

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: SHA 6821 A

Product name(s): PRIORITY

Chemical active substance: Dithianon 350 g/kg +

Dimethomorph 150 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España

Submission date: April 2019

MS Finalisation date: March 2022; January 2024

Version history

| When | What |
|---------------|--|
| December 2021 | Applicant updated document |
| March 2022 | ZRMs evaluated updated by Applicant dRR. |
| January 2024 | The final Registration Report |
| | |

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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 presented 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 marked by grey colour). |
|-------------------|--|

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. * | Member state(s) | Crop and/ or situation (crop destination / purpose of crop) | F, Fn, Fnp G, Gn, Gnp or I ** | Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group) | Application | | | | Application rate | | | PHI (days) | Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max) | 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 | Grapevine | F | Plasmopara viticola | Foliar spray | BBCH 55-79 | a) 3 b) 3 | 10-12 | a) 1.5 b) 4.5 | a) 0.225 dime- thomorph + 0.525 dithianon b) 0.675 dime- thomorph + 1.575 dithianon | 800-1000 | 42 | | To be con- firmed by cMS. |

* 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, Fnp: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gnp: professional and non-professional greenhouse use, I: indoor application

Column 15: zRMS conclusion.

| | |
|------|--|
| 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 35% + Dimethomorph 15% WG (SHA 6821 A / PRIORITY)** containing the active substances dithianon and dimethomorph, which both have been included into Annex I of Council Directive 91/414/EEC.

The SANCO reports for dithianon (SANCO/10349/2011 final) and dimethomorph (SANCO/10040/06 – rev. 3) are 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 reports on the active substances dithianon and dimethomorph, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11th March 2011 and 24th November 2006, respectively, shall be taken into account. Consideration of active substances for Annex I inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of dithianon and dimethomorph relating to efficacy.

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.

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

| | |
|----------------|---|
| Report: | KCP 6.0/001 Biological Assessment Dossier Dithianon 35% + Dimethomorph 15% WG, Central |
|----------------|---|

Description of the plant protection product

Dithianon 35% + Dimethomorph 15% WG is a Water Dispersible Granular (WG) formulation containing 350 grams per kilogram (g/kg) dithianon and 150 grams per kilogram (g/kg) dimethomorph for use in grapevine

Dithianon 35% + Dimethomorph 15% WG is a fungicide active against e.g. downy mildew. Its active ingredients dimethomorph and dithianon, a morpholine and a quinone respectively, have different modes of action that complement each other.

According to the GAP, the proposed application rate of Dithianon 35% + Dimethomorph 15% WG is 1.5 kilograms per hectare (kg/ha), with up to three applications per season in grapevine against Downy mildew (*Plasmopara viticola* – PLASVI). This will deliver 525 g dithianon and 225 g dimethomorph per hectare. In the current document, results obtained in field trials with Dithianon 35% + Dimethomorph 15% WG applied at 0.75 kg/ha to 1.5 kg/ha will be presented where these have been tested against comparable dose rates of dithianon reference products or dithianon + dimethomorph co-formulated reference products currently marketed in the countries where the trials were conducted.

The data presented in this dossier fully support the label claim of Dithianon 35% + Dimethomorph 15% WG for the control of Downy mildew in Grapevine, as listed in the table below.

Table 3.2-1: 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) | | | |
| Grapevine | PLASVI | CEU | 3 x 1.5 kg/ha | BBCH 55 to BBCH 79 |

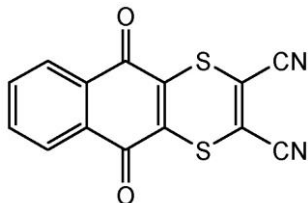
Further details are in the table “All intended uses” in Part B - Section 0.

Description of active substance dithianon

The active substance dithianon belongs to the chemical class of Quinones. Dithianon is a protective fungicide with some curative action, used to control scab, downy mildew and other foliar diseases in fruit orchards.

Today, dithianon is registered and commercialised in several formulations, as straight product as well as in mixtures, around the world.

Table 3.2-2: Identity of dithianon

| | |
|---------------------------------------|---|
| Common name | Dithianon |
| IUPAC name | 5,10-dihydro-5,10-dioxonaphtho[2,3-b]-1,4-dithiine-2,3-dicarbonitrile |
| CA name | 5,10-dihydro-5,10-dioxonaphtho(2,3-b)-1,4-dithiin-2,3-dicarbonitrile |
| CIPAC No | 153 |
| CAS Registry No. | 3347-22-6 |
| EEC No | 222-098-6 |
| Minimum purity | ≥ 930 g/kg |
| Structural formula¹ |  |
| Empirical formula | C ₁₄ H ₄ N ₂ O ₂ S ₂ |
| Molecular mass | 296.32 g/mol |

Mode of action, dithianon

Dithianon is a synthetic compound of the quinine family. It acts as a conventional, protective, broad spectrum fungicide in grapes, apples, pears and many other fruits. Dithianon is applied as a foliar spray and is surface acting. Dithianon adheres well to the surface of the leaves, and once dried gives good persistence and is relatively rainfast. It is also possible for the compound to be reactivated on the surface of the plant by rain and run off, resulting in a certain level of protection to new growth. The mode of action of dithianon is that it 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.

¹ Source: Chem Service Inc. Internet, Monday July 17th, 2017. URL: <https://www.chemservice.com/>

Dithianon is effective at controlling a wide range of fungal foliar diseases, including *Plasmopara viticola* on vines; scab on pome fruit; *Stigmina carpophila*, *Coccomyces hiemalis* and scab on cherries; *Monilinia* spp., rust and leaf curl on peaches and apricots; leaf spot and rust on currants, a.o.

FRAC (Fungicide Resistance Action Committee) presents dithianon as an anthraquinone in the group of multi-site contact fungicides. Due to its primary target site and its chemical family, in the FRAC mode of action classification, it is classified as group M9 Fungicide:

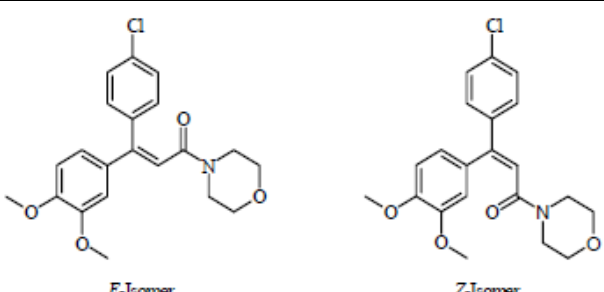
- Mode of Action: Multi-site activity.
- Chemical family: Quinones

Description of active substance dimethomorph

The active substance dimethomorph belongs to the chemical class of cinnamic acid amides. Dimethomorph is a systemic fungicide with protective activity against a broad spectrum of diseases in fruit, vegetables and other crops.

Today, dimethomorph is registered and commercialised in several formulations, as straight product as well as in mixtures, around the world.

Table 3.2-3: Identity of dimethomorph

| | |
|---------------------------------------|--|
| Common name | Dimethomorph |
| IUPAC name | (<i>E,Z</i>)-4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl]morpholine |
| CA name | (<i>E,Z</i>) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxy-phenyl)-1-oxo-2-propenyl]-morpholine |
| CIPAC No | 483 |
| CAS Registry No. | 110488-70-5 |
| EEC No | 404-200-2 |
| Minimum purity | 965 g/kg (<i>E/Z</i> isomer ratio 44/56) |
| Structural formula² |  <p style="text-align: center;"><i>E</i>-Isomer <i>Z</i>-Isomer</p> |
| Empirical formula | C ₂₁ H ₂₂ ClNO ₄ |
| Molecular mass | 387.9 g/mol |

Mode of action, dimethomorph

Dimethomorph is active against fungi in the family of Peronosporaceae and the genus *Phytophthora*. Due to its residual activity in the leaf, the fungicide provides excellent protectant control. When applied to foliage, dimethomorph penetrates leaf surfaces and is translocated within the leaf by diffusion.

When applied to roots, the compound is systemically translocated acropetally in the plant.

² Source: Het College voor de Toelating van Gewasbeschermingsmiddelen en Biociden (CTGB). Internet, Monday May 22nd, 2017. URL: http://www.ctb.agro.nl/ctb_files/11432_15.html

Dimethomorph acts by disrupting fungal cell wall formation. It acts at a unique site which interferes with normal growth and can lead to cell-wall lysis and death of the fungal cell.

Dimethomorph is active at all stages in the fungal life cycle except those of zoospore formation and motility. Fungi are particularly sensitive to the effects of dimethomorph during sporangiophore and oospore formation. When applied before sporulation, almost complete inhibition can be achieved.

FRAC (Fungicide Resistance Action Committee) presents dimethomorph as a cinnamic acid amide into the fungicide group that comprises the Carboxylic Acid Amides (abbreviated CAA fungicides). Due to its primary target site and its chemical family, in the FRAC mode of action classification, it is classified as group H5 Fungicide (FRAC MOA H5, Group code 40):

- Mode of Action: Cellulose synthesis inhibitor.
- Chemical family: Cinnamic acid amides

Summery

Dithianon 35% + Dimethomorph 15% WG, once absorbed by the leaves, has loco-systemic, trans-laminar and coverage activity that can interfere with the biochemical processes that regulate the formation of the cell wall of the fungus, causing degradation of the insulin and the consequent death of the pathogen. The active ingredients, in the complementary mechanism of action, are able to block the germination of the spores, the development of the mycelium and sporulation.

For further physico-chemical properties, please refer to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

Information on similar formulations and current approvals

Data presented in this dossier is generated using this formulation in comparison with BASF reference products containing dithianon and dimethomorph, either in co-formulation or as straight products. Dithianon as well as dimethomorph are currently registered under a variety of trade names and formulations throughout Europe and a selection of these are described in table below.

Table 3.2-4: Current approvals of dithianon as well as dimethomorph-containing products in the EU Central Zone as well as connected EPPO zones where trials were conducted

| Country | Product | Active ingredient | Approval number |
|-------------|--------------|--|------------------|
| Austria | Aktuan Gold | Dithianon 350 g/kg + Dimethomorph 150 g/kg WG | 3207 |
| Belgium | Delan 70 WG | Dithianon 700 g/kg WG | 8850P/B |
| | Paraat | Dimethomorph 500 g/kg WP | 8553P/B |
| Czech Rep. | Forum Gold | Dithianon 350 g/kg + Dimethomorph 150 g/kg WG | 5042-0 |
| France | Forum Gold | Dithianon 350 g/kg + Dimethomorph 150 g/kg WG | 2080121 |
| Germany | Forum Gold | Dithianon 350 g/kg + Dimethomorph 150 g/kg WG | 006393-00 |
| Greece | Forum Gold | Dithianon 350 g/kg + Dimethomorph 150 g/kg WG | 60462 |
| Hungary | Delan 700 WG | Dithianon 700 g/kg WG | 04.2/1418/1/2014 |
| Italy | Forum Gold | Dithianon 350 g/kg + Dimethomorph 150 g/kg WG | 12285 |
| | Forum Gold | Dithianon 350 g/kg + Dimethomorph 150 g/kg WG | 12285 |
| Netherlands | Delan DF | Dithianon 700 g/kg WG | 10001 |
| | Dimix 500 SC | Dimethomorph 500 g/L SC | 15333 |
| Portugal | Forum Gold | Dithianon 350 g/kg + Dimethomorph 150 g/kg WG | 0866 |
| Spain | Forum Gold | Dithianon 350 g/kg + Dimethomorph 150 g/kg WG | 25893 |
| | Forum | Dimethomorph 150 g/L DC | 19411 |

| Country | Product | Active ingredient | Approval number |
|---------|--------------|-------------------------|-----------------|
| UK | Dithianon WG | Dithianon 700 g/kg WG | 17018 |
| | Morph | Dimethomorph 500 g/L SC | 15121 |

Description of the target pests

Key target for this product is Downy mildew, caused by *Plasmopara viticola* in grapevine. Downy mildew of grapevine is present throughout or in parts of the Central zone and in relevant EPPO zones. The key target for this product is described in detail in the Biological Assessment dossier.

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

| EPPO code | Scientific name | Common name |
|-----------|----------------------------|---------------------------|
| PLASVI | <i>Plasmopara viticola</i> | Downy mildew of grapevine |

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 |
| Grapevine | CEU | CEU | <i>Plasmopara viticola</i> | CEU | - |

Compliance with the Uniform Principles

Comprehensive field trials were conducted in Czech Republic, Hungary, France, Spain, Italy and Greece in 2016, 2020 and 2021. 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 considering 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, 21 efficacy trials were conducted in the Maritime EPPO zone (7), the South-east EPPO zone (5) and the Mediterranean EPPO zone (9). In the 21 trials, the level of control obtained by Dithianon 35% + Dimethomorph 15% WG was assessed on downy mildew in grapevine.

Table 3.2-7: Presentation of efficacy 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 | | |
| VITVI | PLASVI | France | 2016 | MED + E | 1 (1) | 3 (3) | - | - | 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 | | |
| | | Czech Rep. | 2016 | MED + E | 2 (2) | - | - | - | GEP | |
| | | | 2021 | MED + E | 4 (4) | - | - | - | GEP | |
| | | Hungary | 2016 | MED + E | - | - | 4 (4) | - | GEP | |
| | | | 2020 | MED + E | - | - | 1 (1) | - | GEP | |
| | | Greece | 2016 | MED + E | - | 2 (2) | - | - | GEP | |
| | | Spain | 2016 | MED + P + E | - | 2 (2) | - | - | GEP | |
| | | Italy | 2016 | MED + E | - | 2 (2) | - | - | GEP | |
| | | | | | | 7 (7) | 9 (9) | 5 (5) | - | - |

In the trials used to assess the level of control obtained with Dithianon 35% + Dimethomorph 15% 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 0.5% in the untreated check or if pest incidence (PESINC) is minimum 5% in the untreated check. The data selected from each trial is either an assessment carried out at one to four weeks after the last of the max recommended number of applications (3) or the assessment carried out at a timing where the level of disease infestation in the trial was considered valid for further assessment.

Climatic zones

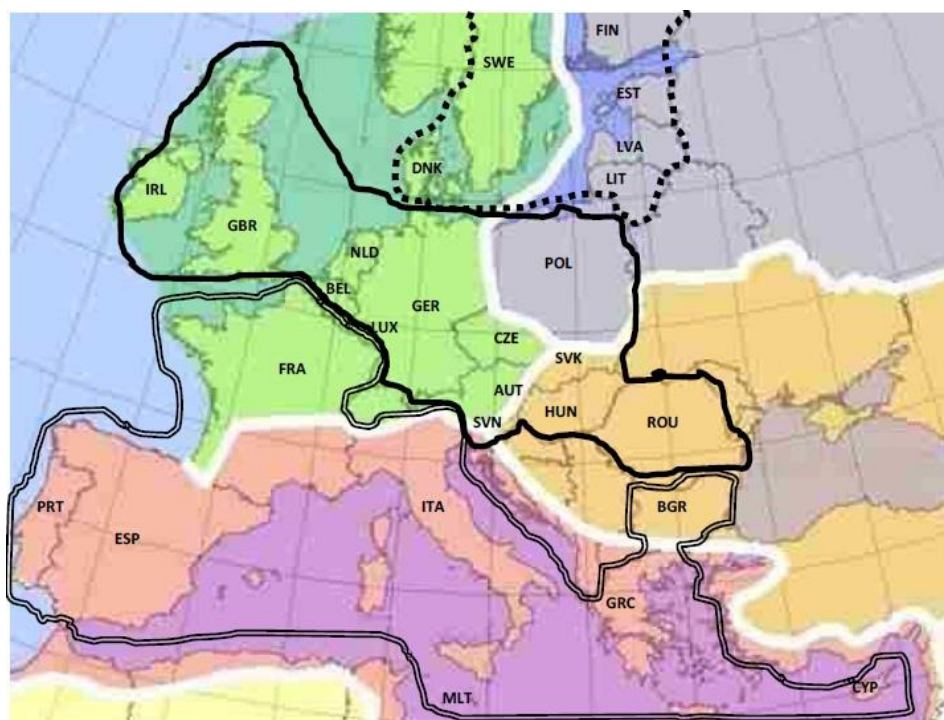
Europe is divided into four climatic zones, according to EPPO standard PP 1/241 (1). Besides providing guidance in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials are performed, the standard also supports the use of data generated in one country to support registration in another country³.

The Czech Republic and N-France are located in the EPPO Maritime zone; Hungary is located in the South-east EPPO zone: and Spain, Italy, Greece and S-France are located in the Mediterranean EPPO zone (Figure 3.2-1).

This document is prepared to support the submission of Dithianon 35% + Dimethomorph 15% WG throughout the Central Registration zone, therefore data from the Maritime and the South-east EPPO zone are included. Data obtained in Mediterranean EPPO zone has also been added as supporting information, however, the data from each climatic zone is summarised separately.

³ 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)



Agronomic conditions

Cultural conditions of the different crops 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 Central and Southern EU, but common is that downy mildew attack grapevine from the South to the North, from East to West when the weather conditions are favourable for the pests to infest the crops.

The same dithianon and/or dimethomorph containing fungicides are already registered and used in the countries where the trials were conducted to support the current application for registration. Please refer to Table 3.2-4 for the registration numbers in the different countries. In all countries, the products are registered for the same use. In each country, these are used at similar application timings when the crops are at similar growth stages.

(i) Pest physiology

The physiology of *Plasmopara viticola* is similar throughout the Central- and Southern part of Europe. Although trials were performed in different countries, sites were selected to exert maximum disease 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

Where the trials were conducted, the sites were carefully selected to ensure that for the fungal disease, the level of control was assessed on a range of populations, when treated at the recommended application timings. To exert maximum control pressure and to exacerbate treatment differences in each country, this included some trials which contained high infestation levels. 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 growing grapevine are similar throughout the Central zone as well as in connected EPPO zones where supporting trials were conducted. 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, observations on selectivity have not indicated any particular varietal sensitivity. The crop safety of Dithianon 35% + Dimethomorph 15% WG has been tested on a wide range of varieties in the efficacy trial. The results from these trials show that there are no particularly sensitive varieties. Crop tolerance and yield data generated in one country is therefore relevant in another Member state. To increase the probability of high levels of disease in the trials, the varieties chosen in each country were the ones with the least resistance to the selected disease. Therefore, the results from each country can be considered as the worst case.

(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 the specific crop 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 in any way 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 35% + Dimethomorph 15% WG, it is the applicant's contention that data from Czech Republic and Hungary is valid in demonstrating the products performance throughout the Central EU zone and the data from Spain, Italy, Greece and France is valid as supporting data.

In 17 of the 21 efficacy trials considered valid for efficacy evaluation, the performance of Dithianon 35% + Dimethomorph 15% WG was measured against a commercial standard co-formulation of dithianon and dimethomorph currently on the market in Central and Southern Europe (Forum Star and Forum Gold; 350 g/kg dithianon + 150 g/kg dimethomorph WG). In four Hungarian trials, a straight formulation of dithianon (Delan 700 WG; dithianon 700 g/kg WG) was used as reference. In two Spanish trials, a dimethomorph-containing reference product (Forum; 150 g/L dimethomorph) was also included, for comparison. In one Hungarian trial, a Dithianon + potassium phosphonates reference product (Delan Pro; 125 g/L dithianon + 561 g/L potassium phosphonate SC) was also included, for comparison. The trials were carried out on grapevine.

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

| Trade name | Formulation | Composition | Rates | Country | N° of Trials |
|---|-------------|---|------------|----------------------------|-----------------------|
| Dithianon + dimethomorph co-formulations | | | | | |
| Forum Gold | WG | 350 g/kg dithianon + 150 g/kg dimethomorph | 1.0 1.5 | CZ FR ES IT GR | 2 4 2 2 2 |
| Forum Star | WG | 350 g/kg dithianon + 150 g/kg dimethomorph | 1.5 | CZ | 4 |
| Dimethomorph | | | | | |

| Trade name | Formulation | Composition | Rates | Country | Nº of Trials |
|--|-------------|--|--------------|---------|--------------|
| Forum | DC | 150 g/L dimethomorph | 2.0 | ES | 2 |
| Dithianon | | | | | |
| Delan 700 WG | WG | 700 g/kg dithianon | 0.35 0.50 | HU | 4 |
| Dithianon + potassium phosphonates co-formulation | | | | | |
| Delan Pro | SC | 125 g/kg dithianon + 561 g/kg potassium phospho- nates | 3.0 | HU | 1 |

| | |
|-------------------|---|
| Comments of zRMS: | <p>This document summarizes the information related to the efficacy of the plant protection product – PRIORITY (product code: SHA 6821 A) and it is containing two active substances: dithianon (350 g/kg) and dimethomorph (50 g/kg). For now, this mentioned active substances are on the list of approved active substances.</p> <p>Dithianon 35% + Dimethomorph 15% WG is a Water Dispersible Granular (WG) formulation containing 350 grams per kilogram (g/kg) dithianon and 150 grams per kilogram (g/kg) dimethomorph for use in grapevine.</p> <p>Dithianon 35% + Dimethomorph 15% WG is a fungicide active against e.g., downy mildew. Its active ingredients dimethomorph and dithianon, a morpholine and a quinone respectively, have different modes of action that complement each other.</p> <p>The product – PRIORITY (product code: SHA 6821 A) by Sharda Cropchem España has not been previously evaluated in any country according to Uniform Principles.</p> <p>This document was submitted as core dossier. Poland is a ZRMs. Member States concerned by the authorization were Czech Republic, France, Greece, Spain, Italy, and Hungary.</p> |
|-------------------|---|

3.2.1 Preliminary tests (KCP 6.1)

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

| | |
|-------------------|--|
| Comments of zRMS: | <p>No results of the preliminary range-finding tests were submitted by the Applicant. The active substances of PRIORITY (product code: SHA 6821 A) – dithianon and dimethomorph are registered and has been commonly used in agricultural practice since 1993. Therefore, there was no need for preliminary range-finding tests.</p> |
|-------------------|--|

3.2.1.1 Justification of the Mixture

Dithianon 35% + Dimethomorph 15% WG is composed of dithianon and dimethomorph. These two active ingredients have different mode of actions, i.e. dithianon is a quinone with multi-site activity and dimethomorph, a CAA fungicide. Using a product which contains two modes of action will help to prevent resistance development. Dithianon 35% + Dimethomorph 15% WG mixture is designed to complement the range of activity of the individual component active substances, to provide contact- as well as systemic protection against Downy mildew in grapevine.

In four Hungarian and four Czech trials, Delan 700 WG (Dithianon 700 g/kg WG) was included to demonstrate the benefits of the mixture and that the co-formulation does not compromise the effectiveness obtained with dithianon applied alone, at comparable dose rates. Similar, in two Spanish trials, Forum (dimethomorph 150 g/L DC) was included to demonstrate the benefits of the mixture and that the co-formulation does not compromise the effectiveness obtained with dimethomorph applied alone, at comparable dose rates. Besides presenting the results obtained in these six trials in the efficacy section under the respective EPPO zones, the results are also summarised here below:

Table 3.2-9: Justification of the mixture – Maritime zone: Mean efficacy against PLASVI in Grapevine from four trials treated with Dithianon 35% + Dimethomorph 15% WG and dithianon reference products.

| Part assessed | Days after Last Treatment. (DALT) | No. of trials | Mean infestation level (%) | Efficacy obtained with | | No. of trials where Dithianon 35% + Dimethomorph 15% WG at 500 g ai/ha is >, < or =, compared to the dithianon straight Ref. product at 350 g ai/ha = : ± 5% control | | | Overall |
|----------------|-----------------------------------|---------------|----------------------------|---|----------------------------------|--|---|---|---------|
| | | | | Dithianon 35% + Dimethomorph 15% WG at: | Dithianon straight ref. prod. At | | | | |
| | | | | Mean (min-max) | | | | | |
| | | | | 350 + 150 g ai/ha | 350 g ai/ha | > | = | < | |
| Pest severity | | | | PESSEV | | | | | |
| Leaves | 9-40 DALT | 4 | 3.29 (2.18-4.93) | 91.6 (85.5-94.9) | 76.7 (75.4-83.7) | 4 | 0 | 0 | > |
| Bunches | 10-40 DALT | 4 | 0.56 (0.2-1.08) | 100 (100-100) | 69.4 (46.6-81.9) | 4 | 0 | 0 | > |
| Pest incidence | | | | PESINC | | | | | |
| Leaves | 9-40 DALT | 4 | 25.4 (19.3-38.5) | 87.9 (85.3-92.2) | 69.5 (55.8-85.6) | 3 | 1 | 0 | > |
| Bunches | 10-40 DALT | 4 | 5.98 (2.8-12.0) | 96.9 (87.5-100) | 57.0 (49.3-63.7) | 4 | 0 | 0 | > |

Table 3.2-10: Justification of the mixture – South-east zone: Mean efficacy against PLASVI in Grapevine from four trials treated with Dithianon 35% + Dimethomorph 15% WG and dithianon reference products.

| Part assessed | Days after Last Treatment. (DALT) | No. of trials | Mean infesta- tion level (%) | Efficacy obtained with | | No. of trials where Dithianon 35% + Dimethomorph 15% WG at 500 g ai/ha is >, < or =, compared to the dithianon straight Ref. product at 350 g ai/ha = : ± 5% control | | | Overall |
|------------------------------|--|---------------------|------------------------------------|--|--|---|---|---|---------|
| | | | | Dithianon 35% + Dimetho- morph 15% WG at: | Dithianon straight ref. prod. At | | | | |
| | | | | Mean (min-max) | | | | | |
| | | | | 350 + 150 g ai/ha | 350 g ai/ha | > | = | < | |
| Pest severity PESSEV | | | | | | | | | |
| Leaves | 10-11 DALT | 4 | 17.6 (1.1-55) | 95.5 (86.4-100) | 92.1 (72.7-100) | 1 | 3 | 0 | = |
| Bunches | 10-21 DALT | 3 | 13.8 (1.0-39) | 100 (100-100) | 100 (100-100) | 0 | 3 | 0 | = |
| Pest incidence PESINC | | | | | | | | | |
| Leaves | 10-14 DALT | 4 | 26.2 (5.3-83) | 95.2 (91.4-100) | 90.3 (76.8-100) | 1 | 3 | 0 | = |

| Part assessed | Days after Last Treatment. (DALT) | No. of trials | Mean infestation level (%) | Efficacy obtained with | | No. of trials where Dithianon 35% + Dimethomorph 15% WG at 500 g ai/ha is >, < or =, compared to the dithianon straight Ref. product at 350 g ai/ha = : ± 5% control | | | Overall |
|---------------|-----------------------------------|---------------|----------------------------|---|----------------------------------|--|---|---|---------|
| | | | | Dithianon 35% + Dimethomorph 15% WG at: | Dithianon straight ref. prod. At | | | | |
| | | | | Mean (min-max) | | | | | |
| | | | | 350 + 150 g ai/ha | 350 g ai/ha | > | = | < | |
| Bunches | 10-21 DALT | 3 | 15.9 (5.3-22) | 100 (100-100) | 100 (100-100) | 0 | 3 | 0 | = |

Table 3.2-11: Justification of the mixture – Mediterranean zone: Mean efficacy against PLASVI in Grapevine from two trials treated with Dithianon 35% + Dimethomorph 15% WG and dimethomorph straight reference products.

| Part assessed | Days after Treatment. No. x (DATx) | No. of trials | Mean infestation level (%) | Efficacy obtained with | | No. of trials where Dithianon 35% + Dimethomorph 15% WG at 750 g ai/ha is >, < or =, compared to the dimethomorph straight Ref. product at 300 g ai/ha = : ± 5% control | | | Overall |
|-----------------------|------------------------------------|---------------|----------------------------|---|-------------------------------------|---|---|---|---------|
| | | | | Dithianon 35% + Dimethomorph 15% WG at: | Dimethomorph straight ref. prod. at | | | | |
| | | | | Mean (min-max) | | | | | |
| | | | | 525 + 225 g ai/ha | 300 g ai/ha | > | = | < | |
| Pest severity | | | | PESSEV | | | | | |
| Leaves | 7-20 DAT3 | 2 | 2.9 (1.8-4.0) | 79.7 (77.1-82.2) | 70.9 (67.5-74.2) | 2 | 0 | 0 | > |
| Bunches | 41-49 DAT3 | 2 | 2.2 (1.7-2.7) | 71.6 (69.8-73.4) | 60.1 (55.6-64.5) | 2 | 0 | 0 | > |
| Pest incidence | | | | PESINC | | | | | |
| Leaves | 6-7 DAT3 | 2 | 15.8 (15.8-15.8) | 60.8 (60.0-61.5) | 45.8 (41.7-49.9) | 2 | 0 | 0 | > |
| Bunches | 48-49 DAT3 | 2 | 19.1 (19.0-19.3) | 53.9 (51.5-56.3) | 46.1 (45.8-46.4) | 2 | 0 | 0 | > |

Conclusion

When applied to the diseases present in the trials, Dithianon 35% + Dimethomorph 15% WG at proposed dose rates gave a more consistent and higher level of disease control compared to that of dithianon as well as dimethomorph. It is therefore considered demonstrated that the co-formulation of dithianon with dimethomorph has its justification when controlling *Plasmopara viticola* in grapevine orchards.

Combining two actives in Dithianon 35% + Dimethomorph 15% WG, which are commonly tank-mixed, also has the benefit of reducing the number of products handled by the spray operator as well as an important tool in resistance management.

3.2.1.2 Justification of Ratio of Active ingredients in the Mixture

Dithianon 35% + Dimethomorph 15% WG is a Water Dispersible Granular (WG) formulation containing 350 grams per kilogram (g/kg) dithianon and 150 grams per kilogram (g/kg) dimethomorph. The co-formulation of dithianon with dimethomorph is not new and has been registered for several years with the same ratio of active substances in markets of Europe.

| | |
|-------------------|--|
| Comments of zRMS: | Statement accepted: “Combining two actives in Dithianon 35% + Dimethomorph 15% WG, which are commonly tank-mixed, also has the benefit of reducing the number of products handled by the spray operator as well as an important tool in resistance management.” Also, the co-formulation of dithianon with dimethomorph is not new and has been |
|-------------------|--|

| | |
|--|--|
| | registered for several years with the same ratio of active substances in markets of Europe. The Concerned Member states should consider whether this is acceptable for them. |
|--|--|

3.2.2 Minimum effective dose tests (KCP 6.2)

Dithianon 35% + Dimethomorph 15% WG was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Dithianon 35% + Dimethomorph 15% WG applied at different dose rates was evaluated in 21 grapevine trials. In the 21 grapevine trials, Dithianon 35% + Dimethomorph 15% WG was applied at 0.75, 1.0 and 1.5 kg/ha for the control of *Plasmopara viticola* (PLASVI). The dose rates tested reflects 50% to 100% of the recommended rate of Dithianon 35% + Dimethomorph 15% WG, in accordance with the EPPO guideline PP 1/225(2) “Minimum effective dose”. The dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy is tested under a range of environmental conditions to fully challenge the product. Data are presented from trials conducted in the Maritime EPPO zone (i.e. N-France and Czech Republic), the South-east EPPO zone (i.e. Hungary) and the Mediterranean EPPO zone (i.e. Spain, Italy, Greece and France).

Control of *Plasmopara viticola* in grapevine

To prove and to support the proposed dose rates of 1.5 kg/ha Dithianon 35% + Dimethomorph 15% WG [525 g dithianon + 225 g dimethomorph per hectare, per application] for the control of Downy mildew (*Plasmopara viticola* (PLASVIN)) in Grapevines, the assessment results of sixteen efficacy trials performed in the Maritime EPPO zone (7), the South-east EPPO zone (5) and the Mediterranean EPPO zone (9) are reported. The trials were conducted in N-France (1), Czech Republic (6), Hungary (5), S-France (3), Spain (2), Italy (2) and Greece (2) in 2016, 2020 and 2021. Dithianon 35% + Dimethomorph 15% WG was included in these trials at 1.5 kg/ha to demonstrate the recommended dose rate as well as at two lower dose rates (0.75 kg/ha and 1.0 kg/ha [262.5 g dithianon + 112.5 g dimethomorph per hectare, per application and 350 g dithianon + 150 g dimethomorph per hectare, per application]). In the trials, specifically targeted for this pathogen, three (18) or four (3) applications were applied in the late spring/summer (May-July) at growth stages ranging between BBCH 14 and BBCH 79.

The results obtained with Dithianon 35% + Dimethomorph 15% WG applied for the control of *Plasmopara viticola* in grapevine are presented in Table 3.2-12, Table 3.2-13 and Table 3.2-14 for results obtained in the Maritime zone (seven trials), the South-east EPPO zone (five trials) and the Mediterranean EPPO zone (nine trials).

The data from the 21 trials proves that the minimum effective dose rate of Dithianon 35% + Dimethomorph 15% WG to control *Plasmopara viticola* in grapevine is 1.5 kg/ha, with up to three applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Table 3.2-12: Minimum effective dose – Maritime zone: Minimum effective dose of Dithianon 35% + Dimethomorph 15% WG against PLASVI in grapevine.

| Target: PLASVI | | No. of trials | Mean % Control from 3 trials in the Maritime EPPO Zone at a range of doses of Dithianon 35% + Dimethomorph 15% WG | | | | | | |
|---|--|---------------|--|------------|-----------|-----------|-----------|-----------|----------|
| | | | Untreated | 0.75 kg/ha | | 1.0 kg/ha | | 1.5 kg/ha | |
| | | | Mean % PESSEV (range) | Mean | Range | Mean | Range | Mean | Range |
| Grapevine | | | | | | | | | |
| Mean % control, one observation on Leaves per trial, PESSEV at 14-18 days after 3 rd appl. | | 3 | 24.5 (0.6-40.8) | 68.7 | 67.6-70.4 | 74.1 | 69.4-77.7 | 85.3 | 72.8-100 |

| | | | | | | | | |
|--|---|----------------------|-------------|--------------|-------------|--------------|-------------|--------------|
| Mean % control, one observation on Bunches per trial, PESSEV at 16-58 days after 3 rd appl. | 3 | 32.9 (0.4-97.8) | 71.1 | 65.4-80.4 | 86.7 | 66.5-100 | 94.5 | 83.4-100 |
| | | Mean % PESINC | Mean | Range | Mean | Range | Mean | Range |
| Mean % control, one observation on Leaves per trial, PESINC at 18-58 days after 3 rd appl. | 3 | 62.6 (12.3-99.5) | 47.3 | 19.6-65.3 | 55.8 | 31.2-73.5 | 64.7 | 29.2-100 |
| Mean % control, one observation on Bunches per trial, PESINC at 14-18 days after 3 rd appl. | 3 | 40.3 (10-100) | 62.6 | 39.5-82.5 | 77.7 | 38-100 | 83.2 | 49.5-100 |

Table 3.2-13: Minimum effective dose – South-east zone: Minimum effective dose of Dithianon 35% + Dimethomorph 15% WG against PLASVI in grapevine.

| Target: PLASVI | No. of trials | Mean % Control from 4 trials in the South-east EPPO Zone at a range of doses of Dithianon 35% + Dimethomorph 15% WG | | | | | | |
|---|---------------|---|-------------|--------------|-------------|--------------|-------------|--------------|
| | | Untreated | 0.75 kg/ha | | 1.0 kg/ha | | 1.5 kg/ha | |
| | | Mean % PESSEV (range) | Mean | Range | Mean | Range | Mean | Range |
| Grapevine | | | | | | | | |
| Mean % control, one observation on Leaves per trial, PESSEV at 10-11 days after 3 rd or 4 th appl. | 4 | 17.6 (1.1-55) | 93.6 | 89.4-100 | 95.5 | 86.4-100 | 98.1 | 94.5-100 |
| Mean % control, one observation on Bunches per trial, PESSEV at 10-21 days after 3 rd or 4 th appl. | 3 | 13.8 (1.0-39) | 99.6 | 98.7-100 | 100 | 100-100 | 100 | 100-100 |
| | | Mean % PESINC | Mean | Range | Mean | Range | Mean | Range |
| Mean % control, one observation on Leaves per trial, PESINC at 10-14 days after 3 rd or 4 th appl. | 4 | 26.2 (5.3-83) | 96.0 | 91.0-100 | 95.7 | 91.4-100 | 98.1 | 96.1-100 |
| Mean % control, one observation on Bunches per trial, PESINC at 10-21 days after 3 rd or 4 th appl. | 3 | 15.9 (5.3-22) | 99.9 | 99.8-100 | 100 | 100-100 | 100 | 100-100 |

Table 3.2-14: Minimum effective dose – Mediterranean zone: Minimum effective dose of Dithianon 35% + Dimethomorph 15% WG against PLASVI in grapevine.

| Target: PLASVI | No. of trials | Mean % Control from 9 trials in the Mediterranean EPPO Zone at a range of doses of Dithianon 35% + Dimethomorph 15% WG | | | | | | |
|---|---------------|--|-------------|--------------|-------------|--------------|-------------|--------------|
| | | Untreated | 0.75 kg/ha | | 1.0 kg/ha | | 1.5 kg/ha | |
| | | Mean % PESSEV (range) | Mean | Range | Mean | Range | Mean | Range |
| Grapevine | | | | | | | | |
| Mean % control, one observation on Leaves per trial, PESSEV at 4-42 days after 3 rd appl. | 9 | 7.2 (1.8-18.8) | 73.6 | 36.1-97.6 | 79.7 | 53.1-97.9 | 87.5 | 77.1-98.9 |
| Mean % control, one observation on Bunches per trial, PESSEV at 4-49 days after 3 rd appl. | 6 | 18.9 (1.0-55.7) | 79.3 | 59.3-98.7 | 84.4 | 59.6-100 | 88.6 | 69.8-100 |
| | | Mean % PESINC | Mean | Range | Mean | Range | Mean | Range |
| Mean % control, one observation on | 7 | 50.8 | 68.7 | 48.9-94.0 | 72.1 | 57.3-96.2 | 73.7 | 60.0-97.3 |

| | | | | | | | | |
|---|---|---------------------|------|-----------|------|-----------|------|-----------|
| Leaves per trial, PESINC at 4-42 days after 3 rd appl. | | (15.8-85.5) | | | | | | |
| Mean % control, one observation on Bunches per trial, PESINC at 4-49 days after 3 rd appl. | 6 | 54.3 (19.0-93.5) | 68.9 | 36.6-85.6 | 73.7 | 44.5-90.7 | 76.7 | 47.2-96.3 |

Summary and conclusions on the minimum effective dose

In summary, reducing the application rate of Dithianon 35% + Dimethomorph 15% WG from the proposed dose rates resulted in decreased efficacy against the causal agents of downy mildew in grapevine.

According to the presented results, the dose of 1.5 kg/ha per application for downy mildew in grapevine provided the optimal overall control and should be considered as effective against the disease, for which activity of Dithianon 35% + Dimethomorph 15% WG is claimed. As diseases often occur as complexes of several pathogens throughout a season, up to three applications of Dithianon 35% + Dimethomorph 15% WG at the proposed rate should be used to efficiently control the pathogen claimed on the label.

This document clearly demonstrates – as will be demonstrated in the following sections – that the efficacy and crop safety of Dithianon 35% + Dimethomorph 15% WG is equivalent to the standard dithianon + dimethomorph co-formulated reference products to which it was compared. The applicant therefore wishes to cite the data on dithianon and dimethomorph now out of protection in additional support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal and national evaluators extrapolate from those data.

| | |
|-------------------|--|
| Comments of zRMS: | <p>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.</p> <p>In the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance with EPPO 1/225 (2). Applicant carried out studies only in one season (2016) for MED EPPO zone. Two growing seasons were studied in S-E and Maritime EPPO zone. Lack of trials for N-E EPPO zone. Three different doses were assessed: 0,75 kg/ha (50% N), 1,0 kg/ha (67% N) and 1,5 kg/ha (100% N).</p> <p>For each of the dose rate treatments the mean values are given in the individual data tables presented by Applicant above for each EPPO climatic zone. The conclusion is, therefore, that in order to obtain a satisfactory level of control against downy mildew in grapevine claimed on the label, a dose rate 1,5 kg/ha of PRIORITY (product code: SHA 6821 A) provided the optimum overall control and should be considered as effective against targeted pest, for which activity of PRIORITY is claimed.</p> <p>Also, proposed dose was derived from registered doses of standard reference products with dithianon and dimethomorph as active compounds. Such products are used across Europe for many years and their MED is justified.</p> |
|-------------------|--|

3.2.3 Efficacy tests (KCP 6.2)

Efficacy data are presented from 21 efficacy trials where the disease pressure was sufficient high for the trial to be claimed valid. Results from these trials have been included in this biological assessment dossier to support the label claims and recommendations on efficacy and selectivity in the EU Central Registration zone. The trials were carried out in 2016, 2020 and 2021 in Czech Republic, Hungary, France, Spain, Greece and Italy. Efficacy was assessed on *Plasmopara viticola* (PLASVI).

In the trials used to assess the level of control obtained with Dithianon 35% + Dimethomorph 15% 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 0.5% in the untreated check or if pest incidence (PESINC) is minimum 5% in the untreated check. The data selected from each trial is either an assessment carried out at one to four weeks after the last of the max recommended number of applications (3) or the assessment carried out at a timing where the level of disease infestation in the trial was considered valid for further assessment.

In 17 of the 21 efficacy trials considered valid for efficacy evaluation, the performance of Dithianon 35% + Dimethomorph 15% WG was measured against a commercial standard co-formulation of dithianon and dimethomorph currently on the market in Central and Southern Europe (Forum Star and Forum Gold; 350 g/kg dithianon + 150 g/kg dimethomorph WG). In four Hungarian trials, a straight formulation of dithianon (Delan 700 WG; dithianon 700 g/kg WG) was used as reference. In two Spanish trials, a dimethomorph-containing reference product (Forum; 150 g/L dimethomorph) was also included, for comparison. In one Hungarian trial, a Dithianon + potassium phosphonates reference product (Delan Pro; 125 g/L dithianon + 561 g/L potassium phosphonate SC) was also included, for comparison. The trials were carried out on grapevine.

Table 3.2-15: Details on trial methodology

| | | |
|----------------------------|--|---|
| Guidelines | General guidelines | EPPO PP 1/152(4), PP 1/181(4), PP 1/135(3/4), PP 1/225(2) |
| | Specific guidelines | Grapevine: EPPO PP 1/31 (3) |
| Experimental design | Plot design | RCBD (21) |
| | Plot size | 9.8-70 m ² |
| | Number of replications | 4 (21) |
| Crop | Trials per crop | Grapevine (21) |
| | Varieties per crop | Barbara, Braucol, Chardonnay, Furmint, Grenache noir, Kékfrankos, Melon de Bourgogne, Merlot, Moschato Tirnavou, Sauvignon blanc (2), Tempranillo, Zweigelt, Blau Frankisch, Palava, Welschriesling, Pinot Gris |
| | Sowing period | n.a. |
| Application | Crop stage (BBCH)* at application | BBCH 14-74 (1 st appl.) and BBCH 56-79 (last appl.) |
| | Timing Pest stage at appl. (1) | Please refer to detailed summary tables in Appenix 5. |
| | Number of appl. Intervals between appl. | 3 (17) or 4 (3) 11-14 days |
| | Spray volumes | 300-1000 L/ha |

| | | |
|-----------------------------------|-------------------------------------|--|
| Assessment | Assessment types | <ul style="list-style-type: none"> - Visual estimation of Pest severity, compared to 'untreated' ('untreated' = 0 % control); total control = 100 % control) – based on the assessment of attacked plant area, as compared to the untreated check. - Visual estimation of Pest incidence, compared to 'untreated' ('untreated' = 0 % control); total control = 100 % control) – based on the percentage of attacked plants or plant parts on a sample of a defined number of plants/plant parts per plot, as compared to the untreated check. - Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms. - Crop yield was assessed in four efficacy trials conducted on grapevine. Yield assessments included yield of grapes [T/ha] and in two of these, also different quality parameters (i.e. sugar- and acid content). |
| | Assessment dates | 4 to 58 DALT |
| Other relevant information | Soil type | Light to heavy soils |
| | Natural / artificial inoculation... | Natural (17) Artificial (4) |
| | Field / Greenhouse... | Field |

Control of *Plasmopara viticola* in grapevine

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

| | |
|--------------------|---|
| Crop | Grapevine |
| Use rate | 1.5 kg/ha Dithianon 35% + Dimethomorph 15% WG |
| Use frequency | Up to 3x |
| Application timing | BBCH 55-79 |
| Target disease | Downy mildew (<i>Plasmopara viticola</i>) |

The effectiveness of applying Dithianon 35% + Dimethomorph 15% WG against *Plasmopara viticola* was evaluated in twenty-one grapevine trials, assessed for pest severity and pest incidence. These trials were carried out in 2016, 2020 and 2021 in the Maritime EPPO zone (i.e. N-France (1) and Czech Republic (6)), the South-east EPPO zone (i.e. Hungary (5)) and the Mediterranean EPPO zone (i.e. Spain (2), Greece (2), Italy (2) and S-France (3)). The objective was to confirm the performance of Dithianon 35% + Dimethomorph 15% WG at 1.5 kg/ha (i.e. 525 g dithianon and 225 g dimethomorph per hectare). In the trials specifically targeted for this pathogen, three (18) or four (3) applications were applied in late spring/early summer (May-July) at growth stages ranging between BBCH 14 and BBCH 79.

In the trials, Dithianon 35% + Dimethomorph 15% WG was tested alongside an EU approved dithianon + dimethomorph co-formulation, i.e. Forum Gold (CZ, FR, IT, ES and GR), Forum Star (CZ) or an EU approved dithianon straight formulation, i.e. Delan 700 WG (HU; dithianon 700 g/kg WG). In the Spanish trials, besides compared against Forum Gold, Dithianon 35% + Dimethomorph 15% WG was compared against an EU approved dimethomorph straight formulation, i.e. Forum (ES; dimethomorph 150 g/L DC).

Maritime zone

In the Maritime trials, *Plasmopara viticola* was assessed at 39 assessments, which were considered valid (i.e. PESSEV > 0.5% or PESINC > 5%). In order not to bias the data from any trials with data from more

than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-16 therefore only contains one assessment per plant part from the Maritime trials assessed repeatedly.

Table 3.2-16: Maritime zone: Efficacy of 1.5 kg/ha Dithianon 35% + Dimethomorph 15% WG and dithianon + dimethomorph co-formulated reference products at equivalent dose rate applied against *Plasmopara viticola* in grapevine in the efficacy tests – 9-58 DAT3.

| Part assessed | Days after Treatm. No. x (DATx) | No. of trials | Mean infesta- tion level (%) | Efficacy obtained with | | No. of trials where Dithianon 35% + Dimethomorph 15% WG at 750 g ai/ha is >, < or =, compared to the dithianon + dimethomorph Ref. product at 750 g ai/ha = : ± 5% control | | | Overall |
|-----------------------|--|---------------------|------------------------------------|--|--|---|----------------------|---|---------|
| | | | | Dithianon 35% + Dimetho- morph 15% WG at: | Dithianon + dimethomorph ref. prod. at | | | | |
| | | | | | | | | | |
| | | | | Mean (min-max) | | 525 + 225 g ai/ha | 525 + 225 g ai/ha | > | = |
| Pest severity | | | | PESSEV | | | | | |
| Leaves | 9-40 DAT3 | 7 | 12.4 (0.6-40.8) | 88.9 (72.8-100) | 81.7 (52.3-100) | 2 | 5 | 0 | = |
| Bunches | 10-58 DAT3 | 7 | 14.4 (0.2-97.8) | 97.6 (83.4-100) | 80.9 (40.3-100) | 4 | 3 | 0 | = |
| Pest incidence | | | | PESINC | | | | | |
| Leaves | 9-58 DAT3 | 7 | 41.3 (17.0-99.5) | 78.0 (29.2-100) | 70.5 (52.4-100) | 2 | 5 | 0 | = |
| Bunches | 10-40 DAT3 | 7 | 20.7 (2.8-100) | 91.0 (49.5-100) | 68.0 (29.9-100) | 4 | 2 | 1 | > |

The individual trial results show that Dithianon 35% + Dimethomorph 15% WG gave moderate to excellent control of *Plasmopara viticola*, equivalent to that achieved by Forum Gold (the dithianon + dimethomorph co-formulated reference product). At twelve of the 28 assessments, Dithianon 35% + Dimethomorph 15% WG performed significantly better than Forum Gold and Forum Star at comparable dose rates. At the remaining 16 assessments, no significant differences were observed between the two tested products.

South-east zone

In the South-east trials, *Plasmopara viticola* was assessed at 16 assessments, which were considered valid (i.e. PESSEV > 0.5% or PESINC > 5%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-17 therefore only contains one assessment per plant part from the South-east trials assessed repeatedly.

Table 3.2-17: South-east zone: Efficacy of 1.5 kg/ha Dithianon 35% + Dimethomorph 15% WG and dithianon straight reference products at registered dose rate applied against *Plasmopara viticola* in grapevine in the efficacy tests – 10-21 DAT3 or DAT4.

| Part assessed | Days after Last Treatment. (DALT) | No. of trials | Mean infesta- tion level (%) | Efficacy obtained with | | No. of trials where Dithianon 35% + Dimethomorph 15% WG at 750 g ai/ha is >, < or =, compared to the dithianon straight Ref. product at 350 g ai/ha = : ± 5% control | | | Overall |
|-----------------------|--|---------------------|------------------------------------|--|--|---|---|---|---------|
| | | | | Dithianon 35% + Dimetho- morph 15% WG at: | Dithianon straight ref. prod. At | | | | |
| | | | | Mean (min-max) | | | | | |
| | | | | 525 + 225 g ai/ha | 350 g ai/ha | > | = | < | |
| Pest severity | | | | PESSEV | | | | | |
| Leaves | 10-11 DALT | 4 | 17.6 (1.1-55) | 98.1 (94.5-100) | 92.1 (72.7-100) | 1 | 3 | 0 | > |
| Bunches | 10-21 DALT | 4 | 14.0 (1.0-39) | 87.5 (49.9-100) | 91.0 (64.1-100) | 0 | 3 | 1 | = |
| Pest incidence | | | | PESINC | | | | | |
| Leaves | 10-14 DALT | 4 | 26.2 (5.3-83) | 98.1 (96.1-100) | 91.3 (76.8-100) | 2 | 2 | 0 | > |

| Part assessed | Days after Last Treatment. (DALT) | No. of trials | Mean infestation level (%) | Efficacy obtained with | | No. of trials where Dithianon 35% + Dimethomorph 15% WG at 750 g ai/ha is >, < or =, compared to the dithianon straight Ref. product at 350 g ai/ha = : ± 5% control | | | Overall |
|---------------|-----------------------------------|---------------|----------------------------|---|----------------------------------|--|---|---|---------|
| | | | | Dithianon 35% + Dimethomorph 15% WG at: | Dithianon straight ref. prod. At | | | | |
| | | | | Mean (min-max) | | | | | |
| | | | | 525 + 225 g ai/ha | 350 g ai/ha | > | = | < | |
| Bunches | 10-21 DALT | 4 | 32.2 (5.3-81.0) | 84.5 (38.0-100) | 85.7 (42.6-100) | 0 | 4 | 0 | = |

The individual trial results show that Dithianon 35% + Dimethomorph 15% WG gave moderate to good control of *Plasmopara viticola*, equivalent to that achieved by Delan 700 WG (the dithianon straight reference product). At all assessments where statistical evaluation was carried out, Dithianon 35% + Dimethomorph 15% WG performed statistically equivalent to the dithianon reference product included in the trials. However, especially when evaluating foliage, the proposed dose rate of 1.5 kg/ha of Dithianon 35% + Dimethomorph 15% WG achieved consistently higher levels of control than obtained with the straight dithianon reference product.

Mediterranean zone

In the Mediterranean trials, *Plasmopara viticola* was assessed at 95 assessments, which were considered valid (i.e. PESSEV > 0.5% or PESINC > 5%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. **Table 3.2-18 and Table 3.2-19** therefore only contains one assessment per plant part from the Mediterranean trials assessed repeatedly.

Table 3.2-18: Mediterranean zone: Efficacy of 1.5 kg/ha Dithianon 35% + Dimethomorph 15% WG and dithianon + dimethomorph co-formulated reference products at equivalent dose rate applied against *Plasmopara viticola* in grapevine in the efficacy tests – 4-49 DAT3.

| Part assessed | Days after Treatm. No. x (DATx) | No. of trials | Mean infesta- tion level (%) | Efficacy obtained with | | No. of trials where Dithianon 35% + Dimethomorph 15% WG at 750 g ai/ha is >, < or =, compared to the dithianon + dimethomorph Ref. product at 750 g ai/ha = : ± 5% control | | | Overall |
|-----------------------|--|---------------------|------------------------------------|--|--|---|---|---|---------|
| | | | | Dithianon 35% + Dimetho- morph 15% WG at: | Dithianon + dimethomorph ref. prod. at | | | | |
| | | | | Mean (min-max) | | | | | |
| | | | | 525 + 225 g ai/ha | 525 + 225 g ai/ha | > | = | < | |
| Pest severity | | | | PESSEV | | | | | |
| Leaves | 4-42 DAT3 | 9 | 7.2 (1.8-18.8) | 87.5 (77.1-98.9) | 86.4 (70.4-99.4) | 3 | 5 | 1 | = |
| Bunches | 4-49 DAT3 | 7 | 16.8 (1.0-55.7) | 81.6 (40.0-100) | 81.9 (59.8-100) | 2 | 4 | 1 | = |
| Pest incidence | | | | PESINC | | | | | |
| Leaves | 4-31 DAT3 | 7 | 47.9 (15.8-85.5) | 74.4 (60.0-97.3) | 79.5 (58.4-97.8) | 0 | 6 | 1 | < |
| Bunches | 4-49 DAT3 | 7 | 48.3 (12.0-93.5) | 72.6 (43.5-96.3) | 74.9 (45.2-100) | 2 | 2 | 3 | = |

Table 3.2-19: Mediterranean zone: Efficacy of 1.5 kg/ha Dithianon 35% + Dimethomorph 15% WG and dimethomorph straight reference products at registered dose rate applied against *Plasmopara viticola* in grapevine in the efficacy tests – 6-49 DAT3.

| Part assessed | Days after Treatment. No. x (DATx) | No. of trials | Mean infestation level (%) | Efficacy obtained with | | No. of trials where Dithianon 35% + Dimethomorph 15% WG at 750 g ai/ha is >, < or =, compared to the dimethomorph straight Ref. product at 300 g ai/ha | | | Overall |
|---------------|------------------------------------|---------------|----------------------------|---|-------------------------------------|--|--|--|---------|
| | | | | Dithianon 35% + Dimethomorph 15% WG at: | Dimethomorph straight ref. prod. at | | | | |

| | | | | Mean (min-max) | | = : ± 5% control | | | |
|-----------------------|------------|---|---------------------|----------------------|---------------------|------------------|---|---|---|
| | | | | 525 + 225 g ai/ha | 300 g ai/ha | > | = | < | |
| Pest severity | | | PESSEV | | | | | | |
| Leaves | 7-20 DAT3 | 2 | 2.9 (1.8-4.0) | 79.7 (77.1-82.2) | 70.9 (67.5-74.2) | 2 | 0 | 0 | > |
| Bunches | 41-49 DAT3 | 2 | 2.2 (1.7-2.7) | 71.6 (69.8-73.4) | 60.1 (55.6-64.5) | 2 | 0 | 0 | > |
| Pest incidence | | | PESINC | | | | | | |
| Leaves | 6-7 DAT3 | 2 | 15.8 (15.8-15.8) | 60.8 (60.0-61.5) | 45.8 (41.7-49.9) | 2 | 0 | 0 | > |
| Bunches | 48-49 DAT3 | 2 | 19.1 (19.0-19.3) | 53.9 (51.5-56.3) | 46.1 (45.8-46.4) | 2 | 0 | 0 | > |

The individual trial results show that Dithianon 35% + Dimethomorph 15% WG gave moderate to excellent control of *Plasmopara viticola*, equivalent to that achieved by Forum Gold (the dithianon + dimethomorph co-formulated reference product) and superior to that achieved with Forum (the dimethomorph straight reference product). At two of the 30 assessments, Forum Gold performed significantly better than Dithianon 35% + Dimethomorph 15% WG at comparable dose rates and at two assessments, Dithianon 35% + Dimethomorph 15% WG performed significantly better than Forum Gold at comparable dose rates. At the remaining 26 assessments, no significant differences were observed between the two tested products. When compared against dimethomorph straight (Forum) at recommended dose rates, it was observed that at five of 8 assessments, Dithianon 35% + Dimethomorph 15% WG performed significantly better than the reference product. At the remaining three assessments, no significant differences were observed between the two tested products, however, the proposed dose rate of 1.5 kg/ha of Dithianon 35% + Dimethomorph 15% WG achieved consistently higher levels of control than obtained with the straight dimethomorph reference product.

Summary and conclusion

Based on the results of 21 field trials carried out in 2016, 2020 and 2021, the following can be concluded for the intended use of Dithianon 35% + Dimethomorph 15% WG applied at the dose rates of 1.5 kg/ha per application in grapevine:

- Dithianon 35% + Dimethomorph 15% WG applied in grapevine provided a moderate to excellent level control of Downy mildew of grapevine with the recommended dose rate of 1.5 kg/ha. As diseases often occur as a complex of several diseases with different susceptibility towards dimethomorph and/or dithianon, up to three applications per season of Dithianon 35% + Dimethomorph 15% WG at the 1.5 kg/ha rate should be used to efficiently control the diseases claimed on the label.
- Compared to the dithianon + dimethomorph co-formulated reference products tested, the efficacy obtained with Dithianon 35% + Dimethomorph 15% WG is comparable against *Plasmopara viticola*.
- Compared to the straight dithianon reference product, the efficacy obtained with Dithianon 35% + Dimethomorph 15% WG is comparable to slightly superior against *Plasmopara viticola*. Compared to the dimethomorph straight reference product tested, the efficacy obtained with Dithianon 35% + Dimethomorph 15% WG is comparable to superior against *Plasmopara viticola*.
- The trial results are considered valid for all intended Central zone countries.

Dithianon 35% + Dimethomorph 15% WG is suitable for the control of downy mildew in grapevine.

This document clearly demonstrates that the efficacy and crop safety of Dithianon 35% + Dimethomorph 15% WG is equivalent to the standard dithianon + dimethomorph co-formulated products and equivalent to superior to the standard dithianon straight products as well as dimethomorph straight products to which the test product was compared. The applicant therefore wishes to cite the data on dithianon and dimethomorph containing products now out of protection in additional support of those recommendations on the

draft label that are not adequately supported by the applicant's data and requests that the zonal and national evaluators extrapolate from those data.

| | |
|-------------------|--|
| Comments of zRMS: | <p>Details of experiment are presented above by Applicant. All used methodology is in accordance with GEP rules.</p> <p>Applicant submitted in total 21 efficacy trials carried out on grapevines in three different EPPO zones: Maritime (7 trials), Mediterranean (9 trials) and South-east (5 trials). The number of trials is accepted for Maritime and MED EPPO zone. cMS from S-E EPPO zone should decide if 5 trials carried out in two growing seasons (2016 and 2020) can be accepted. Lack of trials for N-E EPPO zone.</p> <p>For example, grapevines are minor crops in Poland. So, each cMS should decide if presented number of trials is sufficient according to their national rules. Usually, for minor crops it is enough to submit only 2-3 efficacy tests. In Poland we can use trials from neighbouring countries, so 6 trials from CZ are accepted for registration PRIORITY in Poland.</p> <p>During MED EPPO and Maritime EPPO zone 3 application per season were studied during efficacy trials, in S-E EPPO zone – 4 trials (however, efficacy was evaluated after 2, 3 and 4 appl.). Time between application in Maritime EPPO trials was 12-13 days, S-E EPPO zone: 11-14 days and MED EPPO zone: 11-14 days.</p> <p>Applicant carried out studies in one growing season (2016) in MED EPPO zone, which is not in line with EPPO 1/181 (4). No explanation was provided by Applicant regarding the limitation of the study to one season only. In the opinion of Evaluator, each cMS should decide whether this exception is acceptable to them. In Maritime and S-E EPPO zone two different growing seasons were studied.</p> <p>On the basis on submitted trials window application can be accepted: BBCH 55-79. PRIORITY can be used max. 3 times per season at recommended dose 1,5 kg/ha. Water: 800-1000 l/ha is also accepted (in trials volume 300-1000 l/ha was studied).</p> <ul style="list-style-type: none"> • North-East EPPO zone: <p>Lack of efficacy trials for North-East EPPO zone. For Poland we can use only trials from Czech Republic (Maritime EPPO zone) as neighbouring country to Poland. There are six field trials from Czech Republic performed in 2016 and 2021. It is worth emphasizing that in Poland (according to the register of plant protection products) so far, no plant protection product containing the same substances (dithianon and dimethomorph) as the evaluated product has been registered. In accordance with the Polish harmonization arrangements for a new mixture of substances for minor crops, the Applicant should submit at least 6 field trials carried out in 2 growing seasons. In the opinion of ZRMs, Applicant submitted enough number of trials for registration PRIORITY in Poland. The individual trial results show that Dithianon 35% + Dimethomorph 15% WG gave moderate to excellent control of <i>Plasmopara viticola</i>, equivalent to that achieved by the dithianon + dimethomorph co-formulated reference product.</p> <ul style="list-style-type: none"> • Maritime EPPO zone: <p>Applicant submitted 7 efficacy trials (1 performed in France and 6 in Czech Republic) during two growing seasons (2016 and 2021). The number of tests should be sufficient. The individual trial results show that Dithianon 35% + Dimethomorph 15% WG gave moderate to excellent control of <i>Plasmopara viticola</i>, equivalent to that achieved by the dithianon + dimethomorph co-formulated reference product.</p> |
|-------------------|--|

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| | <p>• Mediterranean EPPO zone:</p> <p>Applicant submitted in total 9 efficacy trials (France – 3 trials, Greece – 2 trials, Spain – 2 trials, Italy – 2 trials). In the opinion of Evaluator, number of trials is sufficient for major crops, according to EPPO rules.</p> <p>The individual trial results show that Dithianon 35% + Dimethomorph 15% WG gave moderate to excellent control of <i>Plasmopara viticola</i>, equivalent to that achieved by Forum Gold (the dithianon + dimethomorph co-formulated reference product) and superior to that achieved with Forum (the dimethomorph straight reference product).</p> <p>• South-East EPPO zone:</p> <p>Applicant submitted in total 5 efficacy trials performed in Hungary. Only in case, if grapevine is a minor crop the number of trials will be sufficient. For major crops at least 6 efficacy trials are required. So, in the opinion of evaluator each CMS should decide if presented documentation is sufficient.</p> <p>The individual trial results show that Dithianon 35% + Dimethomorph 15% WG gave moderate to good control of <i>Plasmopara viticola</i>, equivalent to that achieved by reference product.</p> <p>The relevance of extrapolations should be confirmed at the national level with respect to national conventions. Concerned Member States will need to consider the relevance of the submitted formulation comparability data in relation to the current authorized uses for the standard product in their own Member State.</p> <p>EFFECTIVENESS ACCORDING TO LWA APPROACH:</p> <p>According to EPPO PP 1/239, the application rate should be calculated per treated leaf wall area unit (LWA) and results of the test product should be presented and interpreted according to LWA by the applicant. The applicant did not submit any data and results related to LWA score combined with reference to ha ground area. From efficacy's point of view, the reference to ha ground area is not sufficient anymore (EPPO PP 1/239). Therefore, the Applicant calculated the LWA for PRIORITY, using the treated canopy height as well as the row distance between the rows from the single trial reports (where these parameters were available).</p> <p>Conversion of the application dose in kg/ha LWA</p> <p>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.</p> <p>An easy way to establish correct application dose in three-dimensional crops is to use dose per treated leaf area unit (LWA)</p> <p>To calculate LWA is needed to know distance between rows and between plants in the row, treated foliage height, number of sides per row.</p> <ul style="list-style-type: none"> - Distance between rows - Distance between plants in the row - Treated foliage height - Number of sides per row = 2 side <p>Calculation of LWA</p> <p>Number of trees on 1 ha soil surface:</p> <p><i>Number of trees per hectare x m in row x m crop height x number of sides = LWA (m²)</i></p> |
|--|--|

| Below LWA is calculated for each report: | | | | |
|--|--|-----------------------------|---------------------------|-----------------------|
| Trial report | Tree distance between rows x distance within row (m) | Number of trees per Hectare | Crop height (m) (average) | LWA (m ²) |
| F-111312016 (HU) | 2,1 x 1,0 | no data | no data | no data |
| F -1 1 1 1 12016 (HU) | 2,7 x 1,38 | no data | no data | no data |
| FU/PD/HU/2016/026 (HU) | 2,4 x 1,0 | 4166 | 1,78 | 14790 |
| FU-PD-HU-20S6-a2-6-PAR (HU) | 2,1 x 1,0 | 4762 | no data | no data |
| F-134-PLASVI-2020-PLA (HU) | 2,7 x 1,0 | no data | no data | no data |
| 56216-EVIF.S1 025E16S (SP) | 3,0 x 1,5 | 2222 | 1,57 | 10444 |
| 56216-EVIF.S1 026E16S (SP) | 3,0 x 1,5 | 2222 | 0,99 | 6600 |
| 055.F.SAG16/e (IT) | 2,5 x 0,9 | 4444 | 2,3 | 18398 |
| 56.F.SAG16/e (IT) | 2,8 x 0,8 | 4464 | no data | no data |
| TSTF2016061A (GR) | 2,2 x 1,1 | 4132 | 1,72 | 15606 |
| TSTF2016062A (GR) | 2,2 x 1,1 | 4132 | 1,72 | 15606 |
| FR161006AP103 (FR) | 2,0 x 1,0 | 5000 | 0,68 | 6834 |
| FR161006AS105 (FR) | 2,0 x 1,0 | 5000 | 1,7 | 17000 |
| FR161006MH110 (FR) | 2,7 x 1,1 | 3367 | 1,4 | 10370 |
| SWEPL-CZE16-DIDI-VITVI-PPT13 (CZ) | 2,5 x 1,0 | 4000 | 1,7 | 13600 |
| SWEPL-CZE16-DIDI-VITVI-PPT14 (CZ) | 3,0 x 1,0 | 3333 | 1,67 | 11110 |
| CZOR-SWE21-VITVI-008PPT (CZ) | 3,0 x 1,0 | 3333 | 1,50 | 10000 |
| CZOR-SWE21-VITVI-008PPT (CZ) | 2,4 x 0,9 | 3750 | 1,3 | 10833 |
| CZOR-SWE21-VITVI-009PPT (CZ) | 3,0 x 1,0 | 3333 | 1,4 | 9333 |
| CZOR-SWE21-VITVI-010PPT (CZ) | 2,4 x 0,9 | 4630 | 1,2 | 10000 |
| FR161006DP104 (FR) | 1,4 x 1,0 | 6000 | 1,4 | 16800 |
| <p>As can be observed, range of LWA vary between 6600 and 18398 what indicates that the ratio to calculate application per LWA should be between 0,82 and 2,27 kg/ha LWA.</p> <ul style="list-style-type: none"> • Maritime EPPO zone: range of LWA vary between 9333 and 16800 what indicates that the ratio to calculate application per LWA should be between 0,89 and 1,60 kg/ha LWA. On the basis on the average LWA (11668) the proposed dose LWA should be: 1,29 kg/ha LWA. • Mediterranean EPPO zone: range of LWA vary between 6600 and 18398 what indicates that the ratio to calculate application per LWA should be between 0,82 and 2,27 kg/ha LWA. On the basis on the average LWA (12607) the proposed dose LWA should be: 1,19 kg/ha LWA • South-East EPPO zone: LWA vary 14790 what indicates that the ratio to calculate application per LWA should be 1,01 kg/ha LWA. | | | | |

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| | <ul style="list-style-type: none">• Poland (N-E): lack of trials carried out in Poland. On the basis on results from Czech Republic and average LWA (10813), the proposed dose LWA for Poland should be: 1,39 kg/ha LWA. <p>The final decision to accept this approach and to accept the data is left to cMS</p> |
|--|--|

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 both (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

The active substance dithianon belongs to the chemical class of quinones in the group of multi-site contact fungicides and is classified in Group M9 by FRAC (FRAC MOA Code: Multi-site, Group code M9).

Dithianon is a conventional broad spectrum preventive contact fungicide. It is a multisite inhibitor that acts by modification of sulfhydryl (SH) groups found in the cysteine residues of many proteins. Dithianon was a potent inhibitor of the thiol-containing enzymes glyceraldehyde-3-phosphate dehydrogenase, glucose-6-phosphate dehydrogenase, glutathione reductase and malate dehydrogenase.

Dithianon is effective against fungi, e.g. *Venturia inaequalis*, *Venturia pirinia*, *Gloeosporium* spp. and *Nectria galligena* in pome fruit and *Plasmopara viticola* in grapes. Furthermore, it is effective against various fungi genera, e.g. *Molinia*, *Septoria*, *Sclerotinia*, *Stigmina*, *Taphrina*, *Phytophthora*, *Fusarium* and *Peronospora*, in pome- and stone fruits, leafy/fruit vegetables, etc.

Mode of action of Dimethomorph

Dimethomorph is a cinnamic acid derivative in the group of Carboxylic Acid Amide (CAA) fungicides and is classified in group H5 by FRAC (FRAC MOA Code H5, Group code 40). Dimethomorph is active against fungi in the family of Peronosporaceae and the genus *Phytophthora*. Due to its residual activity in the leaf, the fungicide provides excellent protectant control. When applied to foliage, dimethomorph penetrates leaf surfaces and is translocated within the leaf by diffusion.

When applied to roots, the compound is systemically translocated acropetally in the plant.

Dimethomorph acts by disrupting fungal cell wall formation. It acts at a unique site which interferes with normal growth and can lead to cell-wall lysis and death of the fungal cell.

Dimethomorph is active at all stages in the fungal life cycle except those of zoospore formation and motility. Fungi are particularly sensitive to the effects of dimethomorph during sporangiophore and oospore formation. When applied before sporulation, almost complete inhibition can be achieved.

3.3.2 Mechanism of resistance

Mechanisms of resistance, Dithianon

As mentioned, dithianon has multi-site mode of action and therefore resistance rarely develop.

Mechanisms of resistance, Dimethomorph

Inheritance studies (Gisi et al., 2007) have shown that sexual crosses between sensitive and CAA resistant isolates of *Plasmopara viticola* lead to a co-segregation of resistance to dimethomorph, iprovalicarb, ben-thiavalicarb and mandipropamid, but not to the phenylamide, mefenoxam, which was tested in parallel as an independent marker. Further, the inheritance studies showed that the gene(s) for resistance to CAA fungicides are inherited in a recessive manner. Therefore, the entire F1 generation of crosses between sensitive and CAA resistant isolates were sensitive, and only in the F2 progeny did CAA resistance reappear in some isolates. These results suggest that the resistance risk can be classified as moderate (as compared to high for phenylamide and QoI fungicides) and that it can be managed by appropriate product use strategies.

FRAC Guidelines for using CAA fungicides against *Plasmopara viticola* on grapevine:

Plasmopara viticola is classified by FRAC as a high risk pathogen. Long-term experience with CAA fungicides demonstrates that the resistance risk of *Plasmopara viticola* to this fungicide group is moderate and can be managed through appropriate use strategies.

- Apply CAA fungicides preferably in a preventive manner.
- Apply a maximum of 50% of the total number of applications, not exceeding a total of 4 CAA fungicide sprays during one crop cycle. In areas of high resistance, the total number should not exceed a maximum of 3 applications during one crop cycle.
- Always apply CAA fungicides in mixture with effective partners such as multis-site or other non cross resistant fungicides.
- An effective partner for a CAA fungicide is one that provides satisfactory disease control when used alone at the mixture rate.
- Alternations with fungicides having other modes of action is recommended in spray programs.

3.3.3 Evidence of resistance

Evidence of resistance, Dithianon

Members of the Fungicide Resistance Action Committee (FRAC) have monitored the occurrence of resistance to multisite fungicides across Europe. According to the FRAC, no records of practical resistance to dithianon have been recorded, even after many years of use.

The risk for resistance for dithianon 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 and caution should be taken when using Dithianon 35% + Dimethomorph 15% WG in the recommended crops at the recommended dose rates. Furthermore, it should also be noted that cases of CAA resistance in *Plasmopara viticola* have been reported and this should also be considered when using Dithianon 35% + Dimethomorph 15% WG in grapevine.

Evidence of resistance, Dimethomorph

Members of the Fungicide Resistance Action Committee (FRAC) have monitored the occurrence of resistance to CAA fungicides across Europe. According to the FRAC, isolates of *Plasmopara viticola* have been found in certain regions that are resistant to all CAA fungicides, whereas on the other hand, *Phytophthora infestans* has shown to be fully sensitive to CAA fungicides in sensitivity monitoring studies that have been conducted over several years.

The risk for resistance for CAA fungicides is according to Fungicide Resistance Action Committee (FRAC) Low to Medium.

Plasmopara viticola

In the resistance monitoring 2018 (FRAC), CAA resistant isolates of *Plasmopara viticola* were obtained in low to high frequency from grapevine growing areas in Austria, Czech Republic (2016), France, Germany, Hungary, Italy, Romania, Slovakia (2017), Slovenia (2017), Spain and Switzerland. From samples taken in Bulgaria, Portugal and Greece, no resistance was encountered.

Field performance of registered products in 2018 was good when applied in spray programmes using timely preventive applications, according to the FRAC recommendations.

3.3.4 Cross-resistance

Cross resistance among chemicals with multi-site contact activity

No cross-resistance has been reported between group members M01 to M12, to which dithianon belongs (FRAC, 2012).

Cross resistance among CAA fungicides

Cross-resistance is possible between all CAA fungicide, i.e. dimethomorph, flumorph, pyrimorph, ben-thiavalicarb, iprovalicarb, valifenalate and mandiproamid (FRAC, 2017).

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. Quinone fungicides as well as CAA fungicides have been tested and used worldwide for +30 years (or more) and 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 35% + Dimethomorph 15% WG is composed of dithianon which is a preventive contact fungicide as well as dimethomorph which is a systemic fungicide with good protective activity. In the EU Central zone, the formulation is proposed for control of downy mildew in grapevine (*Plasmopara viticola*). The fungicide is proposed applied up to three times during the season at the recommended dose rates (1.5 kg/ha).

The application may be employed when the climatic conditions are favourable for infestation or when warnings have been released in the different regions. When applied as recommended, with 1.5 kg/ha, this will deliver 525 g/ha dithianon + 225 g/ha dimethomorph per application.

Dithianon as well as dimethomorph have both been used as straight product as well as in mixtures for many years.

3.3.7 Resistance risk assessment of unrestricted use pattern

The active substances

FRAC regards the resistance risk of the Group M9 (dithianon) as low and Group 40 (dimethomorph) as low to medium.

The disease

The target disease for the use of Dithianon 35% + Dimethomorph 15% WG has been shown to be able to develop resistance to a range of fungicide groups, hereunder also CAA fungicides (e.g. Gisi *et al.*, 2007), but today, despite a long use, fungal pathogens rarely develop resistance towards dithianon. 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. *Septoria* spp.) or may not increase resistance risk (*Blumeria graminis* f. sp. *tritici*).

Plasmopara viticola, the intended disease target for Dithianon 35% + Dimethomorph 15% WG, has been characterised by FRAC as having a high inherent risk of developing resistance. The resistance risk of target pathogens of Dithianon 35% + Dimethomorph 15% WG is available at www.frac.info.

Agronomic practice

In terms of agronomic practice, the selection pressure on the intended disease target for Dithianon 35% + Dimethomorph 15% WG may be high in grapevine due to the continuous cropping in grapevine orchards.

The plant protection product

For optimum disease control, Dithianon 35% + Dimethomorph 15% 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 3.2.2).

3.3.8 Test methods

There are several monitoring methods approved by FRAC (available on 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 35% + Dimethomorph 15% WG would be season long usage with an unrestricted number of applications.

Overall it is clear that the unrestricted use of Dithianon 35% + Dimethomorph 15% 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 35% + Dimethomorph 15% 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 were 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
- 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 the change in performance

Monitoring of field performance

Where field performance is significantly less than expected (relative to field trial results presented in section 3.2.3) 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 risk for resistance for dithianon is according to Fungicide Resistance Action Committee (FRAC) low, and for dimethomorph: low to medium. In terms of agronomic practice, the selection pressure on the intended disease target for Dithianon 35% + Dimethomorph 15% WG may be high in grapevine due to the continuous cropping in grapevine orchards.</p> <p>Without any precautions the resistance risk is unacceptable. The abundance 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, Use pattern, Proposed Risk Modifiers) has to be finalized on national level.</p> |
|-------------------|--|

3.4 Adverse effects on treated crops (KCP 6.4)

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

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

As Dithianon 35% + Dimethomorph 15% 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 35% + Dimethomorph 15% WG at the recommended rates in grapevine was evaluated in 21 efficacy trials. In the efficacy trials, Dithianon 35% + Dimethomorph 15% WG was applied at 0.75 kg/ha to 1.5 kg/ha. The results obtained in these trials, where reported, are presented in Appendix 7.

The trials were conducted in the Maritime EPPO zone (7; i.e. N-France (1) and Czech Republic (6)), the South-east EPPO zone (5; i.e. Hungary) and the Mediterranean EPPO zone (9; i.e. Spain (2), Italy (2), Greece (2) and S-France (3)) in 2016, 2020 and 2021 to evaluate the crop safety of Dithianon 35% + Dimethomorph 15% WG in grapevine.

3.4.1.1 Grapevine (VITVI)

Crop phytotoxicity was evaluated in efficacy trials where Dithianon 35% + Dimethomorph 15% WG was applied at three (18) or four (3) applications, when the crop was at growth stages ranging from BBCH 14 to BBCH 79, at the rate of 0.75 to 1.5 kg/ha in grapevine. The 1.5 kg/ha dose rate corresponds to 100% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application

and up to termination of the trial.

Phytotoxicity in grapevine trials, Maritime EPPO zone

A total of **seven** efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Dithianon 35% + Dimethomorph 15% WG when applied as recommended in grapevine. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the **seven** efficacy trials treated with Dithianon 35% + Dimethomorph 15% WG.

Additionally, evaluation of the grapes and bunches harvested in **six** Czech trials confirms that the applied treatments did not have any detrimental effects on quantity nor quality of yield either.

Phytotoxicity in grapevine trials, South-east EPPO zone

A total of **five** efficacy trials were conducted in the South-east EPPO zone to assess the crop safety of Dithianon 35% + Dimethomorph 15% WG when applied as recommended in grapevine. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the **five** efficacy trials treated with Dithianon 35% + Dimethomorph 15% WG.

Phytotoxicity in grapevine trials, Mediterranean EPPO zone

A total of nine efficacy trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Dithianon 35% + Dimethomorph 15% WG when applied as recommended in grapevine. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the nine efficacy trials treated with Dithianon 35% + Dimethomorph 15% WG.

Additionally, evaluation of the grapes harvested in two Spanish trials confirms that the applied treatments did not have any detrimental effects on quantity of yield.

3.4.1.2 Overall conclusion

Dithianon 35% + Dimethomorph 15% WG applied at the recommended dose rate did not cause phytotoxicity in any of the trials conducted on grapevine when applied as recommended.

As the data on grapevine show, the crop safety of Dithianon 35% + Dimethomorph 15% WG is equivalent to that of the dithianon straight reference product, the dimethomorph straight reference product as well as the dithianon + dimethomorph co-formulated reference product tested in the trials. As comparability between the formulations has been demonstrated, the applicant therefore wishes to cite the original registrant's data on dithianon and dimethomorph now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Table 3.4-1: Phytotoxicity of product

| Number of trials with... | | Efficacy trials (21 trials) | | | |
|---|-------------|-------------------------------------|------------|-----------|-----------|
| | | Test product | Dith.+Dmm. | Dith. | Dmm |
| | | 1.5 kg/ha | 1.5 kg/ha | 0.5 kg/ha | 2.0 kg/ha |
| Maximum of phytotoxicity recorded during the trials | 0% to 5% | 21 | 17 | 4 | 2 |
| | >5% to 10% | 0 | 0 | 0 | 0 |
| | >10% to 15% | 0 | 0 | 0 | 0 |

| Number of trials with... | | Efficacy trials (21 trials) | | | |
|---|-------------|-----------------------------|------------|-----------|-----------|
| | | Test product | Dith.+Dmm. | Dith. | Dmm |
| | | 1.5 kg/ha | 1.5 kg/ha | 0.5 kg/ha | 2.0 kg/ha |
| | >15 % | 0 | 0 | 0 | 0 |
| Level of symptoms at the last assessments | 0% to 5% | 21 | 17 | 4 | 2 |
| | >5% to 10% | 0 | 0 | 0 | 0 |
| | >10% to 15% | 0 | 0 | 0 | 0 |
| | >15 % | 0 | 0 | 0 | 0 |

| | |
|-------------------|--|
| Comments of zRMS: | <p>Crop safety was assessed in 21 efficacy trials in the Maritime EPPO zone (7 trials), South-East EPPO zone (5 trials) and Mediterranean EPPO zone (9 trials). Phytotoxic effects (e.g., chlorosis, necrosis, thinning, stunting, growth inhibition, deformation, discolouration, etc.) were visually determined. According to the Applicant, no detrimental effects were observed on grapevines. All results were compared to standard reference products.</p> <p>Dithianon 35% + Dimethomorph 15% WG applied at the recommended dose rate did not cause phytotoxicity in any of the trials conducted on grapevine when applied as recommended.</p> <p>Lack of trials for N-E EPPO zone. For Poland acceptable trials are from CZ as neighbouring country.</p> |
|-------------------|--|

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

To evaluate the effect of Dithianon 35% + Dimethomorph 15% WG on the yield of grapevine, the results obtained in four efficacy trials conducted in 2016, 2020 and 2021 have been included to support the registration of Dithianon 35% + Dimethomorph 15% WG in grapevine.

In the four grapevine efficacy trials, Dithianon 35% + Dimethomorph 15% WG was applied 3 times at growth stages relevant to the proposed GAP. All trials presented in this section of the Biological Assessment Dossier were located within the Mediterranean EPPO zone (2; i.e. Spain) or the Maritime EPPO zone (6; i.e. the Czech Republic), as defined by EPPO Standard PP1/241(1).

3.4.2.1 Materials and methods

Plot yields, as weight of grapevine bunches per plot, were measured at harvest and converted to t/ha. The data of the treated plots are presented as relative values in relation to the weight of grapevine bunches harvested from the untreated plots. For further information on materials and methods used in the efficacy trials, please refer to section 3.2.3.

3.4.2.2 Summary and evaluation of the field trials conducted in grapevine, treated with three applications

A summary of the mean yield assessments, expressed as %-relative of the untreated, are presented in Table 3.4-2 for trials conducted in the Maritime EPPO zone and the Mediterranean EPPO zone.

Grapevine

A total of eight efficacy trials in grapevines were harvested. The trials were conducted in Czech Republic (6) and Spain (2) in 2016 and 2021. In the efficacy trials, Dithianon 35% + Dimethomorph 15% WG was applied with three applications at 0.75, 1.0 and 1.5 kg/ha. The trials were sprayed at crop growth stages ranging between BBCH 53 and BBCH 71. In Table 3.4-2, the results obtained in the efficacy trials when treated with 0.75 kg/ha, 1.0 kg/ha and 1.5 kg/ha are presented.

Neither Dithianon 35% + Dimethomorph 15% WG, nor the dithianon + dimethomorph co-formulated reference products (Forum Gold and Forum Star (Dithianon 35% + Dimethomorph 15% WG)) significantly affected the yield when applied at the proposed dose rate (1.5 kg/ha) in any of the eight trials. Rather, overall Dithianon 35% + Dimethomorph 15% WG provided an increase in the yielded mass of the treated crop which is most likely as a consequence of the disease control in the efficacy trials as presented in Section 3.2.3. The results obtained in the trials supports the label claim that Dithianon 35% + Dimethomorph 15% WG is safe to be applied at the recommended dose rate to grapevine at the recommended number of applications.

Table 3.4-2: Maritime and Mediterranean zone – Crop yield (t/ha) of grapevine crops treated with Dithianon 35% + Dimethomorph 15% WG, 3 applications, as % of untreated (Untreated = 100%)

| Crop, trial type | No. of trials | Untreated | Dithianon 35% + Dimethomorph 15% WG at: | | | Ref. product at: |
|--------------------|---------------|------------------|--|----------------|---------------|------------------|
| | | Mean (min-max) | % relative, compared to untreated (min-max, no. of trials) | | | |
| | | Cm or g | 0.75 kg/ha | 1.0 kg/ha | 1.5 kg/ha | 1.5 kg/ha |
| Maritime zone | 6 | 7.45 (5.0-9.6) | 101 (100-97.4) | 102 (98.1-106) | 102 (100-105) | 101 (100-105) |
| Mediterranean zone | 2 | 12.0 (10.4-13.6) | 107 (105-109) | 112 (107-118) | 117 (113-121) | 114 (111-118) |

| | |
|-------------------|--|
| Comments of zRMS: | To evaluate the effect of PRIORITY on the yield of grapevine, the results obtained in 8 efficacy trials conducted in 2016 and 2021. Trials were performed in Spain (2-Mediterranean EPPO zone) and Czech Republic (6- Maritime EPPO zone). No negative impact or dose response was recorded during submitted trials. So, the results obtained in the trials supports the label claim that Dithianon 35% + Dimethomorph 15% WG is safe to be applied at the recommended dose rate to grapevine at the recommended number of applications. |
|-------------------|--|

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Four efficacy trials treated with Dithianon 35% + Dimethomorph 15% WG were harvested and yields and/or quality of yield recorded. In two of these, assessments were conducted on the potential impact of treatment on grapevine berry acidity (acidity content) as well as sugar content of grapevine berries (Brix).

Quality of grapevine berries

The results obtained from assessments on the quality of the harvested grapevine berries are presented in Table 3.4-3.

In the trials where the parameters for quality of grapevine was evaluated, Dithianon 35% + Dimethomorph 15% WG had no detrimental effect on the quality parameters assessed on the harvested grapevine crop. When comparing the results obtained with Dithianon 35% + Dimethomorph 15% WG against the results obtained with the dithianon + dimethomorph co-formulated reference product (Forum Gold) at the applied dose rates, both products performed statistically similar.

Table 3.4-3: Quality of harvested grapevine berries – Crop treated with Dithianon 35% + Dimethomorph 15% WG with three applications in efficacy trials, as % of untreated (Untreated = 100%)

| Crop, trial type | No. of | Untreated | Dithianon 35% + Dimethomorph 15% WG at: | | | Ref. product at: |
|------------------|--------|----------------|--|--|--|------------------|
| | | Mean (min-max) | % relative, compared to untreated (min-max, no. of trials) | | | |

| | trials | % | 0.75 kg/ha | 1.0 kg/ha | 1.5 kg/ha | 1.5 kg/ha |
|----------------------|--------|-----------------|----------------|-----------------|-----------------|-----------------|
| Maritime zone | | | | | | |
| Acidity content | 6 | 10.9 (6.5-20.6) | 134 (97.1-306) | 99.2 (97.7-101) | 98.9 (94.9-100) | 99.5 (96.3-101) |
| Sugar content (Brix) | 6 | 17.2 (7.6-20.5) | 101 (100-101) | 101 (100-101) | 101 (100-105) | 101 (100-104.5) |

| | | | | | | |
|-------------------|--|--|--|--|--|--|
| Comments of zRMS: | To evaluate the effect of PRIORITY on the quality of yield of grapevine on the basis on acidity and sugar content, the results obtained in trials conducted in 2016 and 2021 in the Maritime EPPO zone. Trials were performed in Czech Republic. No negative impact or dose response was recorded during submitted trials. So, the results obtained in the trials supports the label claim that Dithianon 35% + Dimethomorph 15% WG is safe to be applied at the recommended dose rate to grapevine at the recommended number of applications. | | | | | |
|-------------------|--|--|--|--|--|--|

3.4.4 Effects on transformation processes (KCP 6.4.4)

Processing can include physical processing such as mashing of grapevine berries for must. It has already been shown in section 6.1.4.1 that the application of Dithianon 35% + Dimethomorph 15% WG at the proposed label rate and rates above this rate has no negative effect on the quality parameters assessed in 6.1.4.1.

Other processes depend on biological activity and are referred to as ‘transformation’. These include e.g. wine-making 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 4) 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 as well as dimethomorph containing products do not have any label restrictions concerning their use on crops destined for processing. In addition, both actives are part of many products which have been used for a long time as fungicide in e.g. grapevine. Since the market introduction, no effects on transformation processes have been recorded for any of these products. However, vinification tests conducted on grapes have been carried out and show no effect from Sharda Dithianon 35% + Dimethomorph 15% WG formulation or the reference product on the vinification process of treated grapes.

3.4.4.1 Vinification tests

Three field tests were conducted in the Czech Republic (CZOR-SWE16-VITVI-01PPT) and France (S16-00493-01 and S16-00493-02) by PP Trial s.r.o. and Eurofins, respectively. The objective of the studies was to investigate the potential effect of dithianon and dimethomorph on the vinification process.

Materials and Methods:

Three plot replicated trials were carried out to generate specimens of grapes for vinification and wine taint testing. In the two French trials, Forum Gold (dithianon 35% + dimethomorph 15% WG) was included as the reference standard, whereas in the Czech study, no reference product was included.

Results:

At harvest, assessments were conducted on alcohol content, acidity content, pH and sugar content. These yield quality parameters obtained in these trials are presented in Table 3.4-4.

Table 3.4-4: Quality of harvested grapevine berries – Crop treated with Dithianon 35% + Dimethomorph 15% WG with three applications in vinification studies, as % of untreated (Untreated = 100%)

| Crop, trial type | No. of trials | Untreated | Dithianon 35% + Dimethomorph 15% WG at: | Forum Gold at: |
|---------------------------|---------------|----------------|---|-----------------|
| | | | Mean (min-max) | |
| | | Mean (min-max) | 1.5 kg/ha | 1.5 kg/ha |
| Alcohol content - berries | | | | |
| Mediterranean zone | 2 | - | 10.6 (9.6-11.7) | 10.3 (9.3-10.3) |
| Maritime zone | 1 | 13.3 | 13.7 | - |
| Acidity content - berries | | | | |
| Mediterranean zone | 2 | - | 4.8 (4.0-5.6) | 4.9 (4.1-5.7) |
| Maritime zone | 1 | 7.9 | 7.9 | - |
| pH - berries | | | | |
| Mediterranean zone | 2 | - | 3.2 (3.2-3.2) | 3.2 (3.2-3.2) |
| Maritime zone | 1 | 3.0 | 3.0 | - |
| Sugar content - berries | | | | |
| Maritime zone | 1 | 20.3 | 20.3 | - |

After washing, the grapes were crushed and left for fermentation. Different parameters were assessed on the fresh must, as presented Table 3.4-5.

Table 3.4-5: Quality of fresh grapevine must – Crop treated with Dithianon 35% + Dimethomorph 15% WG with three applications in vinification studies, as % of untreated (Untreated = 100%)

| Crop, trial type | No. of trials | Untreated | Dithianon 35% + Dimethomorph 15% WG at: | Forum Gold at: |
|-------------------------------|---------------|----------------|---|------------------|
| | | | Mean (min-max) | |
| | | Mean (min-max) | 1.5 kg/ha | 1.5 kg/ha |
| Alcohol content – must | | | | |
| Mediterranean zone | 2 | - | 10.6 (9.9-11.3) | 10.8 (10.4-11.3) |
| Acidity content – must | | | | |
| Mediterranean zone | 2 | - | 4.4 (4.0-4.8) | 4.4 (3.9-4.9) |
| Maritime zone | 1 | 7.8 | 7.8 | - |
| pH – must | | | | |
| Mediterranean zone | 2 | - | 3.2 (3.0-3.4) | 3.2 (3.05-3.3) |
| Maritime zone | 1 | 3.0 | 3.0 | - |
| Sugar content – must | | | | |
| Maritime zone | 1 | 20.7 | 20.7 | - |

After fermentation, different quality parameters were assessed on the fermented product, as presented in Table 3.4-6.

Table 3.4-6: Quality of bottled wine – Crop treated with Dithianon 35% + Dimethomorph 15% WG with three applications in vinification studies, as % of untreated (Untreated = 100%)

| Crop, trial type | No. of trials | Untreated | Dithianon 35% + Dimethomorph 15% WG at: | Forum Gold at: |
|--------------------|---------------|----------------|---|------------------|
| | | | Mean (min-max) | |
| | | Mean (min-max) | 1.5 kg/ha | 1.5 kg/ha |
| Alcohol content | | | | |
| Mediterranean zone | 2 | - | 11.5 (10.7-12.3) | 11.3 (10.4-12.2) |
| Maritime zone | 1 | 13.4 | 13.4 | - |
| pH | | | | |
| Mediterranean zone | 2 | - | 3.5 (3.3-3.7) | 3.4 (3.3-3.6) |
| Maritime zone | 1 | 3.5 | 3.5 | - |
| Total acidity | | | | |
| Mediterranean zone | 2 | - | 3.1 (2.6-3.5) | 3.1 (2.8-3.5) |
| Maritime zone | 1 | 7.1 | 7.1 | - |

| Crop, trial type | No. of trials | Untreated | Dithianon 35% + Dimethomorph 15% WG at: | Forum Gold at: |
|-------------------------|---------------|----------------|---|-------------------|
| | | Mean (min-max) | | |
| | | Mean (min-max) | 1.5 kg/ha | 1.5 kg/ha |
| Volatile acidity | | | | |
| Mediterranean zone | 2 | - | 0.2 (0.1-0.3) | <0.2 (<0.1-0.3) |
| Maritime zone | 1 | 0.5 | 0.5 | - |
| Total SO2 | | | | |
| Mediterranean zone | 2 | - | 91.0 (84.0-98.0) | 95.5 (90.0-101.0) |
| Maritime zone | 1 | 181.3 | 181.7 | - |
| Free SO2 | | | | |
| Mediterranean zone | 2 | - | 30.0 (25.0-35.0) | 25.5 (24.0-27.0) |
| Maritime zone | 1 | 20.0 | 19.7 | - |
| Sugar content | | | | |
| Mediterranean zone | 2 | - | <0.2 (<0.2-<0.2) | <1.0 (<0.2-1.8) |
| Maritime zone | 1 | 3.5 | 3.6 | - |

The fresh wine was subjected to a taint test and in all three trials, no significant difference was found between the two treatments, which conclude on a non-perceptible difference between the 2 samples.

| | |
|-------------------|---|
| Comments of zRMS: | Statement accepted. Applicant submitted in total 3 field tests performed in the Czech Republic (CZOR-SWE16-VITVI-01PPT) and France (S16-00493-01 and S16-00493-02). The objective of the studies was to investigate the potential effect of dithianon and dimethomorph on the vinification process. The fresh wine was subjected to a taint test and in all three trials, no significant difference was found between the two treatments, which conclude on a non-perceptible difference between the 2 samples. |
|-------------------|---|

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Dithianon 35% + Dimethomorph 15% WG is composed of dithianon and dimethomorph, which both have been widely used for several years on e.g. grapevine, without identifying any issues in regard to the ability of treated plant part to be used for propagating purposes.

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

The product complies with the Uniform Principles.

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| Comments of zRMS: | No assessments are available. Concerned member states may decide if waiving of propagation data is acceptable. However, ZRMs agree with Applicant that: 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 and phytotoxicity assessments in the performed trials demonstrated the complete crop safety of the product and the absence of any negative effect on the plants or plant products. |
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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)

Not relevant. For the intended use of Dithianon 35% + Dimethomorph 15% WG in the EU Central zone on grapes, no rotational or succeeding crops study is required. Grapevine is a permanent crop and is not grown in rotation with other crops.

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| Comments of zRMS: | No assessment following the EPPO Standard PP 1/207 'Effects on succeeding crops' was carried out. This assessment may be waived because grapes trees are permanent crops. |
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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, it was demonstrated that the co-formulation of dithianon and dimethomorph is not phytotoxic to any of the crops claimed in the GAP.

The maximum proposed rate of application of Dithianon 35% + Dimethomorph 15% WG is 1.5 kg/ha (equivalent to 525 g dithianon/ha and 225 g dimethomorph/ha).

Dithianon

In the seedling emergence study as well as the vegetative vigor study summarized in the DAR, 7 representative species (4 dicotyledonous species and three monocotyledonous species) were tested.

No symptoms of phytotoxicity could be seen 21 days after treatment with Delan 700 WG in all plant species tested. Seedling emergence was not statistically significant affected (ANOVA, $\alpha = 0.05$).

Based on these results conducted under worst-case greenhouse conditions, it can be concluded that applications up to rates of 6.0 kg/ha Delan 700 WG (4.2 kg dithianon/ha) caused no reduced seedling emergence, plant fresh weight and no symptoms of toxicity to onion, oat, sugar beet, radish, soybean, lettuce and field corn.

The dose rates tested in seedling emergence- and vegetative vigor studies is approximately 3 and 8 times higher than applied per application, when Dithianon 35% + Dimethomorph 15% WG is applied at the max recommended dose rate.

Dimethomorph

In the seedling emergence study as well as the vegetative vigor study summarized in the DAR, 7 representative species (4 dicotyledonous species and three monocotyledonous species) were tested.

Concerning phytotoxicity and survival rate, there were no significant effects on the monocotyledonous and dicotyledonous species after soil or foliar application at 600 g dimethomorph/ha and 1800 g dimethomorph/ha. Statistical significant increases were observed on emergence rate and mean plant dry weight, which could be due to the fungicidal action of dimethomorph on plant pathogens. Decreasing effects of max. 18% were always not significant.

For soil applications, statistically significant increase of the emergence rate of *Allium cepa* and *Raphanus sativus* were observed at both rates. The plant dry weight of *Glycine max* and *Zea mays* was statistically significant increased at both application rates. For *Allium cepa* and *Raphanus sativus*, a significant increase were observed only for the higher application rate.

For foliar applications, statistically significant increase of the mean plant dry weight of *Raphanus sativus* were observed only for the lower application rate.

The dose rates tested in seedling emergence- and vegetative vigor studies is approximately 3 and 8 times higher than applied per application, when Dithianon 35% + Dimethomorph 15% WG is applied at the max recommended dose rate.

From the data available, it is concluded that the risk for terrestrial plants is low.

Conclusion

The data presented within this Annex Point justifies the recommendation of no restrictions on adjacent crops regarding the application of Dithianon 35% + Dimethomorph 15% WG.

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| Comments of zRMS: | No assessment following the EPPO Standard PP 1/256 'Effects on adjacent crops' was carried out. This assessment may be waived, since PRIORITY (product code: SHA 6821 A) does not have any herbicidal activity. |
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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 35% + Dimethomorph 15% WG in 2016, 2020 and 2021, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

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

The product complies with the Uniform Principles.

Compatibility with current management practices including IPM

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

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| Comments of zRMS: | ZRMs agree with Applicant. For more information, see the results of the standard ecotoxicological tests being presented in dRR Part B section 6. |
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3.6 Other/special studies

No other studies were conducted.

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| Comments of zRMS: | ZRMs agree. |
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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

| Testing facility | Zone | Country | Year and trial type | | |
|------------------|------|---------|---------------------|------|------|
| | | | 2016 | 2020 | 2021 |
| | | | Efficacy | | |

| Grapevine | | | | | |
|----------------------------------|-----|----|-----------|----------|----------|
| Anadiag | MAR | FR | 1 | | |
| PP Trial | MAR | CZ | 2 | | 4 |
| Gov. Office of BAZ | S-E | HU | 1 | | |
| Gov. Office of Heves | S-E | HU | 1 | | |
| Gov. Office of Komarom-Esztergom | S-E | HU | 1 | | |
| Plant.Art Research | S-E | HU | 1 | 1 | |
| GMW Bioscience S.L. | MED | ES | 2 | | |
| Sagea | MED | IT | 2 | | |
| Novacert | MED | GR | 2 | | |
| Anadiag | MED | FR | 3 | | |
| Total, Grapevine | | | 16 | 1 | 4 |

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|------------|------------|------|---|----------------------------|-------|
| CP 6.0-001 | Hjorth, S. | 2019 | Biological Assessment Dossier: Dithianon 35% + Dimethomorph 15% WG (350 g/kg dithianon + 150 g/kg dimethomorph WG) – EU Central zone Sharda Cropchem España -, - Unpublished | N | SHA |