

# FINAL REGISTRATION REPORT

## **Part B**

### **Section 3**

#### **Efficacy Data and Information**

Concise summary

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: 26/04/2021; 12/2021

## Version history

When	What
April 2021	ZRMs evaluated dRR submitted by Applicant.
December 2021	Final registration report after commenting period

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### **3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)**

#### **Transformation of the dRR (applicant version) into the RR (zRMS version)**

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	Comments of zRMS are in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are in grey).
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#### **3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)**

##### **Abstract**

Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.

**Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)**

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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 safen- er/synergist per ha (f)	zRMS Conclusion (efficacy)
					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	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	To be con- firmed by cMS
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														

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

\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

## 3.2 Efficacy data (KCP 6)

### Introduction

This document summarises the information related to the efficacy data of the plant protection product **DITHIANON 70% WG (DUKES; Product code: SHA 6800 A)** containing the active substance Dithianon, Annex of Reg. 540/2011 (former Annex I of Directive 91/414/EEC (2011/41/EU)).

The SANCO report for Dithianon (SANCO/10349/2011 – 11 March 2011) is considered to provide the relevant review information or a reference to where such information can be found.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the Dithianon, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11/03/2001 shall be taken into account.

These concerns have been addressed within the current submission.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Appendix 2 of this document is the table of intended uses for dithianon.

**The detailed assessment of the individual trial and study data is located in the following report:**

<b>Report: CP 6.0/001 Biological Assessment Dossier DITHIANON 70% WG</b>
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### Description of active substance Dithianon

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

To support the registration of DITHIANON 70% WG, 23 field trials have been conducted with the Shar-da' dithianon formulation in apple. In these trials, DITHIANON 70% WG was compared against the dithianon formulation currently on the market by BASF (e.g. Delan 70 WG), to be able to demonstrate equivalence between the dithianon formulations applied at equivalent rates and therefore to be able to refer to data out of protection on dithianon from BASF, to give additional support to the registration of DITHIANON 70% WG. The trials were conducted in 2015 and 2016 in a wide range of European countries in the North East (Poland, Latvia and Lithuania), the Maritime (Germany and N-France), the South-east (Hungary, Romania) and the Mediterranean (Italy, Greece, Portugal, S-France and Spain) EPPO zones.

According to the GAP, the proposed application rate of DITHIANON 70% WG is 0.5 kilograms per hectare (kg/ha), with four applications per season on pome fruits. This will deliver 0.350 kg dithianon per application per hectare on pome fruits. In the current BAD, results obtained in field trials with DITHIANON 70% WG in apple will be presented where these have been tested against equivalent dose rates of dithianon reference products.

The data presented in this dossier fully support the label claim for dithianon for the control of scab in pome fruits;

**Table 3.2-1: Simplified table of currently registered uses and requested uses for the product code.**

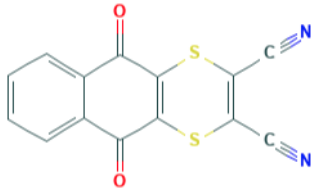
Crop / disease	Application method	Spray volume (L/ha)	Max. individual application rate (kg f.p./ha) [kg a.s./ha]	Max. number of applications	Application timing (e.g. BBCH)
Apple / Venturia spp.	Spray	500-1500	(0.5) [0.350]	4	BBCH 51-79

Further details are in the table “All intended uses” in Part B - Section 0.

### Description of active substance dithianon

Dithianon is used as a fungicide to control black spot and foliar diseases on pome fruits.

**Table 3.2-2: Identity of dithianon**

<b>Common name</b>	Dithianon
<b>IUPAC name</b>	5,10-dihydro-5,10-dioxonaphtho[2,3-b]-1,4-dithiine-2,3-dicarbonitrile
<b>CA name</b>	5,10-Dihydro-5,10-dioxonaphtho[2,3-beta]-1,4-dithi-in-2,3-dicarbonitrile
<b>CIPAC No</b>	153
<b>CAS Registry No.</b>	3347-22-6
<b>EEC No</b>	222-098-6
<b>Minimum purity</b>	930 g/kg
<b>Structural formula<sup>1</sup></b>	
<b>Empirical formula</b>	C <sub>14</sub> H <sub>4</sub> N <sub>2</sub> O <sub>2</sub> S <sub>2</sub>
<b>Molecular mass</b>	296.3 g/mol

### Mode of action, dithianon

Dithianon belongs to the group of fungicides known as Quinone (anthraquinone). Dithianon is a broad spectrum, protective fungicide. The mechanism is a multi-site inhibitor of protein formation that acts by modifying the sulfhydryl groups found in the cysteine residues of many proteins. This protein inhibition prevents spore germination and germ tube growth.

### Information on similar formulations and current approvals

Dithianon 70% is a WG formulation containing 700 g/kg dithianon. Data presented in this dossier is generated using this formulation in comparison with e.g. the Basf reference product containing dithianon. Dithianon is currently registered under a variety of trade names and formulations throughout Europe and a selection of these are described in table below.

<sup>1</sup> Source: Royal Society of Chemistry (RSC). Internet, Friday September 4<sup>th</sup>, 2020. URL: <http://www.chemspider.com/Chemical-Structure.55867.html>

**Table 3.2-3: Current approvals of Dithianon in the EU Central zone and reference products used in the trials**

Country	Product(s)	Approval Number
Belgium	DELAN 70 WG	8850P/B
Czech Republic	Delan 70 WG	4182-4V
Hungary	DELAN 700 WG	04.2/1418-1/2014
France	Delan WG	9600395
Greece	Delan 70 WG	60565
Italy	Delan 70 WG	12437
The Netherlands	Delan DF	10001
Portugal	DELAN 70 WG	3844
Spain	DELAN-75	19.741
Germany	Delan WG	004424-00
Poland	Delan 700 WG	R-46/2006
Poland	Faban 500 SC ( dithianon 250 g/l + pirymethanil 250 g/l)	R- 216/2014
Latvia	Effector	Reg. number
Lithuania	Delan	Reg. number

### Description of the plant protection product

Key targets for this product are foliar- and ear diseases of different crops. The listed pests are present throughout or in parts of the Central zone and in relevant EPPO zones. The key targets for this product are described in detail in the Biological Assessment dossier.

**Table 3.2-4: Simplified table of currently registered uses and requested uses for the product code.**

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Pome fruits	Scab ( <i>Venturia inaequalis</i> )	CEU	0.5 kg product/ha	Major and Minor crop

Further details are in the table “All intended uses” in Part B - Section 0.

### Description of the target pests

All the listed diseases are present throughout or in parts of the Central zone and in relevant EPPO zones.

**Table 3.2-5: Glossary of diseases mentioned in the dossier.**

EPPO code	Scientific name	Common name
VENTSP	<i>Venturia</i> sp.	Scab
VENTIN	<i>Venturia inaequalis</i>	Scab of apple
VENTCA	<i>Venturia carpophila</i>	Scab of almond

**Table 3.2-6: Major / minor status of intended uses (for all cMS and zRMS).**

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Pome fruits, apple	CEU	CEU	<i>Venturia</i> sp.	CEU	

### Compliance with the Uniform Principles

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

### Information on trials submitted (3.1 Efficacy data)

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

In support of the current application, 23 efficacy trials were conducted in the North-east, the Maritime, the South-east and the Mediterranean EPPO zones and under protected conditions.

In the trials used to assess the level of control obtained with Dithianon 70% WG, a different number of assessments were conducted during the course of the trials. In some trials, a single assessment was conducted on the specific plant part and in others, two or more assessments were conducted. Therefore, not to bias the data from any trial with more than one assessment, the summary tables contain the data from one assessment per plant part per trial. An assessment is only considered valid for evaluation if the level of pest severity (PESSEV) is minimum 1% in the untreated check or if pest incidence (PESINC) is minimum 5% in the untreated check. The data selected from each trial is either the final assessment timing on each plant part or the assessment conducted at the most relevant timing

**Table 3.2-7: Presentation of trials (efficacy trials, preliminary trials...)**

Crop(s)	Target(s)*	Country	Years	Type of trial*	Number of trials (number of valid trials)				GEP, non-GEP, official**	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
Apple	<i>Venturia inaequalis</i>	Spain	2015	E + MED	-	<del>7 (7)</del> 2 (2)	-	-	GEP	
		Italy	2015	E + MED	-	<del>4 (4)</del> 2 (2)	-	-	GEP	
		Portugal	2015	E + MED	-	2 (2)	-	-	GEP	
		France	2015/ 2016	E + MED	2 (2)	2 (2)	-	-	GEP	
		Greece	2015	E + MED	-	2 (2)	-	-	GEP	

Crop(s)	Target(s)*	Country	Years	Type of trial*	Number of trials (number of valid trials)				GEP, non-GEP, official**	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
		Germany	2015	E + MED	1 (1)	-	-	-	GEP	
		Romania	2015	E + MED	-	-	2 (2)	-		
		Hungary	2015/ 2016	E + MED	-	-	2 (2)	-	GEP	
		Poland Latvia Lithuania	2015 2015 2015	E + MED				2(2) 3(3) 1(1)	GEP	
		Total, Apple				3 (3)	10 (10)	4 (4)	6 (6)	-

\* P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

\*\* GEP: Good Experimental Practices. Official: carried out by a national official organisation.

\*\*\* under greenhouse conditions

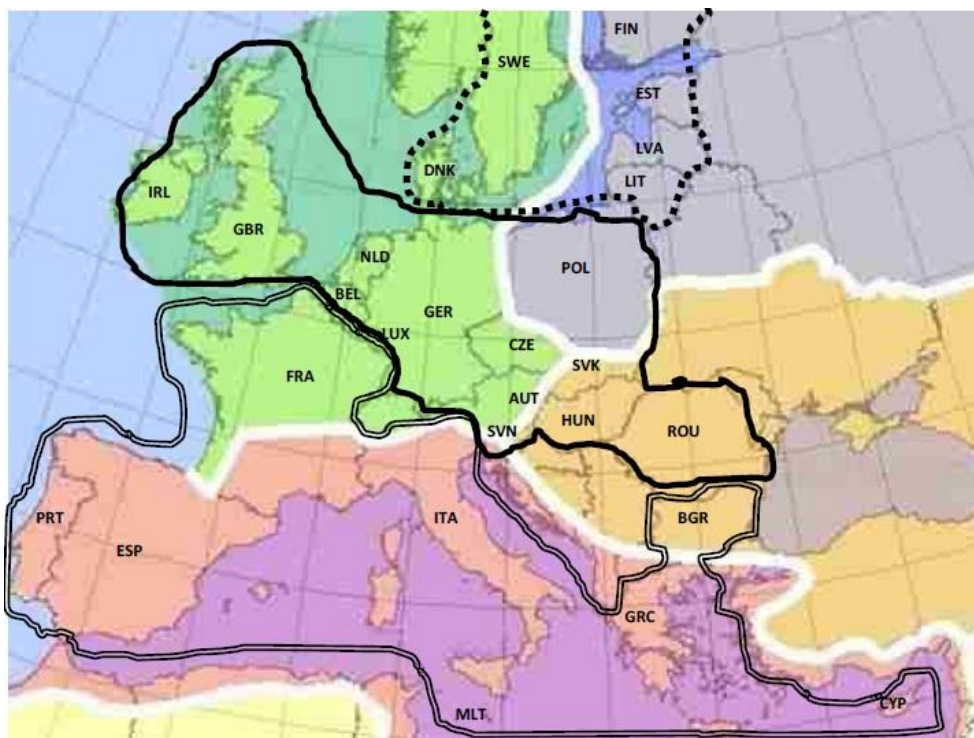
### Climatic zones

Europe is divided into four climatic zones, according to EPPO standard PP 1/241 (1). Besides providing guidance in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials are performed, the standard also supports the use of data generated in one country to support registration in another country<sup>2</sup>.

Poland, Latvia and Lithuania are located in North East EPPO zone. The Northern part of France and Germany are located in the Maritime EPPO zone and Romania and Hungary are located in the South-east EPPO zone. The Southern part of France, Greece, Spain, Italy and Portugal are all located in the Mediterranean EPPO zone; (Figure 3.2-1).

<sup>2</sup> Development of Comparable Agro-Climatic Zones for the International Exchange of Data on the Efficacy and Crop Safety of Plant Protection Products, E. Bouma, 2005 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 35, 233-238.

**Figure 3.2-1: Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, Guidance on comparable climates) superimposed with the 3 European zones (EC Regulation 1107/2009) (Source: EPPO)**



Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC provides in the Article 3(17) that *authorizations granted by one Member State should be accepted by other Member States where agricultural, plant health and environmental (including climatic) conditions are comparable*. Annex I to the Regulation defines three zones with such comparable conditions:

Zone A : North: Denmark, Estonia, Latvia, Lithuania, Finland, Sweden

Zone B : Centre: Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom

Zone C: South: Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal.

We want to present data of efficacy which were done in Centre Registration Zone i.e. Poland, Romania, Hungary in order to support and register throughout zone B.

This document is prepared to support the submission of DITHIANON 70% WG throughout the EU Central Registration zone, therefore there included data from the North East EPPO and from the South-East EPPO zones, however the data from each climatic zone is summarised separately.

### **Agronomic conditions**

Cultural conditions and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between the countries in the EU Central and Southern Registration zone. Dithianon-containing fungicides are used as a protective fungicide in central and Southern zone countries, which should be applied during the growing season, before or shortly after outbreaks of the diseases claimed on the label are foreseen.

The same Dithianon containing fungicides are already registered and used in all countries to control the same key disease species. In each country, these are used at similar application timings when the diseases and crops are at similar growth stages.

(i) *Disease physiology*

The physiology of individual pathogens presented is common throughout Central and Southern Europe. Although trials were performed in different countries, sites were selected to exert maximum control pressure and to exacerbate treatment differences. No difference in the level of control was apparent between the different countries or regions in which the trials were conducted.

(ii) *Site selection*

Although trials were performed throughout the EU, in each country the sites were carefully selected to ensure that for each disease species the level of control was assessed on a range of populations and application timings. To exert maximum control pressure and to exacerbate treatment differences in each country this included some trials which contained high disease densities. No differences in the level of control were apparent between the different countries or regions in which the trials were conducted.

(iii) *Agronomic practices*

Agronomic practices for cultivating apples are similar throughout the EU Central and Southern zone. The levels of inorganic fertilizers and other crop inputs are also generally similar between the countries.

(iv) *Varieties*

Although crop varieties tend to differ between countries the crop safety of DITHIANON 70% WG has been tested on a wide range of varieties in efficacy trials. The results from these trials show that there are no particularly sensitive varieties. Crop tolerance data generated in one country is therefore relevant in another Member state.

(v) *Trial methodology*

Similar trial methodology was used in all countries. All trials were conducted to GEP by officially recognised testing organisations and in accordance with relevant EPPO standards.

(vi) *Locations*

Trials were performed in the major crop growing areas in each respective country. These areas have been found to be particularly suitable for tomato production due to their innate similarity in terms of soil type and climate.

(vii) *Soil*

It is not expected that a foliar applied fungicide will be affected by soil type and so this factor can be ignored for the purposes of this dossier.

On the basis that the above factors do not influence the overall performance of DITHIANON 70% WG, it is the applicant's contention that data from France, Italy, Greece, Spain, Portugal, Germany, Hungary and Romania is equally valid in demonstrating the products performance throughout the Central EU zone.

Efficacy trials were carried out with DITHIANON 70% WG in comparison to the reference Dithianon 700 g/kg/750 g/kg product (DELAN WG, DELAN SC). Trials were carried out on apple.

**Table 3.2-8: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)**

Crop(s)	Reference standard	Country(ies) where the product is registered	Authorization number	Active substance(s)	Formulation	
					Type	Concentration of a.s.
Apple	Delan WG	IT EL PT ES FR DE HU PL	12437 60565 3844 19.741 9600395 004424-00 04.2/1418-1/2014 R - 195/2015d issued 16.03.2015 r.	Dithianon	WG	700 g/kg
	Effector Delan	Latvia Lithuania	0134 0147F/04			

Comments of zRMS:	<p>This document was prepared by Applicant for registration the DUKES (product code: SHA 6800 A) containing dithianom (700 g/kg). The formulation of this product is a water dispersible granules (WG).</p> <p>Dithianon is a broad spectrum, protective fungicide. The mechanism is a multi-site inhibitor of protein formation that acts by modifying the sulfhydryl groups found in the cysteine residues of many proteins. This protein inhibition prevents spore germination and germ tube growth.</p> <p>The product – DUKES (product code: SHA 6800 A) containing dithianom 700 g/kg WG by Sharda Cropchem España has not been previously evaluated in any country according to Uniform Principles.</p> <p>Poland is a ZRMS. In Poland 21 plant protection products containing dithianom are already registered.</p>
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### 3.2.1 Preliminary tests (KCP 6.1)

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.

Comments of zRMS:	Statement accepted. The active substances of DUKES (product code: SHA 6800 A) containing dithianom 700 g/kg WG is registered and have been commonly used in crop protection in EU Countries for many years (since 1960s). Also, a large-scale efficacy trials are available to evaluate the effectiveness of products containing this active compound. Therefore, there was no need for preliminary range-finding tests in the opinion of Evaluator.
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### 3.2.2 Minimum effective dose tests (KCP 6.2)

To determine the minimum effective dose rate 23 trials conducted in apple, from the North East, the Maritime, the South-east and the Mediterranean EPPO zones, as well as under greenhouse conditions have been included in this section. In the 23 trials, the level of control obtained by DITHIANON 70%

WG was assessed on *Venturia inaequalis* present in the trials.

### Control of *Venturia inaequalis* in apple

The 23 field trials were established, in order to determine the minimum effective dose for the control of *Venturia inaequalis* in apple. DITHIANON 70% WG was tested at 0.375 and 0.5 kg/ha (equivalent to 263 and 350 g ai/ha, respectively). The rates reflect the proposed label rate and 75 and 100% of the full recommended rate of DITHIANON 70% WG, in accordance with the EPPO standard PP 1/225 'Minimum effective dose'. In the trials specifically targeted for this pathogen, 5 to 12 applications were applied at growth stages ranging from BBCH 11 to BBCH 87.

A summary of the dose response results obtained in efficacy trials is provided in Table 3.2-9.

**Table 3.2-9: Minimum effective dose: North-east, Maritime, South-east and Mediterranean zone - Efficacy of DITHIANON 70% WG at proposed label rate, at 75% dose rate on *Venturia inaequalis***

				Mean % Control at a range of doses of dithianon DITHIANON 70% WG			
				0.3750 kg/ha = 0.2625 g ai/ha		0.5 kg/ha = 0.35 g ai/ha	
Target: Scab [VENTIN]	No. of trials	Untreated		Mean	Range	Mean	Range
		Mean	Range				
North-east EPPO zone							
<i>PESINC on leaves – 7-10 days after last treatment</i>	6	62.2	5.88-147.8	<b>59.5</b>	35.71-73.29	<b>57.1</b>	27.9-76.6
<i>PESINC on fruits – 9-61 days after last treatment</i>	5	72.68	27.8-100	<b>58.3</b>	16.3-83.2	<b>60.8</b>	15.8-86.4
<i>PESSEV on fruits – 9-61 days after last treatment</i>	6	44.3	1,2-72.1	<b>47.3</b>	18.9-83.2	<b>51.1</b>	20.1-86.4
Maritime EPPO zone							
<i>PESINC on leaves – 12 days after last treatment</i>	1	50	-	<b>48</b>	-	<b>72.7</b>	-
<i>PESSEV on leaves – 13 days after last treatment</i>	2	61.4	28.3-94.4	<b>71.2</b>	57.3-85	<b>76.1</b>	59.2-93
<i>PESSEV on fruits at harvest</i>	2	65.6	34.5-96.6	<b>52.3</b>	24.2-80.4	<b>60.0</b>	28.3-91.7
South-east EPPO zone							
<i>PESINC on leaves – 10 days after last treatment</i>	4	52.1	22.8-94.8	<b>45.1</b>	5-59.9	<b>55.5</b>	17.9-71
	3*	37.8	22.8-58.1	<b>58.4</b>	56.3-59.9	<b>68.0</b>	65.5-71
<i>PESSEV on leaves – 10 days after last treatment</i>	2	18.3	1.6-35.1	<b>63.2</b>	55.4-71	<b>75.5</b>	67.7-83.3
<i>PESSEV on fruits 1-3 – at har- vest</i>	3	16.6	11.8	<b>84.8</b>	67-95.1	<b>92.3</b>	76.9-100
Mediterranean EPPO zone							
<i>PESINC on leaves – 7-10 days after last treatment</i>	8	44.7	16.6-82.9	<b>43.3</b>	9.2-71.2	<b>56.7</b>	17.7-80.2
<i>PESSEV on leaves – 6-9 days after last treatment</i>	4	21.4	8.7-36	<b>41.6</b>	18-74.7	<b>49.2</b>	30.1-67.6
<i>PESINC on fruits – 9-61 days after last treatment</i>	3	15.4	3.5-33	<b>49.0</b>	16.7-78.6	<b>57.3</b>	54.1-71.4
<i>PESSEV on fruits – 9-61 days after last treatment</i>	3	5.3	1.1-13.1	<b>49.9</b>	18.8-76.2	<b>56.9</b>	52.2-61

Results from different EPPO zones provided similar outcomes. The tested product applied at the recommended dose rate obtained the higher level of control in terms of pest incidence and pest severity on fruits and leaves. Furthermore, the control obtained with the recommended dose rate was more persistent and

with less variability during the whole course of the trials than that observed with the lower dose rates. Statistical differences were observed in six trials between the recommended dose rate and the lower dose rates applied.

The data from the 23 trials proves that the minimum effective dose rate of DITHIANON 70% WG to scab in apple is 0.5 kg/ha (350 g ai/ha). Furthermore, the data demonstrated that if the application rate is reduced below this, a clear decrease in control as well as in persistence is observed.

### Summary and conclusions on the minimum effective dose

In summary, reducing the application rate from the proposed dose rates results in decreased efficacy against *Venturia inaequalis* (VENTIN) in apple,

According to the presented results, the dose of 350 g ai/ha of dithianon for apple provided the optimum overall control and should be considered as effective against the diseases, for which activity of Dithianon 70%WG is claimed.

As it will be demonstrated the efficacy of Dithianon 70%WG is equivalent to that of the reference dithianon product. For the minimum effective dose of crops and diseases claimed on the draft Dithianon 70%WG label not adequately supported by the applicant's trials data, Sharda Cropchem wishes to cite the original registrant's data on dithianon now out of protection and requests that the zonal evaluator extrapolate from those data.

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.

Comments of zRMS:	<p>In order to provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate researches of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance to EPPO 1/225 (2).</p> <p>DUKES (product code: SHA 6800 A) containing dithianom 700 g/kg WG was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with DUKES applied at different dose rates was evaluated in 23 apple trials (3 MAR, 10 MED, 4 S-E and 6 N-E).</p> <p>In the 23 apple trials, DUKES was applied at 0,375 kg/ha (0,75N) and 0,5 kg/ha (N dose) for the control of <i>Venturia inaequalis</i> (SCAB). 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.</p> <p>According to the presented results, the dose of 0.5 kg/ha per application for SCAB in apple provided the optimal overall control and should be considered as effective against the disease, for which activity of DUKES is claimed. As diseases often occur as complexes of several pathogens throughout a season, up to four applications of DUKES at the proposed rate should be used to efficiently control the pathogen claimed on the label.</p>
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### 3.2.3 Efficacy tests (KCP 6.2)

Data from 23 efficacy trials conducted in the North-east, the Maritime, the South-east and the Mediterranean EPPO zones have been included in this dossier to support the label claims and recommendations on efficacy and selectivity in the EU South Registration zone.

In the 23 trials, the level of control obtained by DITHIANON 70% WG was assessed on *Venturia inaequalis* presence in field trials.

The efficacy trials were conducted to prove the following label claims:

Crop	Apple
Use rate	0.5 kg/ha Dithianon 70% WG
Use frequency	Up to 4x
Application timing	BBCH 51-79
Target disease	Scab ( <i>Venturia</i> spp.)

**Table 3.2-10: Details on trial methodology**

<b>Guidelines</b>	General guidelines	EPPO PP 1/152(3),(4), PP 1/181(4), PP 1/135(3),(4)
	Specific guidelines	<i>Venturia inaequalis</i> and <i>V. pyrina</i> : PP 1/5(3) Guidance on comparable climates: PP 1/241(2) F : Tavelures du poirier et du pommier: CEB 14 <i>Taphrina deformans</i> : PP 1/82(2) <i>Alternaria solani</i> and <i>Alternaria alternata</i> on potato & outdoor tomato production: PP 1/263(1)
<b>Experimental design</b>	Plot design	RCBD (23)
	Plot size	9-216 m <sup>2</sup>
	Number of replications	4 (23)
<b>Crop</b>	Trials per crop	Apple (23)
	Varieties per crop	<u>Apple</u> : Elstar, Fuji, Gala, Gloster, Granny Smith, Golden, Golden Delicious, Idared, Royal Gala, Berthanne , Idared, Zimnieje limonnoje, Belorusskoje Malinovoje, Cortland.
	Sowing period	Apple: n.a.
<b>Application</b>	Crop stage (BBCH)* at application	Apple: BBCH 11-87
	Timing Pest stage at appl. (1)	Preventative
	Number of appl. Intervals between appl.	4 (7 trials); 5 (3 trials); 6 (2 trials); 8 (1 trial); 9 (4 trials); 10 (1 trial); 12 (12 trials) 7-25 days (average: 16 days); 6-11 days (average: 8.5 days); 7 days; 7-10 days (average: 8.5 days); 7-14 days (average: 10.5 days)
	Spray volumes	Apple: 1000 lt/ha
<b>Assessment</b>	Assessment types	Assessment on leaves (200 leaves/plot) : - Estimated infected area (PESSEV) - Calculated percentage of infected leaves (PESINC) Assessment on fruits (100 fruits/plot) : Assessed attack according to following scale 1= no attack, 2= 1-3 spots per fruit, 3= 3 spots per fruit Phytotoxicity (0-100 scale) and symptoms description Vigor (0-10 or 0-100%)

	Assessment dates	0-93 days after every last treatment
<b>Other relevant information</b>	Soil type	Light to heavy soils
	Natural / artificial inoculation...	Natural
	Field / Greenhouse...	Field (23)

### Control of *Venturia inaequalis* in apple

The summary of efficacy results obtained with the application of DITHIANON 70% WG at 0.5 kg/ha against *Venturia inaequalis* in apple crops are listed in Table 3.2-11, Table 3.2-12, Table 3.2-13 and Table 3.2-14 for results from trials conducted in the North-east, the Maritime, the South-east and the Mediterranean EPPO zones, respectively. The trials were conducted in Poland (2), Latvia (3), Lithuania (1), Italy (2), Greece (2), S-France (2), Spain (2), Portugal (2), N-France (2), Germany (1), Hungary (2) and Romania (2) in 2015 and 2016.

Data is only included from assessments in which a minimum of 1% of disease pressure were seen at the timing of the assessment. The most appropriate timing of assessment to be presented is considered to be the first assessment after the last application. Data is included following 5 to 12 applications, for pest incidence and pest severity on leaves and fruits in the Mediterranean trials, pest incidence on leaves and pest severity on leaves and fruits in the Maritime and the South-east trials.

When applied at 0.5 kg/ha in the North East EPPO zone, DITHIANON 70% WG obtained good levels of control. In all assessments evaluated, the effect obtained with DITHIANON 70% WG was on par with the effect obtained with the Dithianon reference product applied in the trials at the same dose rate. Statistical evaluation revealed a similar picture, i.e. no significant differences were observed between Dithianon 70%WG and the Basf dithianon standard product at the assessments.

In the six trials in which leaves were assessed, the mean pest incidence in untreated plots was 71.3%. In the assessment, conducted at 8 to 9 days after last application, the test product at the recommended dose rate achieved an average level of control of 50.1%. At the same assessments, the dithianon reference product achieved 69.4% when applied at 525 g ai/ha. When assessing pest incidence on fruits, DITHIANON 70% WG achieved 81.3% control in the five trials and the dithianon reference product achieved 91.1% control.

**Table 3.2-11: North-east zone: Efficacy of 0.5 kg/ha DITHIANON 70% WG in 6 efficacy tests 2015-16.**

Part assessed	Days after Last Treatment. (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Dithianon 70% WG at 0.5 kg/ha is >, < or =, compared to the Reference product at 1N = : ± 5% control			Overall
				Dithianon 70% WG at:	Reference product at				
				Mean (min-max)					
				0.5 kg/ha	1N	>	=	<	
Pest incidence PESINC									
LEAF	8-9 DALT	5	71.3 (20.2-147.8)	50.1 (24.5-63.4)	69.4 (34.6-71.4)		1	4	<
LEAF	15 DALT	1	20.5	76.7	74.2		1		=
LEAF	30 DALT	1	40.4	74.3	72.1		1		=
FRUITS	harvest	2	44.9 (27.8-62.0)	81.3 (80.2-82.3)	91.1 (87.6-94.6)		1	1	=

When applied at 0.5 kg/ha in the Maritime EPPO zone, DITHIANON 70% WG obtained good to excellent levels of control. In all assessments evaluated, the effect obtained with DITHIANON 70% WG was on par with the effect obtained with the Dithianon reference product applied in the trials at the same dose

rate. Statistical evaluation revealed a similar picture, but some differences were observed between DITHIANON 70% WG and the Basf dithianon standard product at the assessments, because it is used in higher dose rate.

**Table 3.2-12: Maritime zone: Efficacy of 0.5 kg/ha DITHIANON 70% WG in 3 efficacy tests 2015-16.**

Part assessed	Days after Last Treatment. (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Dithianon 70% WG at 0.5 kg/ha is >, < or =, compared to the Reference product at 1N = : ± 5% control			Overall
				Dithianon 70% WG at:	Reference product at				
				Mean (min-max)					
				0.5 kg/ha	1N	>	=	<	
Pest severity				PESSEV					
LEAF	13 DALT	2	61.4 (28.3-94.4)	76.1 (59.2-93.0)	83.3 (70.1-96.5)		1	1	=
FRUITS	harvest	2	65.6 (34.5-96.6)	60.0 (28.3-91.7)	71.4 (54.2-88.6)		1	1	=
Pest incidence				PESINC					
LEAF	12 DALT	1	50.0 (-)	72.7 (-)	97.8 (-)			1	<

When applied at 0.5 kg/ha in the South-east EPPO zone, DITHIANON 70% WG obtained good to excellent levels of control. In all assessments evaluated, the effect obtained with DITHIANON 70% WG was on par with the effect obtained with the Dithianon reference product applied in the trials at the same dose rate. Statistical evaluation revealed a similar picture, but some differences were observed between DITHIANON 70% WG and the Basf dithianon standard product at the assessments, because it is used in higher dose rate.

**Table 3.2-13: South-east zone: Efficacy of 0.5 kg/ha DITHIANON 70% WG in 4 efficacy tests 2015-16.**

Part assessed	Days after Last Treatment. (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Dithianon 70% WG at 0.5 kg/ha is >, < or =, compared to the Reference product at 1N = : ± 5% control			Overall
				Dithianon 70% WG at:	Reference product at				
				Mean (min-max)					
				0.5 kg/ha	1N	>	=	<	
Pest severity PESSEV									
LEAF	10 DALT	2	18.3 (1.6-35.1)	75.5 (71.1-90.2)	78.7 (71.5-85.8)		2		=
FRUITS	harvest	2	16.6 (11.8-23.0)	92.3 (80.2-100)	93.0 (79.1-100)		2		=
Pest incidence PESINC									
LEAF	10 DALT	4	52.1 (22.8-94.8)	55.5 (14.0-75.8)	56.6 (15.2-72.3)		4		=
LEAF	10 DALT	3	37.8 (22.8-58.1)	68.0 (65.5-71.0)	70.4 (69.0-72.3)		3		=

When applied at 0.5 kg/ha in the Mediterranean EPPO zone, DITHIANON 70% WG obtained good levels of control. In all assessments evaluated, the effect obtained with DITHIANON 70% WG was on par with the effect obtained with the Dithianon reference product applied in the trials at the same dose rate. Statistical evaluation revealed a similar picture, i.e. no significant differences were observed between Dithianon 70%WG and the Basf dithianon standard product at the assessments.

**Table 3.2-14: Mediterranean zone: Efficacy of 0.5 kg/ha DITHIANON 70% WG in 10 efficacy tests 2015.**

Part assessed	Days after Last Treatment. (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Dithianon 70% WG at 0.5 kg/ha is >, < or =, compared to the Reference product at 1N = : ± 5% control			Overall
				Dithianon 70% WG at:	Reference product at				
				Mean (min-max)					
				0.5 kg/ha	1N	>	=	<	
Pest severity				PESSEV					
LEAF	6-9 DALT	4	21.4 (8.7-36)	49.2 (4.3-68.3)	69.7 (55.6-79.8)		2	2	=
FRUITS	9-61 DALT	3	5.3 (1.1-13.1)	56.9 (49.2-66.5)	63.8 (39.0-80.9)		1	2	<
Pest incidence				PESINC					
LEAF	7-10 DALT	8	44.7 (16.6-82.9)	56.7 (50.5-62.4)	69.4 (38.5-88.5)	1	3	4	<
FRUITS	9-61 DALT	3	49.0 (16.7-78.6)	57.3 (41.2-67.4)	63.3 (42.4-78.6)		2	1	=

These results from the North East zone as well as from the Mediterranean, the Maritime and the South-east EPPO zones demonstrated that DITHIANON 70% WG applied at the proposed label rate matched the efficacy of the dithianon standard product.

### Summary and conclusion

Based on the results of 23 efficacy trials carried out in 2015 and 2016, the following can be concluded for the label claims from DITHIANON 70 WG:

- DITHIANON 70% WG applied in apple provided a moderate to high level control of scab (*Venturia* spp.) with the recommended dose rate. As diseases often occur as a complex of several diseases with different susceptibility towards dithianon, with different applications per season of Dithianon 70% WG should be used to efficiently control the diseases claimed on the label.
- Compared to the Dithianon reference product, the efficacy obtained with DITHIANON 70% WG is comparable against target tested.
- The trial results are considered valid for all intended uses, considering that

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.

DITHIANON 70% WG is suitable for the control of fungi diseases in pome fruits.

According EPPO extrapolation table 14/20152 Extrapolation tables for effectiveness of fungicides, diseases on pome fruits, for use against Scab (*Venturia* spp.) indicator con is Apple and extrapolation to the whole group of pome fruits is permitted. Thus, applicant is requesting whole group of pome fruits.

This document clearly demonstrates that the efficacy and cropsafety of DITHIANON 70% WG is equivalent to the efficacy and cropsafety of the standard Dithianon reference product against which DITHIANON 70% WG 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.

### 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 sides

### Calculation of LWA

Number of trees on 1 ha soil surface:

$$\frac{10,000 \text{ (m}^2\text{)}}{(\text{m between rows}) \times (\text{m in row})} = \text{number of trees per hectare}$$

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

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	LWA (m2)
15E FPFSHA IT44	4 x 2	1250	2	10000
15E FPFSHA IT45	4 x 2	1250	2	10000
15 E IOSSHA UK114	3.5 x 2	1428	2.5	14280
1515E FPFSHA GR49	4 x 3	833	2.8	13994
15E FPFSHA PT46	2 x 5	1000	2.2-2.5	22000-25000
15E FPFSHA PT47	2 x 5	1000	2.4-2.5	24000-25000
15E FPFSHA SP40	4.5 x 1.5	1481	2	8886
15E FPFSHA SP41	6 x 6	833	3.5	34986
15E FPFSHA FR42	4 x 2	1250	1.9	9500
15E FPFSHA FR43	4.3 x 1.3	1788	3.5-3.7	16270-17200
15E FPF SHA DE54	4 x 1.6	1562	2.5	12496
15E FPFSHA FR50	4 x 1.0	2500	2.5	12500
15E FPFSHA FR51	4 x 1.2	2083	2.5	12498
15E FPFSHA RO58	4 x 2	1250	2-2.4	10000-12000
15E FPFSHA RO59	4 x 3	833	2.2-2.5	10995-12495
15E IGFP SHA HU52	2 x 4	1250	2.1	21000
15E IGFP SHA HU53	5 x 4	500	2.65	10600
15E FPFSHA PL56	3.9 x 3	855	3.2	16416
15E FPFSHA PL56	4 x 2.2	1136	3.3	16494
F-15-1-51-LGI- 2329	4 x 1.7	1470	2.7-3.2	13494-15993
F-15-1-51-LGI- 2331	3.9 x 2	1282	2.3-3.2	11794-16409
F-15-1-51-LGI- 2330	4 x 1.5	1666	2.7-3.6	13495-17992
SOP931 01, 2015/16/F	4 x 2	1250	2.5-3	12500-15000

Comments of zRMS:	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
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	<p>conditions and technical details of the spraying etc.</p> <p>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).</p> <p>The following efficacy scale was used:</p> <ul style="list-style-type: none"> <li>- L – limiting (0-60% efficacy)</li> <li>- ME – moderately efficiency (60-80%)</li> <li>- E – efficiently (&gt;80%)</li> </ul> <p>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).</p> <p>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.</p> <p>The number of trials is not sufficient in some cases and do not fulfil EPPO requirements:</p> <ul style="list-style-type: none"> <li>• <b>apple:</b> 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.</li> </ul> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>DUKES (product code: SHA 6800 A) applied in apples provided a moderate level</p>
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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 kg/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 slightly 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

	<ul style="list-style-type: none"> <li>• <b>Maritime EPPO zone:</b> 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</li> <li>• <b>North-East EPPO zone:</b> 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.</li> <li>• <b>South- East EPPO zone:</b> 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.</li> <li>• <b>MED EPPO zone:</b> 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.</li> </ul> <p>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.</p> <p>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.</p> <p>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.</p> <p>In the opinion of Evaluator, in cMS pome fruits can be accepted (extrapolations from apple to other pome crops is possible, without additional trials).</p>
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### 3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

The following dossier section follows EPPO standard PP 1/213(4) *Resistance risk analysis* in particular point 6. *Registration requirements* and Appendix I of the standard.

#### Introduction

Resistance to crop protection chemicals is a natural biological phenomenon that occurs in insects, weeds and fungi. It usually becomes evident after the repeated use of a particular pesticide selects the naturally-occurring resistant strains within the wild population and allows them to multiply over several seasons until they become dominant in the population and pose a control problem.

The fungicide-resistant population develops because the sensitive population is suppressed and the rare fungicide-resistant individual can 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.

Reports of the appearance of resistant strains in laboratory studies do not necessarily imply that any loss of control is expected in the field. Likewise, the appearance of less-sensitive strains in the field does not always result in failure of disease control. When the frequency of resistant individuals is low and/or the level of resistance is moderate, fungicide applications in most cases will provide satisfactory control.

To avoid the misinterpretation of potential and/or possible resistance cases, the Fungicide Resistance Action Committee (FRAC) states that the term resistance be limited to situations where the conditions in (a) and (b) below are met:

(a) the development of resistance leads to failure of disease control under practical field conditions following application of a fungicide correctly and according to the label and

(b) a demonstration that a loss of control is due to the presence of pathogenic strains with reduced fungicide sensitivity.

### **3.3.1 Mode of Action**

#### **Mode of Action of dithianon**

Dithianon belongs to the group of fungicides known as Quinone (anthraquinone). Dithianon is a broad spectrum, protective fungicide. The mechanism is a multi-site inhibitor of protein formation that acts by modifying the sulfhydryl groups found in the cysteine residues of many proteins. This protein inhibition prevents spore germination and germ tube growth.

Dithianon is a key component of disease control strategies on e.g. pome fruits throughout Europe due to their persistent broad-spectrum disease control. The anthraquinone fungicides (FRAC group M9) are considered at low risk to fungicide resistance development

### **3.3.2 Mechanism(s) of resistance**

#### **Mechanisms of Resistance, dithianon**

As mentioned, dithianon has multi-site mode of action and therefore resistance rarely develop. In a study conducted by Barak and Edgington (1984), thiol compounds in the fungal cells could be involved in such resistance to a multi-site fungicide like dithianon.

### **3.3.3 Evidence of resistance**

Members of the Fungicide Resistance Action Committee (FRAC) have monitored the occurrence of resistance to phthalimides across Europe. According to the FRAC, anthraquinone have never been known to encounter practical resistance, even after many years of use.

The risk for resistance for anthraquinone is according to Fungicide Resistance Action Committee (FRAC) low.

Even though resistance appears not to be a problem in the EU according to FRAC, it is of course not a guarantee that it does not exist somewhere in Europe and caution should be taken when using DITHIANON 70% WG in the recommended crops at the recommend dose rates. Furthermore, it should also be noted that diseases in the recommended crops have developed resistance (e.g. *Venturia inaequalis* in apple) against e.g. DMI's and this should also be considered when using DITHIANON 70% WG in the recommended crops. For more information please refer to FRAC website <http://www.frac.info/>.

### **3.3.4 Cross-resistance**

No cross-resistance has been reported between group members M1 to M9 (FRAC, 2020). For more information please refer to FRAC website <http://www.frac.info/>.

### **3.3.5 Sensitivity data**

Diseases vary in their sensitivity towards fungicides both between and within populations, and this natural variation should be understood before shifts in sensitivity can be assessed. Guanidines fungicides have been tested and used worldwide for up to 20 years (or more), it is therefore difficult to find unexposed fungal populations. No true base line sensitivity data can therefore be established. FRAC has been monitoring the development in sensitivity in the most important diseases for a number of years, and Sharda will work closely together with FRAC to assist with this work.

### **3.3.6 Use pattern**

Dithianon 70% WG is composed of dithianon which is a systemic fungicide with preventive and curative activity. In the EU Central zone, the formulation is proposed for control of scab (*Venturia* spp.) in apple. The fungicide is proposed applied four times during the season at the recommended dose rate (0.50 kg/ha).

The application may be employed when the climatically conditions are favourable for infestation or when warnings have been released in the different regions. This will deliver 350 g dithianon per hectare, per application.

Dithianon has been used as straight product as well as in mixtures for many years.

### **3.3.7 Resistance Risk Assessment of unrestricted use patterns**

#### **The active substance**

FRAC regards the resistance risk of the Group M9 (dithianon) as low.

#### **The disease**

The resistance risk associated with any individual disease is dependent on a number of factors related to the disease epidemiology, these include:

- Life cycle; the shorter the generation time, the more frequent the need for exposure to the fungicide and the faster the build-up of resistance.
- Abundance of sporulation; the more spores that are released in the crop the greater the availability of individual genomes for mutation and selection and the faster the spread of resistant strains.
- Isolation of pathogen populations; the more isolated the crop, through geography, or protected crops, the less chance of ingress of sensitive forms or loss of resistant forms.
- Occurrence of a sexual stage in the life cycle; this may (e.g. *Venturia* spp.).

The intended disease targets for Dithianon 70% WG vary in terms of their intrinsic resistance risk. Multi-site fungicides have been characterized by FRAC (<http://www.frac.info>) as low risk resistance but as pathogens have different risk levels, combination of both fungicide and pathogen resistance risk should also be investigated. Combined resistant risk based on inherent fungicide risk and inherent pathogen risk is described in Table

**Table 3.3.7-1: Combined resistance risk diagram based on inherent fungicide risk and inherent pathogen risk. (\* only most important classes and groups mentioned) (according to FRAC Monograph No. 2, by K.J. Brent and D.W. Hollomon, 1998)**

Fungicide class	Fungicide risk	Combine risk		
Multi-site fungicides	Low = 1	1	2	3
Pathogen risk		Low = 1	Medium = 2	High = 3
Pathogen groups		<i>Taphrina deformans</i>	<i>Alternaria solani</i> <i>Venturia carpophila</i>	<i>Venturia inaequalis</i>

From this table, 3 cases can be identified:

- Case n°1: low risk pathogen -> combined resistance risk fungicide/pathogen is equal to 1 (low).
- Case n°2: medium risk pathogen -> combined resistance risk fungicide/pathogen is equal to 2 (low).
- Case n°3: high risk pathogen -> combined resistance risk fungicide/pathogen is equal to 3 (medium).

Fungicides and pathogens are two important parameters when inherent resistance risk has to be determined. However, the local intensity of diseases development that is based on weather conditions, fertilization, irrigation, cultural practices and degree of resistance of cultivars should also be included when the resistance risk is estimated. Therefore, should be adapted and modified as follow:

**Table 3.3.7-2: Combined resistance risk diagram based on inherent fungicide risk, inherent pathogen risk and agronomic risk. (\* only most important classes and groups mentioned) (According to Kuck, 2005, “Modern fungicides and antifungal agents”, Dehne, Gisi, Kuck, Russell, eds., BCPC 2005)**

Fungicide class	Fungicide risk	Combined risk			Agronomic risk
Multi site fungicides	Low = 1	1 0.5 0.25	2 1 0.5	3 1.5 0.75	High = 1 Medium = 0.5 Low = 0.25
Pathogen risk		Low = 1	Medium = 2	High = 3	
Pathogen groups		<i>Taphrina deformans</i>	<i>Alternaria solani</i> <i>Venturia carpophila</i>	<i>Venturia inaequalis</i>	

Compared to also includes the agronomic risk to the combined inherent resistance risk fungicide/pathogen. As in 3 cases have to be considered:

- Case n°1: low risk pathogen -> combined resistance risk fungicide/pathogen/agronomic ranges from 0.25 to 1.
- Case n°2: medium risk pathogen -> combined resistance risk fungicide/pathogen/agronomic ranges from 0.5 to 2.
- Case n°3: high risk pathogen -> combined resistance risk fungicide/pathogen/agronomic range from 0.75 to 3.

Therefore, the combined resistance risk fungicide/pathogen/agronomic gives a resistance risk estimation ranging from 0.25 to 1 for *Taphrina deformans* corresponding to a low resistance risk, 0.5 to 2, for *Alternaria solani* and *Venturia carpophila* corresponding to a low resistance risk and a resistance risk estimation ranging from 0.75 to 3 for *Venturia inaequalis* corresponding to a low-medium resistance risk.

### Agronomic practice

In terms of agronomic practice, the selection pressure on the intended disease target for Dithianon 70% WG may be low to high in crops like apple and vegetables (depending on whether a successful crop rotation system is applied or mono-cropping is carried out in the crop, respectively).

#### **The plant protection product**

For optimum disease control, Dithianon 70% WG is applied at the rates recommended on the proposed label. These have been shown to be the minimum effective dose for the major target pathogen (Section 6.2.1).

### **3.3.8 Test methods**

There are several monitoring methods approved by FRAC (available on [www.frac.info](http://www.frac.info)).

### **3.3.9 Acceptability of the resistance risk**

In the absence of any potential resistance risk and in the absence of any other restrictions on the GAP (residues, toxicology etc.), the unrestricted use pattern for Dithianon 70% WG would be season long use with an unrestricted number of applications.

Overall it is clear that the unrestricted use of Dithianon 70% WG presents an unacceptable resistance risk and therefore modifiers as part of a Management Strategy are proposed.

### **3.3.10 Resistance management strategy**

As the unmodified use pattern is considered unacceptable, a number of modifiers are proposed which are entirely in accordance with the general recommendations made by FRAC.

- Use in alternation with fungicides with a different mode of action
- Use as recommended on the label. Do not use reduced doses.
- Application should be as a protective application.
- Use other measures such as resistant varieties, good agronomic practice

### **3.3.11 Implementation of the management strategy**

Information on the management of resistance and the specific Resistance Management Strategy for Dithianon 70% WG is disseminated by a number of routes including, but not exclusively:

- Product label has a clear statement regarding resistance risk and the management strategy
- Pack inserts for general information or to address a particular issue in a specific geographical area where it to occur.
- Leaflets available at, and distributed by distributors/wholesalers/merchants
- Information released by national and local advisory services re. monitoring
- FRAC publications including the web site [www.frac.info](http://www.frac.info)
- Training for distributors/wholesalers/merchants and farmer groups
- Links from company web sites to FRAC and local Fungicide Resistance working groups for information and advice

### **3.3.12 Monitoring, reporting and reaction to changes in performance**

#### Monitoring of field performance

Where field performance is significantly less than expected (relative to field trial results presented in section 6.2.1) and where no other explanation can be found for the reduced performance e.g. application errors, then samples may be taken for sensitivity testing. Where testing is carried out it will be conducted at laboratories experienced in carrying out such testing and using methods recommended by FRAC.

#### Analysis of performance-related complaints

Where no other reason for a failure in performance can be identified, samples may be taken for testing as described above

Where resistance can be confirmed as the cause for loss of field performance this will be reported to the authorities on an annual basis or as required.

#### Containment plan

The above recommendations will be adjusted as needed depending on the success of the proposed strategy. In the event that practical field resistance should occur on any significant scale, Sharda's plan for containing the further development or spread of resistance includes a number of possible actions on a temporary or permanent basis, including but not exclusively:

- Recommendations to use only fungicides from alternative mode of action groups for the remainder of the growing season
- Reduction in number of applications
- Recommendation to use only in a programme e.g. before or after an application of a fungicide from a different mode of action group.

Normally any action taken would be in consultation with the relevant authorities.

Comments of zRMS:	<p>The active substance: dithianom have been commonly used for many years in many countries. The efficacy of the substance against SCAB is well proven.</p> <p>Without any precautions the resistance risk is unacceptable. The abidance of the requirements within the good agricultural practice is necessary. The resistance management is coordinated by FRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label.</p> <p>Since the agronomic factors influencing the risk of resistance development tend to vary between the member states, the individual and detailed assessment of the resistance risk (Evaluation of the Agronomic risk of resistance, Management of resistance should be decided on national level.</p> <p><u>In Poland following restrictions should be put in the label:</u></p> <ul style="list-style-type: none"> <li>• Recommendations to use only fungicides from alternative mode of action groups for the remainder of the growing season</li> <li>• Reduction in number of applications</li> <li>• Recommendation to use only in a programme e.g. before or after an application of a fungicide from a different mode of action group</li> </ul> <p>This restriction were proposed by Applicant and accepted by Evaluator. DUKES for <i>Venturia inaequalis</i> corresponding to a low-medium resistance risk.</p>
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### **3.4 Adverse effects on treated crops (KCP 6.4)**

Information on trials submitted (3.4: Adverse effects on treated crops)

**Table 3.4-1: Presentation of efficacy trials with selectivity assesement**

Crop(s)	Target(s)*	Country	Years	Type of trial*	Number of trials (number of valid trials)				GEP, non-GEP, official**	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
Apple	<i>Venturia inaequalis</i>	Spain	2015	E + MED	-	7 (7) 2 (2)	-	6 (6)	GEP	
		Italy	2015	E + MED	-	4 (4) 2 (2)	-	-	GEP	
		Portugal	2015	E + MED	-	2 (2)	-	-	GEP	
		France	2015/ 2016	E + MED	2 (2)	2 (2)	-	-	GEP	
		Greece	2015	E + MED	-	2 (2)	-	-	GEP	
		Germany	2015	E + MED	1 (1)	-	-	-	GEP	
		Romania	2015	E + MED	-	-	2 (2)	-		
		Hungary	2015/ 2016	E + MED	-	-	2 (2)	2 (2) 3(3) 1(1)	GEP	
		Poland	2015	E + MED						
		Latvia	2015	E + MED						
		Lithuania	2015	E + MED						
Total, Apple					3 (3)	10 (10)	4 (4)	6(6)	-	

Details on methodology of the trials have been presented in Section 3.2.3

### 3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

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. The crop safety of applying DITHIANON 70% WG at the recommended rates was evaluated in 23 efficacy trials, on apple

The trials were conducted in the North-East, Mediterranean, the Maritime and the South-east EPPO zones, during 2015 and 2016 to evaluate the crop safety of DITHIANON 70% WG in apple.

#### 3.4.1.1 Apple

Phytotoxicity was evaluated in 23 efficacy trials presented in this document.

Crop phytotoxicity was evaluated in efficacy trials where DITHIANON 70% WG was applied at growth stages ranging from BBCH 11-87 at the rate of 0.75 kg/ha with 5-12 applications. Crop phytotoxicity was assessed in 23 trials at various intervals during the trials.

#### Phytotoxicity in apple trials, North East EPPO zone

A total of 6 efficacy trials were conducted in the North-east EPPO zone to assess the crop safety of DITHIANON 70% WG when applied as recommended in apple. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity were observed in any of the 6 efficacy trials conducted in the North East EPPO zone.

#### Phytotoxicity in apple trials, Maritime EPPO zone

A total of 3 efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of DITHIANON 70% WG when applied as recommended in apple. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity were observed in any of the 3 efficacy trials conducted in the Maritime EPPO zone.

#### Phytotoxicity in apple trials, South East EPPO zone

A total of 4 efficacy trials were conducted in the South East EPPO zone to assess the crop safety of DITHIANON 70% WG when applied as recommended in apple. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity were observed in any of the 4 efficacy trials conducted in the South East EPPO zone.

#### Phytotoxicity in apple trials, Mediterranean EPPO zone

A total of 10 efficacy trials were conducted in the Mediterranean EPPO zone to assess the crop safety of DITHIANON 70% WG when applied as recommended in apple. The trials were conducted on commercially available varieties. On a total of 10 trials, in 9 trials no signs of phytotoxicity were observed. Only in one French trial, variety Berthanne slight symptoms of phytotoxicity were observed but quickly disappeared.

No adverse effects in regards to phytotoxicity were observed in 9 efficacy trials conducted in the Mediterranean EPPO zone.

**Table 3.4-2: Phytotoxicity of product - Apple**

Number of trials with DITHIANON 70% WG		Efficacy trials (23 trials)							
		North-east EPPO zone (6)		Maritime EPPO zone (3)		South-east EPPO zone (4)		Mediterranean EPPO zone (10)	
		Test product	Standard	Test product	Standard	Test product	Standard	Test product	Standard
		0.75 kg/ha	0.75 kg/ha	0.75 kg/ha	0.75 kg/ha	0.75 kg/ha	0.75 kg/ha	0.75 kg/ha	0.75 kg/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	6	6	3	3	4	4	9	9
	>5% to 10%	0	0	0	0	0	0	1	1
	>10% to 15%	0	0	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	6	6	3	3	4	4	10	10
	>5% to 10%	0	0	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0	0	0

### 3.4.1.2 Overall conclusion

Pome fruits crops are claimed on the label. The claims of crop safety on these crops are supported with a total of 23 efficacy trials conducted in Poland, Latvia, Lithuania, Italy, Greece, Portugal, Spain, France, Germany, Romania and Hungary under protected conditions. DITHIANON 70% WG applied at the maximum proposed rate is safe when used on apple.

As this document also clearly demonstrates, then the efficacy and crop safety of DITHIANON 70% WG is equivalent to the standard Dithianon product to which it was compared, 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 evaluator extrapolate from those data.

Comments of zRMS:	<p>The selectivity trials about tested plant protection product have been carried out in accordance with EPPO-Guidelines PP 1/152 and PP 1/181. The conduct of the field work is principally compliant with “Good Agricultural Practice“ and in accordance with EPPO Guidelines PP 1/135.</p> <p>The trials were performed with the use of different agricultural practice. The trials were performed with the use of cultivars, differing in growth strength as well as soil and water requirements. The appropriate experimental design was applied. In all trials studied product was compared to the standard reference products. Statistical analysis of the data was performed.</p> <p>23 phytotoxicity studies were performed on apple trees:</p> <ul style="list-style-type: none"> <li>• Maritime EPPO zone – 3 trials (DE, FR-2);</li> <li>• North-East EPPO zone – 6 trials (PL-2; LT-1, LV-3);</li> <li>• South-East EPPO zone – 4 trial (HU-2; RO-2);</li> <li>• Mediterranean EPPO zone – 10 trials (FR-2, PT-2, ES-2, IT-2, GR-2).</li> </ul> <p>DUKES (product code: SHA 6800 A) applied at the lower rate (0,375 kg/ha), recommended (0,5 kg/ha) and at the 25% more than recommended dose rate (0,75 kg/ha) did not cause phytotoxicity in any of the trials conducted on apple when applied as recommended. Results were compared to standard reference product at dose 0,75 kg/ha. Detailed results are presented in BAD in Appendix 6.</p> <p>Submitted documentation is acceptable for N-E and MED EPPO zone. cMS from S-E and Maritime should decide if limited number of trials can be accepted.</p>
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### 3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

Trials with quality results are not required for Dithianon 70% WG. According to the specific EPPO PP 1/05 (3) *Venturia inaequalis*, selectivity trials are not required for fungicides. Observations for phytotoxic effects should be made in the direct efficacy (effectiveness) trials. No phytotoxicity was observed in any efficacy trial, thus no selectivity trials are required. Additionally, Table 1 in EPPO PP1/135 (4), indicate that yield in selectivity trials is not required for fungicides. Data is only required for active substances on major uses where no information on effects on yield is available. Dithianon is a well known active substance and has been registered in Europe for more than 20 years so active substance effects are well known. As per all previous references, results for yield are not required.

Comments of zRMS:	<p>ZRMs agree with Applicant. No phytotoxicity was observed in any efficacy trial, thus no selectivity trials are required. Additionally, Table 1 in EPPO PP1/135 (4), indicate that yield in selectivity trials is not required for fungicides. Data is only required for active substances on major uses where no information on effects on</p>
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	yield is available. Dithianon is a well-known active substance and has been registered in Europe for more than 20 years so active substance effects are well known.
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### 3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Trials with quality results are not required for Dithianon 70% WG. According to the specific EPPO PP 1/05 (3) *Venturia inaequalis*, selectivity trials are not required for fungicides. Observations for phytotoxic effects should be made in the direct efficacy (effectiveness) trials. No phytotoxicity was observed in any efficacy trial, thus no selectivity trials are required. Additionally, Table 1 in EPPO PP1/135 (4), indicate that yield in selectivity trials is not required for fungicides. Data is only required for active substances on major uses where no information on effects on yield is available. Dithianon is a well known active substance and has been registered in Europe for more than 20 years so active substance effects are well known. As per all previous references, results for yield are not required.

Comments of zRMS:	ZRMs agree with Applicant. No phytotoxicity was observed in any efficacy trial, thus no selectivity trials are required. Additionally, Table 1 in EPPO PP1/135 (4), indicate that yield in selectivity trials is not required for fungicides. Data is only required for active substances on major uses where no information on effects on yield is available. Dithianon is a well-known active substance and has been registered in Europe for more than 20 years so active substance effects are well known
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### 3.4.4 Effects on transformation processes (KCP 6.4.4)

There are no indications that the use of dithianon will have influence on possible transformation processes. It is therefore expected that Dithianon 70% WG, when applied in accordance with good agricultural practices will not cause any unacceptable adverse effects on transformation processes. It has already been shown in section 6.4.2 that the application of Dithianon 70% WG at the proposed label rate and rates above this rate has no negative effect on the yield assessed in efficacy trials harvested.

Other processes depend on biological activity and are referred to as 'transformation'. These include e.g. brewing and are potentially sensitive to plant protection products. Fungicides are usually only considered with regards to their potential effect on transformation processes if applied close to harvest (EPPO standard PP 1/243(1) Effects of plant protection products on transformation processes). It is also the case that if residues cannot be detected at harvest (dRR Part B Section 7) then it is reasonable to assume that the likelihood of an effect on transformation processes is greatly reduced.

Finally, it should be noted that currently, dithianon containing products do not have any label restrictions concerning their use on crops destined for processing. In addition, the active is part of many products which have been used for a long time as fungicide in e.g. apple. Since the market introduction, no effects on transformation processes have been recorded for any of these products.

Comments of zRMS:	ZRMs agree with Applicant. Dithianon containing products do not have any label restrictions concerning their use on crops destined for processing. Since, the market introduction, no effects on transformation processes have been recorded for any of these products. Also, no negative symptoms were found during trials.
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### 3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Dithianon 70% WG is composed of dithianon, which has been widely used for several years on e.g. apple, without identifying any issues in regard to ability of yield of treated plants.

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 crop safety of the product and the absence of any negative effect on the plants or plant products in the vast majority of the trials.

Comments of zRMS:	The applicant did not submit any data for propagating. However, Applicant's argumentation about regarding propagating material is accepted by Evaluator. No assessments are available. Concerned member states may decide if waiving of propagation data is acceptable.
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### 3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

#### 3.5.1 Impact on succeeding crops (KCP 6.5.1)

The impact on succeeding crops is determined in accordance with guidance provided by EPPO standard PP 1/207(2) '*Effect on succeeding crops*'.

In the study by (Ortlip C. (2001), which appears in section B9 Volumen 3 of the DAR of the dithianon with the title; *Effect of Dithianon 700 g/kg formulation at 1.4 and 1.2 kg a.i./ha on seedling emergence and vegetative vigor of seven terrestrial plant species (California Agricultural Research USA, published on 2001)* analyzes this section.

No symptoms of phytotoxicity could be seen 21 days after treatment with DELAN 70 WG (BAS 216 03F) in all plant species tested. Seedling emergence was not statically significant affected.

#### **Conclusion:**

Based on these results conducted under worst-case greenhouse conditions it can be concluded that application up to rates of 6.0 kg/ha Dithianon caused no reduced seedling emergence, plant fresh weight and no symptoms of toxicity to onion, oats, sugar beet, radish, soybean, lettuce, and field corn.

In conclusion, considering the application rates proposed and taking into account that a part of the applied substance is intercepted by the treated crops, it is concluded that significant levels of dithianon are not expected in rotational crops provided that Dithianon 70% WG is applied according to GAP.

For further information and guidance on the agronomic risk following an application of DITHIANON 70% WG, please refer to Registration Report Part B Section 9: Ecotoxicological studies.

Comments of zRMS:	There should not be any negative effect on succeeding crops when DUKES (product code: SHA 6800 A) is used as recommended. For further information and guidance on the agronomic risk following an application of DITHIANON 70% WG, please refer to Registration Report Part B Section 9: Ecotoxicological studies.
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#### 3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

During the conduct of efficacy trials, no observations about negative or positive effects on other plants or neighbouring crops were reported. Furthermore, in efficacy trials, it was demonstrated that the formulation of dithianon is not phytotoxic to the crop claimed in the GAP.

EPPO guidelines PP1/256(1) is intended to examine whether the active substance of a plant protection product can cause negative effects on crop which would be in contact with that product. Based on the

actual drift value calculated with the Ganzelmeier model and on the bio assay results from the Vegetative vigour test, TER values are obtained.

- If the active substance has no activity against plants at the highest doses tested in the bioassays. Then field trials are unnecessary.
- If the TER values are  $> 1$ . Then no further testing is necessary.
- If the TER values are  $\leq 1$ . Damage to the relevant succeeding crop is possible and further field testing is necessary as described in the EPPO guideline.

The maximum individual proposed rate of Dithianon 70% WG is 0.5 kg/ha (equivalent to 350 g dithianon/ha) and the maximum cumulative application rate per season is 2.0 L/ha (4 x 0.5 L/ha, equivalent to 1400 g dithianon/ha).

### 3.5.2.1 Dithianon

In the same study cited in the previous section, (Ortli C. (2001), which appears in section B9 Volumen 3 of the DAR of the dithianon with the title; *Effect of Dithianon 700 g/kg formulation at 1.4 and 1.2 kg a.i./ha on seedling emergence and vegetative vigor of seven terrestrial plant species (California Agricultural Research USA* , published on 2001) analyzes this section.

Greenhouse trials; 2 trials (one with pre-emergence application and one with post-emergence application), 3 variants per trial (2 treatment rates, water teated control); 4 replicate/variant; 2-3 pots/replicate, 4-25 plants per pot (species dependent). Treatments were applied pre-emergence on the soil and post-emergence at the foliage. BAS 216 03 F was applied using a belt chamber sprayer at a water rate of 400 L/ha. Following the application the plants were cultivated for 21 days in the greenhouse. Assessments for seedling emergence were done 21 days after application (DAA) for all plants. Assessments for phytotoxicity (overall injury) were done 7, 14 and 21 DAA and determination of fresh weight of the plant biomass above ground were done 21 DAA.

No symptoms of phytotoxicity could be seen 21 days after treatment with DELAN 70 WG (BAS 216 03F) in all plant species tested. Seedling emergence was not statically significant affected.

Based on these results conducted under worst-case greenhouse conditions it can be concluded that application up to rates of 6.0 kg/ha Dithianon caused no reduced seedling emergence, plant fresh weight and no symptoms of toxicity to onion, oats, sugar beet, radish, soybean, lettuce, and field corn.

Comments of zRMS:	There should not be any negative effect on adjacent crops when DUKES (product code: SHA 6800 A) is used as recommended. Dithianon caused no reduced seedling emergence, plant fresh weight and no symptoms of toxicity to onion, oats, sugar beet, radish, soybean, lettuce, and field corn.
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### 3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

From the experimentation carried out with DITHIANON 70% WG, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

### Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

Comments of zRMS:	Efficacy evaluator did not evaluate the studies to beneficial and other non-target organisms presented by the applicant. Reference should be made to the Ecotoxicology assessment. Moreover, for details concerning adverse effects on beneficial and other non-target organisms see Part B9 of the dossier (eco-toxicological data).
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#### 3.5.4 Tank cleaning

Relevant information on tank cleaning is included in dRR Part B124. Please refer to this section for complete evaluation.

Comments of zRMS:	Accepted this approach
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#### 3.6 Other/special studies

No other studies were conducted

#### 3.7 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials mentioned in this document were conducted. All facilities are certified and the trials were conducted according to GEP guidelines.

**Table 3.7-1: List of test facilities**

Test facility	GEP cert. yes/no	Country	Efficacy trials
			2015/2016
BioChem agrar GmbH	Yes	Germany (DE)	1
Promovert crop services s.l.	Yes	France (FR)	4
Agrolab	Yes	Greece (EL)	2
Promovert crop services s.l.	Yes	Italy (IT)	2
Promovert crop services s.l.	Yes	Portugal (PT)	2
Promovert crop services s.l.	Yes	Spain (ES)	2
Eurofins	Yes	Hungary (HU)	2
Eurofins	Yes	Romania (RO)	2
Field Research Support	Yes	Poland (PL)	2
Latvian Plant Protection Research Centre Ltd/ Latvia	Yes	Latvia (LV)	3
Institute of horticulture lithuanian research centre for agriculture and forestry	Yes	Lithuania (LT)	1
Total			23

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

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

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