

# **FINAL REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: SHA 6800 A**

**Product name(s): DUKES**

**Chemical active substance:**

**Dithianon, 700 g/kg**

### **Central Zone**

**Zonal Rapporteur Member State: Poland**

### **CORE ASSESSMENT**

**Applicant: Sharda Cropchem España S.L.**

**Submission date: September 2020**

**MS Finalisation date: August 2021; December 2021;**

**April 2022 May 2022; June 2022**

## Version history

When	What
August 2021	RMS finalised the dRR assessment
December 2021	Final registration report after commenting period
April 2022	Minor corrections of the final RR
May 2022	Revision with regard to consumer risk assessment
June 2022	Addendum

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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 DUKES, a water dispersible granule formulation containing 700 g/kg of dithianon, for use as a fungicide in pome fruits.

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 rely on new test and studies providing data and information specific to the formulation DITH 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 4.

### 2 Details of the authorization decision

#### 2.1 Product identity

Product code	SHA 6800 A
Product name in MS	DUKES
Authorization number	-
Function	Fungicide
Applicant	Sharda Cropchem España S.L.
Active substance(s) (incl. content)	Dithianon; 700 g/Kg
Formulation type	[WG] Water dispersible granule
Packaging	60 mL, 100 mL, 250 mL, 500 mL, 1L, 5L, 10L COEX (HDPE-EVOH) and 20L COEX (HDPE-Fluorinated), professional user
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 DUKES resulted in the decision to grant the authorization.**

### Section phys-chem:

No data gaps.

### Section analytical methods:

No data gaps.

### Efficacy section:

In Poland only apple can be accepted. For other pome crops, ex. pear – at least 1-2 selectivity/phytotoxicity trials are required. Pear can be accepted only in line to Article 51 (without any trials). However, pome fruits can be accepted in cMS (extrapolations from apple to other pome crops is possible, without additional trials).

### Toxicology section:

Classification of DUKES 70 WG : Acute Tox.4/H302; Eye Irrit. 2/H319 and Contains dithianon and 1,2-benzisothiazolin-3(2H)-one (CAS 2634-33-5). May produce an allergic reaction [EUH208]. No unacceptable risk for operators, workers and bystanders/ residents was identified when the product is used as intended. **Buffer zone – 5m**

### Ecotoxicology Section:

The risk for non-target organism is considered as acceptable for use with 12 d interval provided in the GAP.

### Metabolism and Residues section:

**No data gaps.** Use on pears is not acceptable. Acceptable use: apples

## 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, Eye Irrit. 2 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:	<b>GHS07, GHS09</b>
Signal word:	<b>Warning</b>
Hazard statement(s):	<b>H302, H319, H400, H410</b>
Precautionary statement(s):	<b>P280, P305+P351+P338, P312, P333+P313, P337+P313, P391, P501</b>
Additional labelling phrases:	<b>To avoid risks to man and the environment, comply with the instructions for use. [EUH401] Contains 1,2-benzisothiazolin-3-one (2634-33-5). May produce an allergic reaction. [EUH208]</b>

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:	
<b>EUH208</b>	Contains 1,2-benzisothiazolin-3-one (2634-33-5). May produce an allergic reaction.

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).
Spe 3	<ul style="list-style-type: none"> <li><b>Pome fruits (early application) – Spe3:</b> To protect aquatic organisms no-spray buffer zone of 15 m + 90% of nozzles reduction or no-spray buffer zone of 20 m + 75% of nozzles reduction or no-spray buffer zone of 30 m.</li> <li><b>Pome fruits (late application) – Spe3:</b> To protect aquatic organisms respect no-spray buffer zone of 5 m + 90% of nozzles reduction or no-spray buffer zone of 10 m + 75% of nozzles reduction or no-spray buffer zone of 15 m + 50% of nozzles reduction or no-spray buffer zone of 30 m.</li> </ul>

## 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	Vehicle mounted - Work wear (arms, body and legs covered) M/L and A Manual (early) - Work wear (arms, body and legs covered) M/L and A Manual (late) - Do not apply with manual equipment
Worker protection:	
280	Work wear and gloves – re-entry after 2 days or Work wear – re-entry after 7 days

-	Treated crops should not be re-entered before 15 after application.
Integrated pest management (IPM)/sustainable use:	
-	-
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	<ul style="list-style-type: none"> <li>• <b>Pome fruits (early application) – Spe3:</b> To protect aquatic organisms no-spray buffer zone of 15 m + 90% of nozzles reduction or no-spray buffer zone of 20 m + 75% of nozzles reduction or no-spray buffer zone of 30 m.</li> <li>• <b>Pome fruits (late application) – Spe3:</b> To protect aquatic organisms respect no-spray buffer zone of 5 m + 90% of nozzles reduction or no-spray buffer zone of 10 m + 75% of nozzles reduction or no-spray buffer zone of 15 m + 50% of nozzles reduction or no-spray buffer zone of 30 m.</li> </ul>
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)

GAP rev. 0, date: 2020-August-17th

PPP (product name/code): Dithianon 70% WG  
Active substance 1: Dithianon  
Active substance 2: -  
Safener: -  
Synergist: -  
Applicant: SHARDA EUROPE bvba  
Zone(s): CEU  
Verified by MS: yes/no

Formulation type: WG (Water dispersible granules)  
Conc. of as 1: 700 g/L  
Conc. of as 2: -  
Conc. of safener: -  
Conc. of synergist: -  
Professional use: ☒  
Non professional use: ☐

Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>
					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	Pome fruits Apple	F	Scab ( <i>Venturia sp.</i> )	Foliar Spray	BBCH 51 - 79	a) 4 b) 4	7-12	a) 0.50 b) 2.0	a) 0.35 b) 1.4	1000- 1500	21	Preventive treatment  <b>Efficacy section:</b> in Poland only, apple can be accepted. Pear can be accepted in line to Article 51.  <b>Ecotox Section:</b>  Only application with 12 days interval is considered acceptable.  B7: use on pears is not acceptable. Acute risk for consumers
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3													
4													
Minor uses according to Article 51 (zonal uses)													
5													
6													
Minor uses according to Article 51 (interzonal uses)													
7													
8													

**Remarks table heading:**

(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

(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.

<b>Remarks columns:</b>	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

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

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of brown solid granules, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable and is not self-ignition. In aqueous solution, it has a pH value around 4.5. 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 *HDPE* container. Its technical characteristics are acceptable for a water dispersible granules formulation.

The intended concentration of use is 0.33 to 0.5 g/l.

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

Dithianon 70% WG is a preventive contact fungicide for use on pome fruits, almond. Dithianon is a Water Dispersible granular (WG) formulation, containing 700 grams per kilogram (g/kg) dithianon.

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

- 4 applications in pome fruits to control scab, target rate: 0.50 kg/ha per application; max 2.0 kg/ha per season.

This document serves the registration of DITHIANON 70% WG in the Centre zone of the EU. The objective is to prove and support the label claims of the efficacy and crop safety of DITHIANON 70% WG in pome fruits, almond as claimed in the GAP table.

Comprehensive field trials were conducted in the North-east EPPO (Poland, Latvia, Lithuania), the Maritime (Germany, N-France), the South-east (Hungary, Romania) and the Mediterranean (Italy, Greece, Portugal, S-France and Spain) zones in 2015 and 2016. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

The data demonstrate that the control and safety to the crop of DITHIANON 70% WG is comparable to that of the dithianon reference products registered in the EU central zone, and the applicant therefore wishes to cite the original registrant's data on dithianon 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 Efficacy data**

#### **Preliminary tests**

The activity of dithianon is well known, as it has been marketed since 1960s as a broad-spectrum fungicide on a wide range of crops. Based on the knowledge about the active substance (+50 years) and the experiences with using the product 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.

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

DITHIANON 70% WG was tested in the efficacy trials at a range of dose rates. The purpose of ‘‘Minimum effective dose tests’’ is to demonstrate the dose response of DITHIANON 70% WG against *Venturia* sp. on pome fruits and almond.

#### **Control of *Venturia inaequalis* in apple:**

In order to prove and to support the requested dose rate of 0.75 Kg/ha DITHIANON 70% WG [525 dithianon per hectare] for the control of *Venturia inaequalis* in apple, the assessment results of 23 efficacy trials performed in the North East (6), the Maritime (3), the South-east (4) and the Mediterranean (10) EPPO zone in 2015 and 2016 are reported. DITHIANON 70% WG was included in these trials at 0.75 Kg/ha to demonstrate the recommended dose rate as well as at lower dose rates (0.375 and 0.5 Kg/ha). As the most accurate representation of whole plot product performance, the assessment data, obtained by pest incidence and pest severity control obtained by the applied products are summarized and presented.

Based on results achieved in 23 trials, it can be concluded that the recommended dose rate of 0.75 Kg/ha DITHIANON 70% WG applied is required for consistent control of the label claimed *Venturia inaequalis* in apple.

**Conclusion:** DITHIANON 70% WG applied at 0.5 Kg/ha to control *Venturia* achieved moderate to excellent control of all target diseases. Twelve applications on apple at the recommended rates should be used to efficiently control all diseases claimed on the label.

23 trials from different EPPO zones against the key target *Venturia inaequalis* on apple were presented and are deemed to be sufficient to extrapolate data for the claimed uses on the whole disease group scab (*Venturia* sp.) on Pome fruits and Almond.

This document clearly demonstrates that the efficacy and crop safety of DITHIANON 70% WG is equivalent to that of the standard reference product to which it was compared. The applicant therefore wishes to cite the original registrant’s data on dithianon 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.

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

All details about efficacy methodology used during efficacy trials are presented above by Applicant in BAD. The reports include a detailed data on soil and field conditions, agro-technological procedures, fore-crop as well as meteorological conditions and technical details of the spraying etc.

Submitted efficacy trials are correctly performed according to appropriate EPPO standards. Applicant submitted in total 23 field trials showing the results in research into product efficacy carried out on apples. Those efficacy trials were performed in North-East EPPO zone (PL, LT, LV), Maritime (FR, DE), MED (ES, GR, IT, PT, FR) and S-E (RO, HU).

The following efficacy scale was used:

- L – limiting (0-60% efficacy)
- ME – moderately efficiency (60-80%)
- E – efficiently (>80%)

We are dealing with the active substance used commonly for many years in many countries. We must emphasize that each pest should be representative by sufficient number of field efficacy tests (at least 6 for major pest and at least 3 for minor pest).

Applicant submitted trials carried out in two growing seasons (2015 and 2016), which is in line with EPPO standard. Studies were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially

GEP recognized.

The number of trials is not sufficient in some cases and do not fulfil EPPO requirements:

- **apple:** Maritime: 3 trials (DE-1, FR-2); MED: 10 trials (ES-2, GR-2, IT-2, FR-2, PT-2), S-E: 4 trials (RO-2, HU-2); N-E: 6 trials (PL-2, LT-1, LV-3). In all trials the level of PESINC was acceptable.

For N-E and MED EPPO zone Applicant submitted enough number of trials. CMS from S-E and MAR should decide if submitted number of trials can be acceptable, in view of the importance of SCAB and apples and any national extrapolations.

In MAR different number of applications were studied: in DE – DUKES was applied in 12 applications and in FR– during 5 applications. However, observations and assessments were done after each application. So, in the opinion of Evaluator up to 4 application per season can be accepted.

In MED different number of applications were studied: in FR – DUKES was applied in 6 applications (1 trial) and 5 applications (1 trial); in PT – DUKES was applied 9 times per season and in IT, GR, ES – 12 applications per season. However, observations and assessments were done after each application. So, in the opinion of Evaluator up to 4 application per season can be accepted.

In S-E different number of applications were studied: in RO – DUKES was applied in 9 applications and in HU – 8 times per season (1 trial) and 6 times per season (1 trial). However, observations and assessments were done after each application. So, in the opinion of Evaluator up to 4 application per season can be accepted.

In N-E different number of applications were studied: in PL – DUKES was applied in 12 applications and in LV and LT – 10 times per season. However, observations and assessments were done after each application. So, in the opinion of Evaluator up to 4 application per season can be accepted.

Application window of BBCH 51-79 can be accepted on the basis on submitted documentation. Following BBCH were studied: MED – BBCH 69-89, MAR – BBCH 69-89; S-E – BBCH 64-89 and N-E – BBCH 50-85.

DUKES (product code: SHA 6800 A) applied in apples provided a moderate level control of SCAB with the recommended dose rate of 0,5 kg/ha. Up to 4 applications per season of DUKES at the proposed dose rate should be used to efficiently control the disease claimed on the label.

#### **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. From efficacy's point of view, the reference to ha ground area is not sufficient any more (EPPO PP 1/239). Therefore, the Applicant should calculate the LWA for DUKES (product code: SHA 6800 A), 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 l/ha LWA for apples:**

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 treated foliage height.

#### **Calculation of LWA:**

$$\text{Leaf Wall Area (LWA)} = \frac{2 \times \text{tree height [m]}}{\text{Distance between rows [m]}} \times 10\,000 \text{ m}^2/\text{ha}$$

**Below LWA is calculated for each report: some** results can differ to those calculated by Applicant whose use different model

EPPO zone	Spacing row (m)	Height plants (m)	LWA	Calculated dose (l/10000 m <sup>2</sup> LWA)
MAR (DE)	4 x 1,6	3,5	17500	0,29
MAR (FR)	4 x 1,0	2,5	12500	0,40
MAR (FR)	3,8 x 1,0	2,5	13158	0,38
S-E (RO)	4 x 2,0	2 -2,4	10000-12000	0,42 – 0,50
S-E (RO)	4 x 3,0	2,2-2,5	11000-12500	0,40-0,45
S-E (HU)	2 x 4,0	2,1	21000	0,24
S-E (HU)	5 x 4,0	2,5 – 2,6	12500-13000	0,38—0,40
N-E (PL)	3,9 x 3,0	3,2	16410	0,30
N-E (PL)	4,0 x 2,2	3,3	16500	0,30
N-E (LV)	4,0 x 1,7	2,7-3,0	13500-15000	0,33-0,37
N-E (LV)	3,9 x 2,0	2,3-3,2	11795-16410	0,28-0,42
N-E (LV)	4,0 x 1,5	2,7-3,6	13500-18000	0,28-0,37
N-E (LT)	4,0 x 2,0	2,5-3,0	12500-15000	0,33-0,40
MED (ES)	4,5 x 1,5	3,5	15555	0,32
MED (ES)	6,0 x 6,0	3,5	11667	0,43
MED (FR)	4,0 x 2,0	1,9	9500	0,53
MED (FR)	4,3 x 1,3	3,54-3,7	16465-17209	0,29-0,30
MED (GR)	3,5 x 2,0	2,5	14285	0,35
MED (GR)	4,0 x 3,0	2,8	14000	0,36
MED (IT)	4,0 x 2,0	3,0	15000	0,33
MED (IT)	4,0 x 2,0	3,0	15000	0,33
MED (PT)	2,0 x 5,0	2,2	22000	0,23
MED (PT)	2,0 x 5,0	2,4-2,5	24000-25000	0,20-0,21

- **Maritime EPPO zone:**

Range of LWA vary between 12500 and 17500 (average: 14386), what indicates that the ratio to calculate application per LWA should be for 0,35 kg/ha LWA, which corresponds to dose 0,5 kg/ha per ground

- **North-East EPPO zone:**

Range of LWA vary between 11795 and 18000 (average: 14862), what indicates that the ratio to calculate application per LWA should be for 0,34 kg/ha LWA, which corresponds to dose 0,5 kg/ha per ground.

- **South- East EPPO zone:**

Range of LWA vary between 10000 and 21000 (average: 13143), what indicates that the ratio to calculate application per LWA should be for 0,38 kg/ha LWA, which corresponds to dose 0,5 kg/ha per ground.

- **MED EPPO zone:**

Range of LWA vary between 9500 and 25000 (average: 16640), what indicates that the ratio to calculate application per LWA should be for 0,30 kg/ha LWA, which corresponds to dose 0,5 kg/ha per ground.

The final decision to accept this approach and to accept the data is left to cMS. The dose of LWA depends to a large extent on the height of the seedlings, therefore it should be individualized by each cMS based on the average height of crops, row spacing, etc. The field tests presented by the Applicant are characterized by very different testing conditions, e.g. height or row spacing which directly translates into the proposed dose of LWA. Therefore, as ZRMs we present only the obtained results, and we expect their detailed interpretation by each cMS, accordingly to agro-climatic conditions and average LWA of apple crops.

The applicant wishes to cite the original registrant's data on dithianom now out of protection in support of those recommendations on the draft label that are not adequately supported. However, such extrapolations should be considered by individual member states on a national level based on current registration, data protection and experience with similar dithianom products.

In Poland only use on apple can be accepted. For other pome fruits, ex. pear – at least 1-2 selectivity/phytotoxicity trials are required. Without any trials, pear in Poland can be accepted according to Article 51.

In the opinion of Evaluator, in cMS pome fruits can be accepted (extrapolations from apple to other pome crops is possible, without additional trials).

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

Resistance is a natural phenomenon embodied in the process of the evolution of biological systems and has been experienced over and over again in the past. The fungicide-resistant population develops because the sensitive population is suppressed and the rare fungicide-resistant individual is allowed to multiply and occupy the biological niche previously filled by the sensitive population. An increase in the frequency of such resistant strains may result in loss of disease control. As a general principle, resistance develops at different rates depending on the pathogen type, nature of the epidemic (or disease severity) and use pattern of the fungicide.

The risk of resistance was analyzed following the EPPO-Standard (2003<sup>1</sup>) and the classification of the Fungicide Resistance Action Committee (FRAC)<sup>2</sup>. So far, no cases of resistance have been reported to Dithianon, despite the long use. The active substance is therefore classified as having a low inherent risk.

The evaluation of the combined fungicide/pathogen/agronomic risk, comes to the conclusion, that DITHIANON 70% WG bears a low to medium risk of resistance.

The Registration of DITHIANON 70% WG is endorsed.

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

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

No specific selectivity trials were conducted. As DITHIANON 70% WG is a fungicide, no specific studies are required as long as in the efficacy trials no negative effects are observed. Phytotoxicity was assessed in 23 efficacy trials, which were conducted in North-east (6) i.e. Poland (2), Latvia (3) and Lithuania (1), the Maritime, i.e. N-France (2), Germany (1), the South-east, i.e. Hungary (2) and Romania (2) and the Mediterranean, i.e. Italy (2), Greece (2), S-France (2), Spain (2), Portugal (2) EPPO zones in 2015 and 2016.

DITHIANON 70% WG applied at the recommended dose rate did not cause phytotoxicity in 23 trial conducted on apple. In one trial on apple, variety Berthanne slight symptoms of phytotoxicity were observed but were transient and quickly disappeared. It is therefore considered safe to apply DITHIANON 70% WG in the GAP claimed crops at the recommended dose rate.

As this document also clearly demonstrates, then the efficacy and crop safety of DITHIANON 70% WG is equivalent to the standard products to which it was compared. Therefore, the applicant wishes to cite the original registrant's data on dithianon now out of protection in additional support of any 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**

Based on the favourable phytotoxicity situation, no negative effects on the yield of plants are expected. The control of diseases claimed on GAP is expected to positively impact the quality of plants and plant products and the yield of treated crops.

As this document clearly demonstrates, the efficacy and crop safety of DITHIANON 70% WG is equivalent to the standard products to which it was compared. The applicant therefore wishes to cite the original

<sup>1</sup> EPPO 2003: Standard PP 1/213 (2): Resistance risk analysis.

<sup>2</sup> FRAC: <http://www.frac.info/>.



registrant's data on dithianon 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.

### **Effect on transformation processes**

No processing has been conducted. There are no indications that the use of DITHIANON 70% WG will have influence on possible transformation processes. It is therefore expected that application of DITHIANON 70% WG, when applied in accordance with good agricultural practices, including label recommendations, will not cause any unacceptable adverse effects on transformation processes.

For further information on residues, please refer to Metabolism and residues.

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

Special tests to investigate this purpose are not required.

DITHIANON 70% WG is a fungicide without herbicidal activity. According to EPPO PP 1/135(4), no data are normally required for non-systemic fungicide such as Dithianon 70% WG. In addition, no phytotoxic or other adverse effects were recorded at the recommended rates on several crops targeted for this registration during efficacy trials reported in this document.

### **3.3.3 Observations on other undesirable or unintended side-effects**

#### **Impact on succeeding crops.**

Not relevant.

Pome fruits and almond are permanent crops. No significant residue levels are to be expected in rotational crops following application of DITHIANON 70% WG according to the proposed GAP.

No label restrictions on succeeding crops following application of DITHIANON 70% WG are proposed, in accordance with current labelling of existing dithianon containing products.

#### **Impact on other plants including adjacent crops**

Dithianon is not phytotoxic and has a very low vapour pressure, therefore volatilization from soil or water is not expected to be significant.

#### **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 and crop safety trials conducted.

### **3.4 Methods of analysis (Part B, Section 5)**

#### **3.4.1 Analytical method for the formulation**

An analytical method for the determination of Dithianon in DUKES has been developed and sufficiently validated. Dithianon content in the preparation DUKES is determined by using reversed phase HPLC-UV using UV detection at 225 nm and external standardization.

According to the SANCO/3030/99 rev.4 guidance document, the analytical method for the determination of Dithianon in DITH was validated.

	<b>Dithianon</b>
<b>Author, year</b>	Jose Angel Escudero, 2016
<b>Principle of method</b>	Reverse phase HPLC using UV detection at 225 nm
<b>Linearity</b> (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	Linear between 20.2 and 404.0 mg/l R = 0.99992
<b>Precision – Repeatability Mean</b> <b>n = 5</b> (%RSD)	%RSD= 0.5 and is lower than %RSD based on the Horwitz equation (1.41%).
<b>Accuracy</b> <b>n = 3</b> (% Recovery)	99.9 ± 0.6 %
<b>Interference/ Specificity</b>	There are no interference from other substance present in the formulation. Representative chromatograms are provided.
<b>Comment</b>	-

### 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:

- ILV method for drinking water. Method should be provided at renewal of the product.
- Statement on the extraction efficiency of methods for determining residues in plant matrices should be provided at renewal of the product.

<b>Commodity/crop</b>	<b>Supported/ Not supported</b>
Pome fruits	<b>Supported</b>

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

The assessment of all acute toxicological properties of DUKES are derived from the classification of the active compound and co-formulants. When considering the properties of all co-formulants and toxicity study DUKES is classified as Acute Tox. 4, Eye Irrit. 2 Therefore the Signal Word “Warning” and the Hazard Statement “H302: Harmful by swallow” “H319: Causes serious eye irritation are proposed and Contains dithianon and 1,2-benzisothiazolin-3(2H)-one (CAS 2634-33-5). May produce an allergic reaction [EUH208].

### 3.5.1 Operator exposure

Operator exposure to DUKES was not evaluated as part of the EU review of dithianon. Therefore all relevant data and risk assessments are provided here and are considered adequate.

Estimations of potential operator exposure have been undertaken for dithianon using the AOEM model.

According to the AOEM model calculations, it can be concluded that:

The risk for the operator using vehicle-mounted application equipment is acceptable when work wear M/L and A + gloves M/L and A.

The risk for the operator using vehicle-mounted application equipment is acceptable even not considering the use of PPE.

The risk for the operator using manual application equipment is acceptable for early season (without leaves) but is not acceptable for late season (dense foliage) even considering the use of PPE.

#### Implication for labelling:

Do not apply to pome fruits and almond with manual equipment for late season (dense foliage).

### 3.5.2 Worker exposure

Worker exposure to DUKES was not evaluated as part of the EU review of dithianon.

Calculations were made using the standard dermal absorption value and the AOEM 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 pome fruits treated with DUKES a time period of 2 days after application is respected or without gloves when a time period of 7 days after application is respected. 7 days is below PHI and therefore is acceptable.

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 pome fruits treated with DUKES a time period of 7 days after application is respected or without gloves when a time period of 12 days after application is respected. 7 days is below PHI and therefore is acceptable.

### 3.5.3 Bystander and resident exposure

Bystander and resident exposure to DUKES was not evaluated as part of the EU review of dithianon.

Calculations were made using the default dermal absorption values and the AOEM.

Calculations show that there is no risk for bystanders and resident after accidental short-term exposure to DUKES.

**Buffer zone: 5 (m)**

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

The preparation SHA 6800 A is composed of DITH

Toxicological reference values for the dietary risk assessment of dithianon.

Reference value	Source	Year	Value	Study relied upon	Safety factor
ADI	11/41/EU		0.01	long-term rat study	100
ARfD			0.12	7-day and 28-day oral rat studies (mechanistic studies)	100

#### 3.6.1 Residues

##### Storage stability

According to the EU agreed data (EFSA, 2011 and 2015) the available stability of residues data can cover the uses on pome fruits (matrix with high water content). This data were confirmed in EFSA Journal 2020;18(9):6189.

EFSA Journal 2020;18(9):6189: *The submitted data demonstrated stability of dithianon residues under frozen conditions in apples for up to 24 months.*

No additional information is required.

##### Metabolism in plants and animals

The metabolism of dithianon has been investigated in fruit crops (apple and orange), leafy vegetables (spinach) and cereals (wheat).

Plant residue definition for monitoring and risk assessment: Dithianon (open for processed commodities – data gap (EFSA, 2015, EFSA Journal 2020;18(9):6189)

This data gap can be completed only at the stage of evaluating an active substance.

##### Magnitude of residues in plants

Proposed GAP:

4 x 0.35 kg as/ha, interval: 7-12 days, BBCH 51 – 79, PHI: 21.

EU GAP (EFSA Journal 2020;18(9):6189, SANCO/10349/2011 final 11 March 2011)

1-12 x 0.525 kg as/ha, interval: 7-12 days, BBCH 10 – 79, PHI: 21.

Proposed GAP is less critical than EU GAP (application rate).

Applicant refers to the unprotected EU data\*::

RMS, 2006 Apple	N-EU	GAP on which EU a.s. assessment is based: 12 x 0.525 kg as/ha, PHI 21-22d, outdoor <del>&lt;0.03, &lt;0.05</del> , 0.36, <del>0.38</del> , 2 x 0.48, 0.62, 0.76, <del>1.03</del> , 1.5, 1.7, 1.89 mg/kg
RMS, 2006 Pear	N-EU	GAP on which EU a.s. assessment is based: 12 x 0.525 kg as/ha, PHI 21-22d, outdoor 0.19, 0.37, 0.39, <del>0.69</del> 0.87 mg/kg

\* Conclusion on the peer review of the pesticide risk assessment of the active substance dithianon. EFSA Journal 2010;8(11):1904

Updated peer review of the pesticide risk assessment for the active substance dithianon in light of confirmatory data submitted. EFSA Journal 2020;18(9):6189

Overall supporting data for cGAP (NEU): 0.19, 0.36, 0.37, 0.39, 2x0.48, 0.62, 0.76, 0.87, 1.5, 1.7, 1.89

STMR 0.55 (NEU); HR 1.89 (NEU)

According to the SANTE/2019/12752 extrapolation from apples to pears is possible.

The residues arising from the proposed uses will not exceed the MRLs established for apples and pears (3.0 mg/kg, Regulation (EC) No 839/2008).

Available data can cover the proposed use.

##### Magnitude of residues in livestock

EFSA Journal 2020;18(9):6189:

Ruminant:

No cow feeding study conducted - metabolism results indicate that the residues will be far below the LOQ (milk, tissues 0.01 mg/kg)

Poultry:

No hen feeding study conducted - metabolism results indicate that the residues will be far below the LOQ (eggs, tissues: 0.01 mg/kg)

Pig

No hen feeding study conducted – metabolism in rat and ruminant similar, residues will be below 0.01 mg/kg (LOQ).

No additional studies or calculations are required.

Note

according to the *Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009, (2019/C 229/01)\** above data are not protected.

\* *Official Journal of the European Union, C 229, 8 July 2019*

### Processing studies

Applicant refer's to the unprotected EU studies

According to the EFSA Journal 2020;18(9):6189:

*Dithianon was the predominant compound of the total applied radioactivity (TAR) for pasteurisation (up to 47.3% TAR) while it was extensively degraded at baking/brewing/boiling and sterilisation into Reg. No 4107273 (up to 12.7 % TAR), Reg. No 4110904 (up to 9.4% TAR), Reg. No 31062 (up to 10.5% TAR) and to a lesser extension to Reg. No 4005234 (Phthalic acid) and Reg. No 4110933 (up to 2.2% and 4.1% TAR, respectively).*

*Data gap: The general toxicity of metabolites Reg. No. 4107273 and Reg. No. 4005234 (Phthalic acid) recovered at significant levels in apples and grapes processed commodities is required.*

This data gap can be completed only at the stage of evaluating an active substance.

According to the *Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009, (2019/C 229/01)\** above data are not protected.

\* *Official Journal of the European Union, C 229, 8 July 2019*

Processing factors were established for apples

Apple/washed apples, 10 trials, transfer factors: 0.23–1.8

Apple/juice, 13 trials , transfer factors: 0.0045–0.1

Apple/wet pomace, 13 trials , transfer factors: 0.49–3.5

Apple/dry pomace, 9 trials , transfer factors: 0.43–1.35

Apple/sauce 11 trials , transfer factors: 0.006–0.125

Apple/dried apples, 5 trials , transfer factors: 0.029, 2.18

Apple/canned apples, 7 trials, transfer factors: 0.033–0.125

### Magnitude of residues in representative succeeding crops

No new data submitted in the framework of this application. Since the intended uses on pome fruits concern permanent crops, further investigation of residues in rotational crops is therefore not required..

No risk mitigation measure are considered necessary.

## 3.6.2 Consumer exposure

### Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	585 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	84 % (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities Results for children 346.23% Pears 269.46% Apples Results for adults 76.36% Pears

	<p>70.18% Apples</p> <p>Processed commodities</p> <p>Results for children</p> <p>135.4% Apples / juice</p> <p>81.5% Pears / juice</p> <p>Results for adults</p> <p>83.3% Apples / juice</p>
<p>IESTI (% ARfD) according to EFSA PRIMo*</p>	<p>Unprocessed commodities</p> <p>Results for children</p> <p>96.46% Apples</p> <p>54.51% Pears</p> <p>Results for adults</p> <p>29.03% Apples</p> <p>14.93% Pears</p> <p>Processed commodities</p> <p>Results for children</p> <p>28.0% Apples / juice</p> <p>10.6% Pears / juice</p> <p>Results for adults</p> <p>17.2% Apples / juice</p>

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

Acute risk for children was identified in relation to pears. Use on apples is acceptable

Input Values for pome fruits: STMR 0.55 (NEU); HR 1.89 (NEU); VF: 3.8

<p>IEDI (% ADI) according to EFSA PRIMo rev.3.1</p>	<p>83 % (based on NL toddler)</p>
<p>IESTI (% ARfD) according to EFSA PRIMo rev.3.1</p>	<p>Unprocessed commodities</p> <p>Results for children</p> <p><b>118% Pears</b></p> <p>96% Apples</p> <p>Results for adults</p> <p>32% Pears</p> <p>29% Apples</p> <p>Processed commodities</p> <p>Results for children</p> <p>25% Apples / juice</p> <p>15% Pears / juice</p> <p>Results for adults</p> <p>15% Apples / juice</p>

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

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

PEC soil calculations were realised following the ESCAPE model for pome fruits. Maximal concentration for Dithianon and Phthalic acid in soil was calculated to 0.622 and 0.017 mg/kg respectively for 4 applications in pome fruits.

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

PEC<sub>gw</sub> calculation were realised following the FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models for all calculations. In all scenarios, the content in Dithianon and Phthalic acid has not exceeded the threshold value of 0.1 µg/L.

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

The PEC<sub>sw/sed</sub> of DITH has been assessed with the models FOCUS STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5, SWAN 5.0.0, the DT<sub>50</sub> and the soil sorption values established in the EU review for Dithianon and its metabolites.

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

Not relevant, no PEC<sub>air</sub> calculation were submitted.

## 3.8 Ecotoxicology (Part B, Section 9)

According to the risk assessment for Dukes the following risk mitigation measure should be considered:

- **Pome fruits (early application) – Spe3:** To protect aquatic organisms respect no-spray buffer zone of 15 m + 90% of nozzles reduction or no-spray buffer zone of 20 m + 75% of nozzles reduction or no-spray buffer zone of 30 m.
- **Pome fruits (late application) – Spe3:** To protect aquatic organisms respect no-spray buffer zone of 5 m + 90% of nozzles reduction or no-spray buffer zone of 10 m + 75% of nozzles reduction or no-spray buffer zone of 15 m + 50% of nozzles reduction or no-spray buffer zone of 30 m.

### 3.8.1 Effects on terrestrial vertebrates

#### Birds

In the Tier I risk assessment the TER<sub>It</sub> value for small insectivorous bird “tit” in pome fruits is 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 focal species, PD, PT, FIR/bw and the TER values were above the trigger showing no risk. Therefore, the long-term risk to birds after the application of Dukes according to the GAP is considered acceptable.

No risk from drinking water neither due to secondary poisoning is expected.

#### Mammals

In the Tier I risk assessment the TER<sub>It</sub> value for all focal species except the small herbivorous mammal “vole” and frugivorous mammal “dormouse” in pome fruits, are above the trigger of 5 for Dithianon. A further refinement of the long-term risk for these species is needed. A refinement of the risk was done by refining the focal species, PD, FIR/bw, RUD, DF, MAF and ftwa, and the TER value was above the trigger of 5 for “dormouse” and focal species bank “vole”. In addition, a refinement of focal species based on studies from Monograph has been included by the Applicant.

After the refinement, unacceptable long-term risk is expected for vole. Nevertheless, a weight of evidence approach based on Monograph of Dithianon is proposed below:

According to the *Additional Report to the DAR-January 2010*:

*The vole has been identified by SANCO/4145/2000 as the small herbivorous indicator species feeding in different grass-like crop types, because of its strong preference for grassland habitats. Typical central European orchards have ground vegetation cover between the tree rows. Hence, typical central European orchards can also be interpreted somehow as grassland habitats.*

*In Central Europe the most frequent vole species in agricultural land, particularly in grassland habitats, is the common vole (*Microtus arvalis*; Niethammer & Krapp 1982<sup>3</sup>). The population densities vary seasonally as well as annually. The common vole is well known to show characteristic population cycles with years of mass occurrences (gradation), in which densities may reach up to more than 3000 individuals per hectare (e.g. Truszkowski 1982<sup>4</sup>). In Central Europe mass occurrences of common voles take place every 2-4 years and are generally followed by a population break-down, the so-called latency phase (e.g. Heise & Stubbe 1987<sup>5</sup>, Niethammer & Krapp 1982<sup>3</sup>).*

*For the common vole primary habitats are open, dry, grassy and largely undisturbed areas such as permanent grassland or set-aside (Niethammer & Krapp 1982<sup>3</sup>, Lauenstein 1979<sup>6</sup>; Dieterlen 2005<sup>7</sup>). These primary habitats are permanent habitation and retreat for common voles even in latency phase. However, the species also occurs in secondary habitats (sub-optimal habitats) like intensively managed agricultural landscape (including orchards), areas with high groundwater or occasional flooding and hedgerows (Niethammer & Krapp 1982<sup>3</sup>, Lauenstein 1979<sup>6</sup>; Dieterlen 2005<sup>7</sup>). If the conditions are favorable, secondary habitats are colonized with increasing population density especially in mass occurrence (gradation) years. While regular extinction occurs in secondary habitats, prime habitats harbour permanent vole populations and hence are essential strongholds (source habitats) for the survival of common vole populations.*

*Orchards are intensively managed crops, in particular during the reproduction season of voles in spring and summer. Besides the use of pesticides particularly mechanical husbandry activities such as mowing, mulching and pruning take place. Despite the fact that common voles are capable of enormous population increases and thus are able to rapidly colonize new habitats, populations of this species are more sensitive to disturbances (Adamczewska-Andrzejewska 1981<sup>8</sup>) compared to other small mammal species, not least due to their small home ranges (Jacob & Hempel 2003<sup>9</sup>) and ultradian rhythm with short-term polyphasic activity patterns (i.e. diurnal and nocturnal activity; Halle 2000<sup>10</sup>).*

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<sup>3</sup> Niethammer, J. & F. Krapp (1982). *Microtus arvalis* (Pallas, 1779) – Feldmaus; pp 285-318 in J. Niethammer & F. Krapp (eds) *Handbuch der Säugetiere Europas*. Aula-Verlag, Wiesbaden

<sup>4</sup> Truszkowski, J. (1982). The impact of common vole on the vegetation of agroecosystems. *Acta Theriologica* 27(23): 105-106

<sup>5</sup> Heise, S. & Stubbe, M. (1987). Populationsoekologische Untersuchungen zum Massenwechsel der Feldmaus *Microtus arvalis* (Pallas, 1778). *Säugetierkundliche Informationen* 11(2): 403-414

<sup>6</sup> Lauenstein, G. (1979). Zur Problematik der Bekämpfung von Feldmäusen (*Microtus arvalis* (Pall.)) auf Grünland. *Zeitschrift für angewandte Zoologie* 66: 35-59

<sup>7</sup> Dieterlen, F. (2005). Feldmaus *Microtus arvalis* (Pallas, 1778) pp 297-311 in M. Braun & F. Dieterlen (eds) *Die Säugetiere Baden-Württembergs*. Ulmer, Stuttgart

<sup>8</sup> Adamczewska-Andrzejewska, K. A. (1981). Population structure of *Microtus arvalis* (Pall.) against the background of a community of rodents in crop fields. *Polish Ecological Studies* 7(2): 193-211

<sup>9</sup> Jacob, J. & Hempel, N. (2003). Effects of farming practices on spatial behaviour of common voles. *Journal of Ethology* 21: 45-50

<sup>10</sup> Halle, S. (2000). Voles – small graminivores with polyphasic patterns. In: *Activity patterns in small mammals. An ecological approach*. (Ed.: Halle, S. & Stenseth, N.C.). Pp. 191-215. Springer-Verlag, Berlin, Heidelberg, New York.



Mowing as typical cultural practice in commercial orchards is known to reduce the attractiveness of orchard habitats for voles substantially (Jaworska 1996<sup>11</sup>, Sullivan & Hogue 1987<sup>12</sup>). Regular disturbances and lower/lack of vegetation cover (also by herbicidal weeding) lead to vole population decline predominantly through increased exposure to predation through both diurnal and nocturnal predators. In conventional silage grassland, frequent mowing was even followed by 'crashes' in common vole numbers (Jacob & Halle 2001<sup>13</sup>) which was largely due to an increased predation risk through birds of prey, owls and mammalian predators. Likewise, Edge et al. (1995)<sup>14</sup> found populations of grey-tailed voles (*Microtus canicaudus*) reduced by 50 % after mowing. Hence, the ground vegetation height seems to be a central point for spatial common vole population dynamics and is considered to be a main factor determining the habitat quality. Therefore, intensively managed orchards by mowing, mulching and herbicidal weeding pose adverse habitat conditions for the common vole and are therefore considered only as secondary habitats for this species (Lauenstein 1979<sup>15</sup>, Dieterlen 2005<sup>7</sup>).

Besides the colonization behavior of primary and secondary habitat of common voles, hints for a possible source - sink model (Pulliam 1988<sup>15</sup>, Dias 1996<sup>16</sup>, Tattersall et al. 2004<sup>17</sup>) were found in a study conducted on voles in old field and orchards habitats in Canada. According to this model animals from "source" populations, which produce surplus individuals (birth rates are higher than mortality rates), migrate to "sink" populations, which can not sustain themselves alone (birth rate are lower than mortality rates). On the long term "sink" populations can not survive without the regularly introduction of animals from "source" populations. In the study of Sullivan et al. (2003)<sup>18</sup>, orchard populations might represent "sink" populations, which are supplied by animals from primary habitats. A four year study on the montane vole (*Microtus montanus*) was conducted in two orchard habitats and 'old fields'. The orchards were mowed 5-6 times in each summer. The 'old field' habitats were abandoned ( \_ 25 years) hay fields. The study showed that population dynamics in orchards followed the population dynamic of voles in 'old fields', but at a significant lower level. Mean body mass of voles was consistently higher in old field than orchard sites. The mean survival of voles tended to decline through time in orchard sites. Therefore, the orchards seemed to be linked to source area dynamics of populations in old fields 10.

Orchards are mulched regularly during the vegetation season in contrast to primary vole habitats like setasides. Regular mulching reduces the vegetation height which increases the predation risk. Therefore orchards are secondary habitats which will be colonized only in high density years.

In zRMS opinion based on WoE approach for vole species presented above and TER<sub>LT</sub> value of 4.25 for application with 12 d interval the risk is considered as acceptable taking into account that DT 50 is below default value of 10 ( being 8.35 d , 90<sup>th</sup> percentile and 6.48 d mean value).

#### Refinement of the long-term risk for vole.

Indicator/generic focal species	Typ of food	FIR/bw	RUD <sub>mean</sub>	DF*	PD	SV <sub>m</sub>
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<sup>11</sup> Jaworska, K. (1996). The cover of herbaceous plants in an IPM apple orchard and its influence on the occurrence of rodents. *Acta Horticulturae* 422: 431-432

<sup>12</sup> Sullivan, T. P. & Hogue, E. J. (1987). Influence of orchard floor management on vole and pocket gopher populations and damage in apple orchards. *J. Am. Soc. Hort. Sci.* 112: 972-977

<sup>13</sup> Jacob, J., & S. Halle (2001). The importance of land management for population parameters and spatial behaviour in common voles (*Microtus arvalis*); pp 319-330 in H.-J. Pelz & C.J. Feare (eds) *Advances in Vertebrate Pest Management*. Filander-Verlag, Fürth

<sup>14</sup> Edge, W. D., Wolff, G. O. & Carey, R. L. (1995). Density-dependent responses of grey-tailed voles to mowing. *Journal of Wildlife Management* 59: 245-251

<sup>15</sup> Pulliam H.R. (1988). Sources, sinks, and population regulation. *Am. Nat.* 132: 652-661.

<sup>16</sup> Dias, P.C. (1996). Sources and sinks in population biology. *Trends Ecol. Evol.* 11: 326-330

<sup>17</sup> Tattersall F.H., Macdonald D.W., Hart B.J., and Manley W. (2004). Balanced dispersal or source-sink - do both models describe wood mice in farmed landscapes? *Oikos* 106: 536-550

<sup>18</sup> Sullivan, T.P., Sullivan, D.S. & E.J. Hogue (2003). Demography of montane voles in old field and orchard habitats in Southern British Columbia. *Northwest Science* 77: 228-236

Small herbivorous mammal "vole"	Monocotyledons	1.33	54.2	0.4	0.25	2.52
	Dicotyledonos	1.46	28.7	0.4	0.75	4.4
SUM					1.0	6.52
Reprod. toxicity (mg/kg bw/d)		25				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV <sub>mean</sub>	MAF	f <sub>TWA</sub>	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>LT</sub>
Orchard Application crop directed BBCH ≥ 40 4 x 0.35 kg a.s./ha	Small herbivorous mammal "vole"	6.52	1.7**	0.53	5.87	4.25**

\*\* 12 days

The risk is considered as acceptable for vole.  
No risk from drinking water neither due to secondary poisoning is expected.

### 3.8.2 Effects on aquatic species

Conclusions of aquatic risk assessment are presented in tables below:

#### Pome fruits-early application (single/multiple application)

##### Dithianon

Non sprayed buffer using DRN [m]					
Scenario	None	50 %	75 %	90 %	
D3/ditch	30	30	20	15	
D4/pond	10	5	5	5	
D4/stream	30	30	20	15	
R1 pond	15	10	5	5	
R1 stream	30	30	20	15	

DRN: Drift Reducing Nozzles

#### Pome fruits-late application (single/multiple application)

##### Dithianon

Non sprayed buffer using DRN [m]				
Scenario	None	50 %	75 %	90 %
D3/ditch	20	15	10	5
D4/stream	30	15	10	5
R1 stream	20	15	10	5

DRN: Drift Reducing Nozzles

- **Pome fruits (early application) – Spe3:** To protect aquatic organisms no-spray buffer zone of 15 m + 90% of nozzles reduction or no-spray buffer zone of 20 m + 75% of nozzles reduction or no-spray buffer zone of 30 m.
- **Pome fruits (late application) – Spe3:** To protect aquatic organisms respect no-spray buffer zone of 5 m + 90% of nozzles reduction or no-spray buffer zone of 10 m + 75% of nozzles reduction or no-spray buffer zone of 15 m + 50% of nozzles reduction or no-spray buffer zone of 30 m.

**Metabolites of Dithianon:** for all intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

### **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 Dukes at all proposed label rates. According to the Reg. 284/2009 the chronic test for adults bees and chronic test for bee larvae should be submitted **to the end of 2021, when GD for Bees will be implemented 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 Dukes according to the proposed GAP.

### **3.8.5 Effects on soil organisms**

No chronic risk for earthworms and for other soil macro- and mesofauna are expected after the application of Dukes according to the proposed GAP. The risk to soil microbial processes from the proposed uses of Dukes is considered to be acceptable when applied according to the proposed use rates.

### **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 Dukes 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 required.

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

Not relevant.

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

Not relevant.

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



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

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

### Sekcja pozostałości

### Brak zgody na zastosowanie w ochronie grusz

Załącznik do zezwolenia MRiRW nr R - ...../..... z dnia .....2020

#### Posiadacz zezwolenia:

Sharda Cropchem España S.L., Edificio Atalayas Business Center  
Carril Condomina nº3, 12<sup>th</sup> Floor, 30006 Murcia, Hiszpania tel. +34868127589, e-mail:  
eu.sales@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.


## DUKES

### Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

**Ditianon** (związek z grupy antrachinonów) - 700 g/L

Zezwolenie MRiRW nr R- /2020 z dnia . .2020 r.

	
<b>UWAGA</b>	
H302	Działa szkodliwie po połknięciu.
H319	Działa drażniąco na oczy.
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH208	Zawiera 1,2-benzisothiazolin-3-one. Może powodować wystąpienie reakcji alergicznej.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska należy postępować zgodnie z instrukcją użycia.
P273	Nie wypuszczać do środowiska.
P280	Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy.

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.
P337+P313	W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza
P391	Zebrać wyciek.
P501	Zawartość / pojemnik usuwać zgodnie z przepisami miejscowymi / regionalnymi / narodowymi / międzynarodowymi

## OPIS DZIAŁANIA

DUKES jest środkiem grzybobójczym, koncentratem w formie granul do sporządzania zawiesiny wodnej, o działaniu układowym, stosowanym nalistnie, zapobiegawczo i interwencyjnie w uprawie polowej i sadowniczej jabłoni oraz gruszy przed chorobami grzybowymi spowodowanymi przez parcha jabłoni i gruszy (*Venturia sp.*).

Środek przeznaczony do stosowania przy użyciu opryskiwaczy polowych, sadowniczych i ręcznych.

## STOSOWANIE ŚRODKA

### Jabłoń

*Parch jabłoni*

**Maksymalna dawka dla jednorazowego zastosowania:** 0,5 kg/ha (0,34 kg /10 000 m<sup>2</sup> LWA – powierzchnie ściany owoconośnej)

**Zalecana dawka dla jednorazowego zastosowania:** 0,5 kg/ha (0,34 kg /10 000 m<sup>2</sup> LWA – powierzchnie ściany owoconośnej)

Liczba zabiegów: 4

Termin stosowania środka: stosować od początku fazy nabrzmiewania pąka do osiągnięcia przez owoc 90% typowej wielkości (BBCH 51-79)

Zalecana ilość wody: **1000-1500 l/ha.**

Odstęp między zabiegami: 7-12 dni

Zalecane opryskiwanie: **średniokropliste**

**Maksymalna liczba zabiegów w sezonie wegetacyjnym: 4**

## STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOOBSZAROWYCH

**Odpowiedzialność za skuteczność działania i fitotoksyczność  
środka ochrony roślin stosowanego w uprawach małoobszarowych  
ponosi wyłącznie jego użytkownik**

**Grusza**

*Parch gruszy*

**Maksymalna dawka dla jednorazowego zastosowania:** 0,5 kg/ha (0,34 kg /10 000 m<sup>2</sup> LWA – powierzchnie ściany owoconośnej)

**Zalecana dawka dla jednorazowego zastosowania:** 0,5 kg/ha (0,34 kg /10 000 m<sup>2</sup> LWA – powierzchnie ściany owoconośnej)

**Liczba zabiegów:** 4

**Termin stosowania środka:** stosować od początku fazy nabrzmiewania pąka do osiągnięcia przez owoc 90% typowej wielkości (BBCH 51-79)

**Zalecana ilość wody:** 1000-1500 l/ha.

**Odstęp między zabiegami:** 7-12 dni

**Zalecane opryskiwanie:** średniokropliste

**Maksymalna liczba zabiegów w sezonie wegetacyjnym:** 4

Zabieg wykonać opryskiwaczem wyposażonym w rozpylacze antyznoszeniowe.

## **ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ**

Środka nie stosować:

- na rośliny osłabione i uszkodzone przez przymrozki, suszę, szkodniki lub choroby
- na plantacjach nasiennych.

Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

## **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość.

Odmierzoną ilość środka wlać 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 wlewaniu środka do zbiornika opryskiwacza nie wyposażonego 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 należy postąpić tak, jak z resztkami cieczy użytkowej.



## 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.

### Środki ostrożności dla osób stosujących środek: (pracowników oraz osób postronnych)

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

Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.

Ryzyko dla operatora używającego ręcznego sprzętu do aplikacji jest akceptowalne we wczesnym sezonie (bez liści), ale niedopuszczalne w późnym sezonie (gęste liście), nawet biorąc pod uwagę stosowanie środków ochrony osobistej.).

Okres prewencji z z użyciem rękawiczek ochronnych wynosi 7 dni z

Okres prewencji bez użycia rękawiczek ochronnych wynosi 12 dni .

Strefa buforowa 5 m

### Środki ostrożności związane z ochroną środowiska naturalnego:

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

### SPe3

Owoce ziarnkowe (wczesna aplikacja)

~~W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 10 m (w tym 5 m zadarnionej strefy ochronnej) od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 95%.~~

~~LUB~~

~~strefy ochronnej o szerokości 15 m (w tym 10 m zadarnionej strefy ochronnej) od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%~~

~~LUB~~

~~strefy ochronnej o szerokości 20 m (w tym 15 m zadarnionej strefy ochronnej) od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%~~

~~LUB~~

~~strefy ochronnej o szerokości 30 m (w tym 20 m zadarnionej strefy ochronnej) od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%~~

~~LUB~~

~~strefy ochronnej o szerokości 40 m (w tym 30 m zadarnionej strefy ochronnej) od zbiorników i cieków wodnych.~~

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej

o szerokości 15 m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%

LUB

strefy ochronnej o szerokości 20 m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%

LUB

strefy ochronnej o szerokości 30 m od zbiorników i cieków wodnych.

### **SPe3**

**Owoce ziarnkowe (wczesna późna aplikacja)**

~~W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 5 m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%.~~

~~LUB~~

~~strefy ochronnej o szerokości 10 m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%~~

~~LUB~~

~~strefy ochronnej o szerokości 15 m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%~~

~~LUB~~

~~strefy ochronnej o szerokości 30 m od zbiorników i cieków wodnych.~~

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości strefy ochronnej o szerokości 5 m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%

LUB

strefy ochronnej o szerokości 10m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%

LUB

strefy ochronnej o szerokości 15 m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%

LUB

strefy ochronnej o szerokości 30 m od zbiorników i cieków wodnych.

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

Nie dotyczy

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

Jabłoń – 21 dni

**Grusza – 21 dni**

## **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 uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0°C - 30°C, z dala od źródeł ciepła.

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 3 Letter of Access**

No letters of access to protected data are required.

## Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data pro- tection is claimed	Owner
KCP 2.1 KCP 2.2.1 KCP 2.2.2 KCP 2.3.2 KCP 2.3.3 KCP 2.4.1 KCP 2.4.2 KCP 2.6.2 KCP 2.7.1 KCP 2.8.1 KCP 2.8.2 KCP 2.8.3.1/02 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.5.2.1 KCP 2.8.5.3 KCP 2.8.7.1	Jose Angel Escudero Garcia	2016	Physico-Chemical Characterization of DITHIANON 70% WG Laboratorios Munuera Report No 15-4150-07 GLP Unpublished	N	Y	Data/study report never submitted before to Po- land	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data pro- tection is claimed	Owner
KCP 2.7.5	Jose Angel Escudero Garcia	2019	Storage stability for two years at 25 ± 2 °C of DITHIANON 70% WG Laboratorios Munuera Report No 15-4150-08 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.8.3.1/02	Micaela Baños Gonzales	2018	Gravimetric suspensibility at 1.9 g/l of DITHIANON 70% WG before and after storage at 54°C for 14 days. Laboratorios Munuera Report No 18-4150-10 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
CP 6.0-001	Anonymous	2020	Biological Assessment Dossier: DITHIANON 70 WG (700 g/kg Dithianon) – EU Central zone Sharda Cropchem España S.L. -, - Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 5.1.1	Jose Angel Escudero	2016	Physico-Chemical Characterization of DITHIANON 70% WG Laboratorios Munuera Report No 15-4150-07 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 1.2.1-01	Kull, S.	2019	Residue study (Decline) in cereals following four sequential applications with Dithianon 70% WG in Germany 2018 – field part CT18-1-15 CropTrials GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data pro- tection is claimed	Owner
KCP 1.2.1-02	Rump, K.	2020	Determination of residues at decline of Dithianon in Winter Wheat, following four broadcast applications of DITHIANON 70% WG, under open field conditions Germany - Season 2018 FRS 058/18 Field Research Support GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.2.1-01	...	2016	Dithianon 70% WG Rainbow trout Acute toxicity test ... ... GLP Unpublished	Y	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.2.1-02	Konfederak, E.	2016	Dithianon 70% WG <i>Daphnia magna</i> , Acute Immobilization Test W/83/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.2.1-03	Konfederak, E.	2016	Dithianon 70% WG <i>Pseudokirchneriella subcapitata</i> SAG 61.81 Growth inhibition test W/82/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.2.1-04	Konfederak, E.	2016	Dithianon 70% WG <i>Lemna gibba</i> CPCC 310, Growth inhibition test W/84/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data pro- tection is claimed	Owner
KCP 10.3.1.1.1	Małgorzata, C.	2016	Dithianon 70% WG Honeybees ( <i>Apis mellifera</i> L.), Acute Oral Toxicity Test B/164/15 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.1.1.2	Małgorzata, C.	2016	Dithianon 70% WG Honeybees ( <i>Apis mellifera</i> L.), Acute Contact Toxicity Test B/165/15 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.2.1-01	Luna, F.	2017	DITHIANON 70% WDG: Toxicity to the Predatory Mite, <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) under Laboratory Conditions TRC17-139BA Trialcamp S.L.U. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.2.1-02	Varela Cervero, S.	2017	Dithianon 70%, WDG: Toxicity to the Aphid Parasitoid <i>Aphidius rhopalosiphi</i> De Stefani Perez (Hymenoptera, Braconidae) under Laboratory Conditions TRC17-100BA Trialcamp S.L.U. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.4.1.1	Weronika, D.	2017	Dithianon 70% WG Earthworm Reproduction Test ( <i>Eisenia fetida</i> ) G/278/15 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data pro- tection is claimed	Owner
KCP 10.4.2.1-01	Weronika, D.	2016	Dithianon 70% WG Collembolan ( <i>Folsomia candida</i> ) Re- production Test G/279/15 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Po- land	Sharda Cropchem Limited
KCP 10.4.2.1-02	Lozano Garcia, J.	2017	Dithianon 70% WDG: Effects on the Reproductive Output of the Predatory Soil Mite <i>Hypoaspis (Geolaelaps) aculeifer</i> <i>Canestrini</i> (Acari: Laelapidae) in Artificial Soil TRC17-127BA Trialcamp S.L.U. GLP Unpublished	N	Y	Data/study report never submitted before to Po- land	Sharda Cropchem Limited
KCP 10.5-01	Weronika, D.	2016	Dithianon 70% WG Soil Microorganisms: Nitrogen Trans- formation Test G/277/15 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Po- land	Sharda Cropchem Limited
KCP 10.5-02	Weronika, D.	2016	Dithianon 70% WG Soil Microorganisms: Carbon Transformation Test G/276/15 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Po- land	Sharda Cropchem Limited
KCP 10.6.2-01	Weronika, D.	2017	Dithianon 70% WG Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test G/281/15 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Po- land	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.6.2-02	Weronika, D.	2017	Dithianon 70% WG Terrestrial Plant Test: Vegetative Vigour Test G/282/15 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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

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

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
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS>  If previously submitted in <b>this</b> MS: Data protection started with: <insert authorization number of first authorization>	Owner

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Data protection claimed</b> <b>Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS>  If previously submitted in <b>this</b> MS: Data protection started with: <insert authorization number of first authorization>	Owner