by refining the DF and PT, and the TER value was above the trigger showing no risk. Therefore, the acute long-term risk to birds after the application of PRIORITY according to the GAP is considered acceptable. In addition, no unacceptable acute and long-term risk were obtained in grapevine according to the proposed GAP due to combined exposure.

The justification:

the comment from part B9 relates to assessment long-term risk for individual member states.

For the application in Poland, the refinement of the parameters used in the risk assessment was accepted. Therefore, no unacceptable long-term risk to birds is expected.

Higher-tier risk assessment

In order to refine the risk assessment, the following parameters DF and PT was refined below.

Higher-tier assessment of long-term risk for birds due to the use of PRIORITY in grapevine– refined parameters (*) are further described

Intended use		Grapevine					
Active substance/product		PRIORITY					
Application rate (g/ha)		3 x 750					
NOEL (mix) (mg/kg bw)		27.90					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD _m × DF* (mg/kg food)	MAF _m × TWA	PT*	DDD _m (mg/kg bw/d)	TER _{lt}
Black Redstart (Phoenicurus ochruros)	50% ground arthropods	0.81	3.5 ¹ × 0.5 ²	1.8 × 0.53	0.28 0.75 ³	0.14 0.38	15.11 5.64
	50% foliar arthropods	0.81	21.0 ¹ × 1.0	1.8 × 0.53	0.28 0.75 ³	1.70 4.56	
	Whole diet					1.85 4.94	

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹According Table 1 in Appendix F of EFSA/2009/1438.

²Mean deposition factor of 0.4 according to FOCUS 2012.

³90th percentile PT determined for black redstar in vineyards (Brown et al., 2008).

No risk for birds was identified via drinking water exposure and secondary poisoning for both Dimethomorph and Dithianon following the intended uses of PRIORITY on grapevine.

- Mammals

In the Tier I risk assessment, the TERa values were greater than the Annex VI trigger of 10, indicating that PRIORITY presents no unacceptable acute risk to mammals according to the intended uses. However, the TERlt value for small herbivorous mammal "vole" in grapevine was below the trigger of 5 for both active substance. A further refinement of the long-term risk was needed. A refinement of the risk was done by refining the focal species to woodmouse. The TERlt value for this species was above the trigger showing no risk. Therefore, the acute and long-term risk to mammals after the application of PRIORITY according to the GAP is considered acceptable. In addition, no unacceptable acute and long-term risk were obtained for the wood mouse (*Apodemus sylvaticus*) in vineyard according to GAP for combined exposure.

No risk for mammals was identified via drinking water exposure and secondary poisoning for both Dimethomorph and Dithianon following the intended uses of PRIORITY on grapevine.

3.8.2 Effects on aquatic species

Regarding Dithianon, most PEC/RAC values taken from the assessment of most aquatic organisms are above the trigger value of 1 in most scenarios for grapevine, indicating that PRIORITY poses a potential risk to aquatic organisms. A further refinement and PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw}. Based on the results of the risk assessment at step 4, the following conclusions regarding buffer zones, buffer strips and nozzles reduction may be drawn.

The risk mitigation for formulation Priority as worst case covers for all scenarios and should be included in the label.

Regarding the formulated PRIORITY, after the risk assessment no unacceptable risk was obtained with the following risk mitigation measures:

- Grapevine - 50m no spray buffer zone with 90% of nozzles reduction are required.

SPe 3: Grapevine - To protect aquatic organisms respect an unsprayed buffer zone of 50 m to surface water bodies with 90% of nozzles reduction.

Grapevine

- R1 stream scenario - A 5m no-spray buffer zone with 75% of nozzles reduction OR a 10m no-spray buffer zone with 50% of nozzles reduction OR a 15m no-spray buffer zone are required.
- D3 ditch scenario - 10m no-spray buffer zone with 90% of nozzles reduction OR a 15 m no-spray buffer zone with 75 % of nozzles reduction are required or 20m no-spray buffer with 50 % of nozzles reduction (relevant for PL).
- D4 stream scenario - 10m no-spray buffer zone with 90% of nozzles reduction OR a 15 m no-spray buffer zone with 75 % of nozzles reduction are required or 20m no-spray buffer with 50 % of nozzles reduction.

3.8.3 Effects on bees

The risk assessment for bees has been done. All the hazard quotients are considerably less than 50, indicating that the active substances pose a low risk to bees. Therefore a low risk to bees is expected from the application of PRIORITY at all proposed label rates.

According to EU Reg. 284 /2009 the chronic toxicity test for adult bees, chronic test for larvae should be provided for plant protection product Priority when GD for Bees , 2013 will be applied at EU level.

3.8.4 Effects on other arthropod species other than bees

No in-field and off-field risk to non-target arthropods is expected after the application of PRIORITY according to the proposed GAP.

3.8.5 Effects on soil organisms

An application of PRIORITY in respect of the GAP should not represent an acute and long term risk to earthworm and the other soil meso/microfauna. The use of PRIORITY at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

3.8.6 Effects on non-target terrestrial plants

The risk assessment for non-target plants has been done with EU agreed endpoint and the risk to non-target plants for PRIORITY is considered to be acceptable when applied according to the proposed use rates.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant for Dithianon and Dimethomorph.

3.9 Relevance of metabolites (Part B, Section 10)

No Dithianon's metabolites are predicted to occur in groundwater at concentrations above 0.1 µg/L. Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required. There are not metabolites from Dimethomorph.

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

PRIORITY contains Dimethomorph and Dithianon which are not approved as candidates for substitution, therefore the intended GAP is not suitable for substitution and no comparative assessment was required.

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.

Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 1 Copy of the product label

Toksykologia:

Dodano UWAGA: Wchodzenie dzieci w uprawy traktowane zabronione.

Dodano frazę H317, H360F

Skreślono frazę H318, dodano H319

Dodano frazy P301+P312 I P302+P352

Skreślono Należy dodać pictogram GHS08 i oznakowanie Niebezpieczeństwo

Dodano oznakowanie Uwaga

Ekotoksykologia: wniesiono poprawny zapis dotyczący ograniczenia ryzyka dla roślin wodnych.

Sekcja pozostałości: okres karencji: 42 dni

Załącznik do decyzji MRiRW nr R - z dnia r.

Posiadacz zezwolenia:

Sharda Cropchem España S.L., Edificio Atalayas Business Center, Carril Condomina nº 3, 12th Floor, 30006 Murcia, Królestwo Hiszpanii, tel.: +34868127589, fax.: +34868127588, e-mail: eu.regn@shardaintl.com

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

Sharda Poland Sp. z o.o., ul. Bonifraterska 17, 00-203 Warszawa, tel.: +48 17 240 13 07, e-mail: eu.sales@shardaintl.com

**Przestrzegaj etykiety środka ochrony roślin
w celu ograniczenia ryzyka dla ludzi i środowiska**

PRIORITY

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

dimetomorf (związek z grupy morfolin) - **150 g /kg (15.23 %)**

ditianon (związek z grupy triazoli) – **350 g/kg (35.71 %)**

Zezwolenie MRiRW nr R - z dnia r.



Niebezpieczeństwo - Uwaga

H302	iDziała szkodliwie po połknięciu.
H317	Może powodować reakcję alergiczną skóry.
H318- H319	Powoduje poważne uszkodzenie oczu. Działa drażniąco na oczy.
H360F	Może działać szkodliwie na płodność
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia
P273	Unikać uwalniania do środowiska.
P280	Stosować rękawice ochronne, odzież ochronną/ ochronę oczu, twarzy.
P301+P312	W PRZYPADKU POŁKNIĘCIA: W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUCIE/lekarzem/
P302+P352	W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody
P305+P351+P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P310	Natychmiast skontaktować się z lekarzem, z OŚRODKIEM ZATRUCIE.
P391	Zebrać wyciek.
P501	Zawartość / pojemnik usuwać zgodnie z przepisami krajowymi.

OPIS DZIAŁANIA

PRIORITY jest fungicydem w formie granul do sporządzania zawiesiny wodnej do stosowania zapobiegawczego i interwencyjnego w zwalczaniu mączniaka winorośli.

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy sadowniczych oraz opryskiwaczy ręcznych (winorośl, ~~pomidor, obożyna~~).

ZAKRES STOSOWANIA, TEMRINY I DAWKI

Winorośl

Mączniak rzekomy winorośli

Środek zastosować od fazy wydłużania się kwiatostanów do końca fazy rozwoju owoców (BBCH 55-79).

Maksymalna dawka dla jednorazowego zastosowania: 1,5 kg/ha ~~1/ha~~ (1,39 kg / 10 000 m² opryskiwanej powierzchni ściany owoconośnej)

Zalecana ilość wody: 800-1000 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3

Odstęp pomiędzy zabiegami: co najmniej 10 dni

Zalecane opryskiwanie: średniokropliste.

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

Środek stosować przemiennie ze środkami grzybobójczymi, zawierającymi substancje czynne należące do innych grup chemicznych, o odmiennym mechanizmie działania.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem. Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Odmierzoną ilość środka wsypać do zbiornika opryskiwacza napełnionego do połowy 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 wleaniu 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

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych, w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:

- 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.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

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

Po wykonanym zabiegu umieścić w widocznych miejscach wokół pola tablice ostrzegawcze o brzmieniu: UWAGA: Dzieciom zabronione jest wejście na teren upraw poddanych działaniu środka. W czasie oprysku należy zastosować 10 m strefę ochronną od zabudowań mieszkalnych/siedlisk oraz osób postronnych

Środki ostrożności dla osób stosujących środek:

Nie jeść, nie pić ani nie palić podczas używania produktu.

Unikać wdychania rozpylonej cieczy.

Stosować rękawice ochronne/odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (*np. kalosze*) w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.

Dokładnie umyć ręce po użyciu środka.

Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

Środki ostrożności związane z ochroną środowiska naturalnego:

Zebrać wyciek.

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.

~~W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 20 m od zbiorników i cieków wodnych z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%.~~

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 50 m od zbiorników i cieków wodnych z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta:

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

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

Nie dotyczy 42 dni

Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz):

Nie dotyczy

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:

Nie dotyczy

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiających kontakt z żywnością, napojami lub paszą
- w temperaturze 0°C - 30°C.

Zabrania się wykorzystywania opróżnionych.

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.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 2 Letter of Access

No letter of Access to protected data are required.

Appendix 3 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 2.4.2, 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	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
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	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd

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 2.2.2, 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 Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 5.1.1	Małgorzata Wołoszynowska	2017	Dimethomorph 15% + Dithianon 35% WG: Method development and validation for the determination of active substances content in the formulation Study code no. BA-21/17 Institute of Industrial Organic Chemistry GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
CP 6.0-001	Hjorth, S.	2019	Biological Assessment Dossier: Dithianon 35% + Dimethomorph 15% WG (350 g/kg dithianon + 150 g/kg dimethomorph WG) – EU Central zone Sharda Cropchem España -, - Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 7.1.1	xxxxxx	2018	Dimethomorph 15% + Dithianon 35% WG: Acute Oral Toxicity Study in Rat xxxxxx., Report No. R/16776/AOR/18 GLP, Unpublished	Y	Y	Data/study report never submitted before to Poland	
KCP 7.1.2	xxxxxx	2018	Dimethomorph 15% + Dithianon 35% WG: Acute Dermal Toxicity Study in Rat xxxxxxxxx Report No. R/16777/ADR/18 GLP, Unpublished	Y	Y	Data/study report never submitted before to Poland	
KCP 7.1.4	xxxxxx	2018	Dimethomorph 15% + Dithianon 35% WG: Acute Dermal Irritation / Corrosion Study in Rabbit xxxxxx., Report No. R/16779/ADI/18 GLP, Unpublished	Y	Y	Data/study report never submitted before to Poland	
KCP 7.1.5	xxxxxx	2018	Dimethomorph 15% + Dithianon 35% WG: Acute Eye Irritation / Corrosion Study in Rabbit xxxxxx., Report No. R/16780/AEI/18 GLP, Unpublished	Y	Y	Data/study report never submitted before to Poland	
KCP 7.1.6	xxxxxx	2018	Dimethomorph 15% + Dithianon 35% WG: Skin Sensitisation Study by Guinea Pig Maximization Test (GPMT)	Y	Y	Data/study report never submitted before to Poland	

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
			xxxxxxx., Report No. R/16781/SS-GPMT/18 GLP, Unpublished				
KCP 10.2.1-01	xxxxxxx	2019	Dimethomorph 15% + Dithianon 35% WG Rainbow trout, Acute toxicity test Report No. W/82/18 xxxxxxx GLP Unpublished	Y	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 10.2.1-02	Turek, T.	2018	Dimethomorph 15% + Dithianon 35% WG <i>Daphnia magna</i> , acute immobilisation test Report No. W/84/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 10.2.1-03	Turek, T.	2018	Dimethomorph 15% + Dithianon 35% WG <i>Raphidocelis subcapitata</i> SAG 61.81 (formerly <i>Pseudokirchneriella subcapitata</i>) Growth inhibition test Report No. W/83/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 10.2.1-04	Turek, T.	2019	Dimethomorph 15% + Dithianon 35% WG <i>Lemna gibba</i> CPCC 310, Growth inhibition test Report No. W/85/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 10.3..1.1.1	Lemańska, N.	2018	Dimethomorph 15% + Dithianon 35% WG Honeybees (<i>Apis mellifera</i> L.), Acute Oral Toxicity Test Report No. B/45/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 10.3..1.1.2	Lemańska, N.	2018	Dimethomorph 15% + Dithianon 35% WG Honeybees (<i>Apis mellifera</i> L.), Acute Contact Toxicity Test Report No. B/46/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd

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 10.3.2.2-01	Lemańska, N.	2019	Unpublished An extended laboratory test for evaluating the effects of Dimethomorph 15% + Dithianon 35% WG on the predatory mite, <i>Typhlodromus pyri</i> (Sch.) Report No. B/46/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 10.3.2.2-02	Lemańska, N.	2018	Unpublished An extended laboratory test for evaluating the effects of Dimethomorph 15% + Dithianon 35% WG on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani Perez) Report No. B/47/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 10.4.1.1	Weronika, D.	2018	Unpublished Dimethomorph 15% + Dithianon 35% WG Earthworm Reproduction Test (<i>Eisenia andrei</i>) Report No. G/81/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 10.4.2.1-01	Weronika, D.	2018	Unpublished Dimethomorph 15% + Dithianon 35% WG Collembolan (<i>Folsomia candida</i>) Reproduction Test Report No. G/80/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 10.5.1	Weronika, D.	2018	Unpublished Dimethomorph 15% + Dithianon 35% WG Soil Microorganisms: Nitrogen Transformation Test Report No. G/78/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 10.5.2	Weronika, D.	2018	Unpublished Dimethomorph 15% + Dithianon 35% WG Soil Microorganisms: Carbon Transformation Test Report No. G/79/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd

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 10.6.2-01	Weronika, D.	2018	Unpublished Dimethomorph 15% + Dithianon 35% WG Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Report No. G/75/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 10.6.2-02	Weronika, D.	2018	Unpublished Dimethomorph 15% + Dithianon 35% WG Terrestrial Plant Test: Vegetative Vigour Test Report No. G/77/18 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd

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