# ctgb

#### HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

#### 1. BESLUIT

Op 15 december 2014 is van

Belchim Crop Protection N.V./S.A. Technologielaan 7 B-1840 LONDERZEEL Belgium

een aanvraag tot toelating van gewasbeschermingsmiddel met Nederland als zonaal rapporteur ontvangen als bedoeld in artikel 33 Verordening (EG) 1107/2009 (verder te noemen: de Verordening) voor het gewasbeschermingsmiddel

#### Valis M

op basis van de werkzame stoffen mancozeb en valifenalaat.

#### HET COLLEGE IS VOORNEMENS TE BESLUITEN tot toelating van bovenstaand middel.

Alle bijlagen, waaronder registratierapport deel A en deel B, vormen een onlosmakelijk onderdeel van dit besluit.

#### 1.1 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

#### 1.2 Gebruik

Het middel mag slechts worden gebruikt volgens het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.

#### 1.3 Classificatie en etikettering

Mede gelet op de onder "wettelijke grondslag" vermelde wetsartikelen, dienen alle volgende aanduidingen en vermeldingen conform de geldende regelgeving op of bij de verpakking te worden vermeld:

- De aanduidingen, <u>letterlijk en zonder enige aanvulling</u>, zoals vermeld onder "verpakkingsinformatie" in bijlage I.
- Het wettelijk gebruiksvoorschrift, <u>letterlijk en zonder enige aanvulling</u>, zoals opgenomen in deel A van het registratierapport, Appendix I.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.

#### 15718 N

 De classificatie die overeenkomstig het toelatingsbesluit is vastgesteld, moet volgens de voorschriften op de verpakking worden vermeld, zoals beschreven in bijlage II en in hoofdstuk 2 van deel A van het registratierapport.

#### 1.4 Aflever- en opgebruiktermijn (respijtperiode)

Niet van toepassing. Het betreft een nieuwe toelating.

#### 2. WETTELIJKE GRONDSLAG

Besluit	artikel 28 Verordening (EG) Nr. 1107/2009	
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009	
Gebruikt toetsingskader	Conform Bgb en Rgb d.d. 16 december 2011 en Evaluation Manual	
	Zonaal 2.0.	

#### 3. BEOORDELINGEN

#### 3.1 Fysische en chemische eigenschappen

De aard en de hoeveelheid van de werkzame stoffen en de in humaan-toxicologisch en ecotoxicologisch opzicht belangrijke onzuiverheden in de werkzame stof en de hulpstoffen zijn bepaald. De identiteit van het middel is vastgesteld. De fysische en chemische eigenschappen van het middel zijn vastgesteld en voor juist gebruik en adequate opslag van het middel aanvaardbaar geacht.

#### 3.2 Analysemethoden

De geleverde analysemethoden voldoen aan de vereisten om de residuen te kunnen bepalen die vanuit humaan-toxicologisch en ecotoxicologisch oogpunt van belang zijn, volgend uit geoorloofd gebruik.

#### 3.3 Risico voor de mens

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

#### 3.4 Risico voor het milieu

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

#### 3.5 Werkzaamheid

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften verwacht dat het werkzaam is.

Voor nadere onderbouwing van de beoordelingen verwijzen wij u naar deel A en B van het registration report als toegevoegd aan de bijlagen van dit besluit overeenkomstig Besluit beleidsregel bekendmaken delen A en B van het Registration Report.

#### Zienswijzenprocedure

Ingevolge artikel 2:3 Besluit bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden Ctgb 2007 geldt dat dit ontwerpbesluit gedurende twee weken ter inzage wordt gelegd op het Ctgb; hiervan wordt mededeling gedaan in de Staatscourant. Het ontwerpbesluit wordt gedurende deze periode tevens op de website van het Ctgb geplaatst.

Belanghebbenden kunnen gedurende de ter inzagenlegging schriftelijk bij het Ctgb aangeven dat zij een zienswijze zullen indienen; de zienswijze dient schriftelijk binnen twee weken na de inzagenperiode te worden ingediend.

Ede, 31 oktober 2018

Het College voor de toelating van gewasbeschermingsmiddelen en biociden, voor deze: de voorzitter,

Ir. J.F. de Leeuw

#### **BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING**

Aangezien Valis M een voor Nederland nieuwe werkzame stof bevat (zie hieronder), is de zienswijzenprocedure zoals bedoeld in artikel 2:3 Besluit bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden Ctgb 2007 van toepassing.

#### 2.1 Aanvraaginformatie

Aanvraagnummer:	20130916 ZTG
Type aanvraag:	Aanvraag tot toelating van gewasbeschermingsmiddel met Nederland als zonaal rapporteur
Middelnaam:	Valis M
Verzenddatum aanvraag:	12 juni 2013
Formele registratiedatum: *	16 december 2014

\* Datum waarop zowel de aanvraag is ontvangen als de aanvraagkosten zijn voldaan.

#### 2.2 Stofinformatie

Werkzame stof	Gehalte
mancozeb	60 %
Valifenalaat	6,0 %

- Mancozeb is per 1 juli 2006 geplaatst op Annex I van Richtlijn 91/414/EEG ((Dir 2005/72/EC d.d. 21 oktober 2005), en vervolgens bij Uitvoeringsverordening (EU) 540/2011 d.d. 25 mei 2011 goedgekeurd. De goedkeuring van deze werkzame stof expireert op 31 januari 2019.
- Valifenalaat is per 7 januari 2014 goedgekeurd krachtens Verordening (EG) No 1107/2009, bij uitvoeringsverordening (EU) Nr 144/2014 d.d. 14-02-2014 . De goedkeuring van deze werkzame stof expireert op 30 juni 2024.

#### 2.3 Toelatingsinformatie

Toelatingsnummer:	15718 N
Expiratiedatum:	31 januari 2020
Afgeleide parallel of origineel:	Nieuw middel
<i>Biocide, gewasbeschermingsmiddel of toevoegingsstof:</i>	Gewas
Gebruikers:	Professioneel

#### 2.4 Verpakkingsinformatie

Aard van het preparaat: Water dispergeerbaar granulaat

#### 15718 N

#### HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

#### BIJLAGE II Etikettering van het middel Valis M

Professioneel gebruik			
de identiteit van alle stoffe	n in het	mengse	l die bijdragen tot de indeling van het mengsel:
mancozeb			
Valifenalaat			
Pictogram	GHS07		
	GHS08		
	GHS09		
Signaalwoord	Waarso	huwing	
Gevarenaanduidingen	H317	Kan een	allergische huidreactie veroorzaken.
	H351	Verdach	nt van het veroorzaken van kanker.
	H361d	Wordt e	ervan verdacht het ongeboren kind te schaden.
	H410	Zeer gif	tig voor in het water levende organismen, met langdurige
	gevolge	en.	
Voorzorgsmaatregelen	P273	Voorkoi	m lozing in het milieu.
	P280	Bescher	mende handschoenen/beschermende
	kleding	/oogbes	cherming/gelaatsbescherming dragen.
	P302 +	P352	BIJ CONTACT MET DE HUID: Met veel water/ wassen.
	P308 +	P313	Na (mogelijke) blootstelling: een arts raadplegen.
	P391	Gelekte	/gemorste stof opruimen.
	P501	Inhoud/	/verpakking afvoeren naar
	SP 1	Zorg erv	voor dat u met het product of zijn verpakking geen water
	verontr	reinigt.	
Aanvullende	EUH40	1	Volg de gebruiksaanwijzing om gevaar voor de menselijke
etiketelementen	gezond	heid en l	het milieu te voorkomen.
Kinderveilige sluiting verpl	icht		Nee
Voelbare gevaarsaanduidir	ng verpli	cht	Nee

Valis M BCP382F

Page 1 of 80

REGISTRATION REPORT Part A		
Risk Management		
Product code: BCP382F Active Substances: Valifenalate 60 g/kg Mancozeb 600 g/kg		
Central Zone Zonal Rapporteur Member State: The Netherlands		
NATIONAL ASSESSMENT		
Applicant:Belchim Crop ProtectionDate:October 2018		

Valis M BCP382F

Page 2 of 80

### **Table of Contents**

PART A	– Risk Management
1	Details of the application
1.1	Application background5
1.2	Annex I inclusion
1.3	Regulatory approach5
1.4	Data protection claims
1.5	Letters of Access
2	Details of the authorisation7
2.1	Product identity7
2.2	Classification and labelling7
2.2.1	Classification and labelling under 1272/2008/EC7
2.2.3	Other phrases
2.3	Product uses applied for9
3	Risk management11
3.1	Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles
3.1.1	Physical and chemical properties (Part B, Section 1, Points 2 and 4)11
3.1.2	Methods of analysis (Part B, Section 2, Point 5)11
3.1.2.1	Analytical method for the formulation (Part B, Section 2, Point 5.2)11
3.1.2.2	Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)11
3.1.3	Mammalian Toxicology (Part B, Section 3, Point 7)12
3.1.3.1	Acute Toxicity (Part B, Section 3, Point 7.1)12
3.1.3.2	Operator Exposure (Part B, Section 3, Point 7.3)12
3.1.3.3	Bystander Exposure (Part B, Section 3, Point 7.4)13
3.1.3.4	Worker Exposure (Part B, Section 3, Point 7.5)13
3.1.5	Environmental fate and behaviour (Part B, Section 5, Point 9)16
3.1.5.1	Predicted Environmental Concentration in Soil (PECsoil) (Part B, Section 5, Points 9.4 and 9.5)
3.1.5.2	Predicted Environmental Concentration in Groundwater (PECgw) (Part B, Section 5, Point 9.6)17
3.1.5.3	Predicted Environmental Concentration in Surface Water (PECsw) (Part B, Section 5, Points 9.7 and 9.8)
3.1.5.4	Predicted Environmental Concentration in Air (PEC <sub>Air</sub> ) (Part B, Section 5, Point 9.9)

3.1.6	Ecotoxicology (Part B, Section 6, Point 10)23		
3.1.6.1	Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)23		
3.1.6.2	Effects on Aquatic Species (Part B, Section 6, Point 10.2)		
3.1.6.3	Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)		
3.1.6.4	Effects on Earthworms and Other Soil Marco-organisms (Part B, Section 6, Point 10.6)		
3.1.6.5	Effects on organic matter breakdown (Part B, Section 6, Point 10.6)28		
3.1.6.6	Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)28		
3.1.6.7	Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)		
3.1.7	Efficacy (Part B, Section 7, Point 8)		
3.2	Conclusions		
3.3	Substances of concern for national monitoring		
3.4	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation		
Appendi	ix 1: Provisional label		
Appendi	ix 2: Letter of Access		
Applica	nt has provided a letter of access to Ctgb. Appendix 3: Glossary		
Appendi	ix 4: List of data submitted in support of the evaluation40		

#### PART A – Risk Management

This document describes the acceptable use conditions required for the registration of Valis M containing Valifenalate and Mancozeb in The Netherlands. This evaluation is required subsequent to the renewal of authorisation of Valifenalate. This submission has the purpose to obtain the first registration of Valis M in The Netherlands.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C and where appropriate the addendum for The Netherlands. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national re-registration/registration by the EU review. It also includes assessment of data and information relating to Valis M where that data has not been considered in the EU review. Otherwise assessments for the safe use of Valis M have been made using endpoints agreed in the EU review of Valifenalate and Mancozeb.

This document describes the specific conditions of use and labelling required for The Netherlands for the registration of Valis M.

Appendix 1 of this document is a copy of the proposed product label for The Netherlands.

Appendix 2 of this document contains copies of the letter of access to the protected data / third party data data for the active substance Mancozeb that was needed for evaluation of the formulation.

#### **1** Details of the application

#### **1.1** Application background

This application was submitted by Belchim Crop Protection NV/SA in December 2014.

The application was for approval of Valis M, a WG containing Valifenalate 60 g/kg and Mancozeb 600 g/kg for use as a fungicide in potatoes and grapes.

#### 1.2 Annex I inclusion

Valifenalate and Mancozeb were evaluated according to of Directive 91/414 (Commission Implementing Regulation (EU) No 144/2014 for Valifenalate and Inclusion Directive 2005/72/EC for Mancozeb).

The Commission Implementing Regulation (EU) No 144/2014 for Valifenalate and Inclusion Directive 2005/72/EC for Mancozeb provide specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on Valifenalate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13.12.2013, shall be taken into account. In this overall assessment:

Member States should/must/may pay particular attention to the:

• the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate.

This concern was addressed in the submission.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on Mancozeb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 03.06.2005, shall be taken into account. In this overall assessment no particular issues for this section have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate, relevant in this section.

#### **1.3** Regulatory approach

To obtain approval the product Valis M must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

This application was submitted in order to allow the first approval of this product in The Netherlands in accordance with the above.

#### **1.4 Data protection claims**

Belchim Crop Protection NV/SA claims data protection for all newly submitted Annex II and Annex III data, which is provided to support this application.

#### **1.5** Letters of Access

A Letter of Access of Indofil Chemical Company to studies related on Mancozeb is enclosed to this submission (see appendix 2 of this document).

#### 2 Details of the authorisation

#### 2.1 **Product identity**

Product Name	VALIS M	
	Internal Product Code for Belchim : BCP382F	
	Internal Product Code of the former owner (Isagro) of the product: IR5885 M	
Authorization Number (for re- registration)	None up to now	
Function	Fungicide	
Applicant	Belchim Crop Protection NV/SA	
Composition	60 g/kg Valifenalate and 600 g/kg Mancozeb	
Formulation type	Water dispersible granules [Code : WG]	
Packaging	Carton box including 10 x 1 kg folding boxes with inner bag (PA/Al/PE)	
	Carton box including 6 x 2 kg triplex bags (PA/Al/PE)Carton box including 4 x 5 kg bags (PA/Al/PE)	
	10 kg Alu bag (multilayer structure) (paper/Al/PE) / (paper/PE/Al/PE)	

#### 2.2 Classification and labelling

#### 2.2.1 Classification and labelling under 1272/2008/EC

Based on the profile of the substance, the provided toxicology of the preparation, the characteristics of the co-formulants, the method of application and the risk assessment for the operator, as mentioned above, the following labeling of the preparation is proposed:

The identity of all substan	ces in the m	ixture that contribute to the clas	sification of the
mixture *:			
Mancozeb, valifenalate			
Pictogram:	GHS07	Signal word:	Warning
-	GHS08	-	-
	GHS09		
H-statements:	H317	May cause an allergic skin rea	action.
	H351	Suspected of causing cancer.	
	H361d	Suspected of damaging the un	ıborn child.
	H410	Very toxic to aquatic life with	long lasting effects.
P-statements:	P273	Avoid release to the environm	ient.
	P280	Wear protective gloves/protective	ctive clothing/eye protection/face
		protection.	

	P302 +	IF ON SKIN: Wash with plenty of water/
	P352	
	P308 +	IF exposed or concerned: Get medical advice/attention.
	P313	-
	P391	Collect spillage.
	P501	Dispose of contents/container to
Supplemental Hazard information:	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.
	SP1	Do not contaminate water with the product or its container.
Child-resistant fastening	obligatory?	n.a.
Tactile warning of dange	er obligatory?	n.a.

Explanation:	
Pictogram:	-
H-statements:	H351 is assigned for valifenalate based on the proposed classification in the EFSA conclusion.
P-statements:	P280 is assigned based on classification for H351 and H361d. P280c (protective gloves and clothing) is also required based on the risk assessment.
Other:	-

\* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

#### 2.2.3 Other phrases

None

#### Valis M BCP382F

Page 9 of 80

#### 2.3 **Product uses applied for**

			GAP rev. 0, date:2014-05-09
PPP (product name/code)	Valis M (BCP382F)	Formulation type:	WG
active substance 1	valifenalate	Conc. of as 1:	60 g/kg
active substance 2	mancozeb	Conc. of as 2:	600 g/kg
active substance	n/a	Conc. of as:	n/a
safener	n/a	Conc. of safener:	n/a
synergist	n/a	Conc. of synergist:	n/a
Applicant: Zone(s):	Belchim Crop Protection NV/SA Central Zone	professional use non professional use	

Verified by MS: j

1		2		3	4	5	6	7	8	10	11	12	13	14
Use- No.	e- Member state(s) Crop and/ or situation			F G	Pests or Group of pests		Application	1	A	pplication rate		PHI (days)	Remarks:	
	Registered	Ongoing	Intended	(crop destination / purpose of crop)	or I	controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	Kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
1a	-	-	NL	Potatoes SOLTU	F	Phytophthora infestans (Late blight) PHYTIN	Foliar application	BBCH 21 to 89* April – August	a) 4 € (7 5 days b) 4 € (7 5 days)	b) 10 kg/ha	a) valifenalate: 150 g/ha + mancozeb: 1500 g/ha b) valifenalate:	150-400	7	The interval between applications May vary according to the warning system *Max. one application

Applicant : Belchim Crop Protection NV/SA

#### Valis M BCP382F

Registration Report – Central Zone

Page 10 of 80

											900 600 g/ha + mancozeb: 9000 6000 g/ha			before BBCH 40 and max. three applications after BBCH40
2	<del>CZ, HU,</del> <del>RO, SK</del>	-	NL	<del>Wine grape</del> <del>VITVI</del>	Ŧ	Plasmopara viticola (Downy mildew) PLASVI	<del>Foliar</del> application	BBCH 53 to 79 15 to 83 April – August October	<del>a) 2 3 (10 days)</del> <del>b) 2 3 (10 days)</del>	<del>a) 2.0 kg/ha</del> <del>b) 4.0 kg/ha 6.0</del>	a) valifenalate: 120 g/ha + mancozeb: 1200 g/ha b) valifenalate: 360 240 g/ha + mancozeb: 3600 2400 g/ha	200- 800 1200	28	
3	<del>CZ, HU,</del> <del>RO, SK</del>	-	NL	<del>Table_grape</del> <del>VITVI</del>	Ŧ	Plasmopara viticola (Downy mildew) PLASVI	<del>Foliar</del> application	BBCH 53 to 69 15 to 69 April mid July	<del>a) 2 3 (10</del> <del>days)</del> <del>b) 2 3 (10</del> <del>days)</del>	<del>a) 2.0 kg/ha</del> <del>b) 4.0 kg/ha 6.0</del>	a) valifenalate: 120 g/ha + mancozeb: 1200 g/ha b) valifenalate: 360 240 g/ha + mancozeb: 3600 2400 g/ha	200- 800 1200	70	

#### 3 Risk management

## **3.1** Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

#### **3.1.1** Physical and chemical properties (Part B, Section 1, Points 2 and 4)

**Overall Summary:** The product Valis M is a water dispersible granule containing Valifenalate (6 % w/w corresponding to 60 g/kg) and Mancozeb (60 % w/w corresponding to 600 g/kg) active ingredients. All studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable. The appearance of the product is that of yellowish coloured, free flowing fine granule, with a faint aromatic odour. It is not explosive, has no oxidising properties. It has a self-ignition temperature of 382°C. In aqueous solution, it has a pH value around 6.49. The stability data indicate a shelf life of at least 2 years at ambient temperature in polyester/aluminium/polyethylene bags.

Its technical characteristics are acceptable for a water dispersible granule formulation, except that the suspensibility of the product at the lowest tested concentration, was below 60% after storage. It is therefore recommended to require label instructions for continuous agitation of the spray fluid during application.

Implications for labelling: continuous agitation of the spray fluid is recommended

Compliance with FAO specifications: The product Valis M complies with FAO specifications.

**Compatibility of mixtures:** Tank mixtures with the product are not foreseen

**Nature and characteristics of the packaging:** Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

**Nature and characteristics of the protective clothing and equipment:** Information regarding the required protective clothing and equipment for the safe handling of Valis M has been provided and is considered to be acceptable.

#### **3.1.2** Methods of analysis (Part B, Section 2, Point 5)

#### **3.1.2.1** Analytical method for the formulation (Part B, Section 2, Point 5.2)

Analytical methods for determination of Valifenalate and Mancozeb and their impurities and relevance of CIPAC methods in Valis M were not evaluated as part of the EU review of Valifenalate. Therefore all relevant data are provided and are considered adequate.

For mancozeb a iodometric titration method is available. Valifenalate and ETU are determined using HPLC methods.

#### 3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)

For both Valifenalate and Mancozeb an adequate set of residue analytical methods is available. A new method for the determination of Valifenalate in surface water was included in the submission, which was sufficient to address the national requirement of an LOQ of  $0.1 \mu g/L$  in surface water.

#### 3.1.3 Mammalian Toxicology (Part B, Section 3, Point 7)

The Plant Protection Product Valis M containing 60 g/kg Valifenalate and 600 g/kg Mancozeb is intended to be used outdoors on vine (table grapes and vine grapes) and potatoes as a fungicide. The product is a WG formulation commercialized in standard containers.

#### 3.1.3.1 Acute Toxicity (Part B, Section 3, Point 7.1)

Acute toxicity studies for Valis M were not evaluated as part of the EU review of the active substances Valifenalate and Mancozeb. Therefore, all relevant data were provided in the Core Assessment (Part B3) and are considered adequate.

Valis M containing 60 g Valifenalate/kg and 600 g Mancozeb/kg has a low toxicity with respect to acute oral and dermal toxicity and has not to be classified as irritant to the rabbit's skin and eye. Since it is a skin sensitizer, it has been found to be classified with H317. The classification according to Regulation (EC) No 1272/2008 as amended is given in the table below.

Parameter [Reference]	Species	Result [mg/kg or mg/m³ or effect]	Classification according Regulation (EC) No 1272/2008 as amended
Acute oral toxicity	Rat (female)	$LD_{50}$ > 5000 mg/kg bw	None
Acute dermal toxicity	Rat (male/female)	$LD_{50} > 5000 \text{ mg/kg bw}$	None
Acute inhalation toxicity*	-	-	-
Skin irritation	Rabbit (female)	Slightly irritating	None
Eye irritation	Rabbit (female)	Slightly irritating	None
Skin sensitisation	Guinea-pig (female)	Sensitising	H317

Table 3.1.3.1-1:Acute toxicological data obtained with Valis M

\* A statement on acute inhalation toxicity is provided which demonstrates that there is no need to classify the product (see MIIA 7.1.3).

#### **3.1.3.2** Operator Exposure (Part B, Section 3, Point 7.3)

Operator exposure to Valis M was not evaluated as part of the EU review of Valifenalate and Mancozeb.

Operator exposure was assessed against the AOEL for Valifenalate agreed in the EU review (0.07 mg/kg bw/d) and against the AOEL for Mancozeb agreed in the EU review (0.035 mg/kg bw/d).

Proposed dermal absorption values of Valifenalate (concentrate: 0.6%, spray dilution: 12%) and of Mancozeb (concentrate: 0.5%, spray dilution: 3%) were derived based on previous performed *in vitro* dermal absorption studies in human skin.

Operator exposure estimations were performed according to NL requirements, i.e. using the NL-model for mixing/loading, EUROPOEM I or German BBA model (90th percentile) for mechanical and manual application, respectively. These estimations show that the risk for the operator using Valis M with tractor mounted equipment for the treatment of potatoes is acceptable without PPE. The estimated exposure without PPE for this application was 9% and 53% of the AOEL for valifenalate and mancozeb, respectively. This conclusion is also valid when taking into account the simultaneous exposure to valifenalate and mancozeb.

All application types in high crops (grapes) result in systemic exposure levels above the AOEL without PPE. For the treatment of grapes with tractor-mounted equipment, PPE is needed during application (protective coverall and gloves). The estimated exposure with adequate PPE for this application was 14% and 80% of the AOEL for valifenalate and mancozeb, respectively. This conclusion is also valid when taking into account the simultaneous exposure to valifenalate and mancozeb.

With regard to hand-held application in grapes, no safe use could be demonstrated according to NL requirements for Mancozeb with pre-defined PPE (protective coverall, gloves and RPE). The estimated exposure with PPE for this application was 54% and 172% of the AOEL for valifenalate and mancozeb, respectively. As no further refinement of the risk assessment is provided, manual application is excluded by adding a restriction sentence to the legal instructions.

The following restriction sentence should be added to the legal instructions for use: "Voor op- en zijwaartse veldtoepassingen is gebruik uitsluitend toegestaan door middel van daartoe geëigende apparatuur, te weten een machinaal voortgetrokken veldspuit, omdat gezondheidseffecten niet zijn uit te sluiten bij toepassing met een handspuit."

#### **3.1.3.3** Bystander Exposure (Part B, Section 3, Point 7.4)

Bystander exposure and resident exposure to Valis M was **not** evaluated as part of the EU review of Mancozeb. Relevant data and risk assessments are provided in the Core Assessment (Part B3).

#### Valifenalate and Mancozeb

The estimated bystander exposure for arable and orchard spraying is below the EU-AOEL for both valifenalate and mancozeb. Therefore, it is concluded that there is no risk to any bystander during and following application of Valis M (the highest estimated exposure is 62% of the EU-AOEL).

In addition, no adverse health effects are expected for nearby non-work related bystanders and residents due to exposure to both valifenalate and mancozeb during application of Valis M (the highest estimated exposure is 5% of the EU-AOEL).

This conclusion is also valid when taking into account the simultaneous exposure to valifenalate and mancozeb.

#### 3.1.3.4 Worker Exposure (Part B, Section 3, Point 7.5)

Worker exposure to Valis M was **not** evaluated as part of the EU review of Valifenalate and Mancozeb. Relevant data and risk assessments are provided in the Core Assessment (Part B3).

Based on the outcome of the EUROPOEM II model, it is concluded that there is no unacceptable health risk anticipated for the worker wearing gloves (PPE) when re-entering potatoes and grapes for scouting activities directly after application and for harvesting at least 28 days after application of Valis M (the highest estimated exposure is 49% and 21% of the EU-AOEL for valifenalate and mancozeb, respectively). As the sum of the estimated levels of systemic worker exposure to valifenalate and mancozeb for each application type, when expressed as percentages of the respective AOELs, is less than 100%, no further combined bystander risk assessment is required. Therefore, the conclusion is also valid for the simultaneous exposure to both active substances.

The following restriction sentence should be added to the legal instructions for use:

"Wear suitable gloves when handling treated crops".

As a standard rule, treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

#### 3.1.4 Residues and Consumer Exposure

#### 3.1.4.1 Residues

This dossier is presented to support the product Valis M for the use on grapes and potatoes. For the active substances valifenalate and mancozeb the main information and data are presented in Part B Section 4. For further information on valifenalate please refer to the DAR and its Final Addendum, the EFSA Conclusion (EFSA Journal 2013;11(6):3253) and the Review Report (SANCO/12600/2013, rev. 2). For further information on mancozeb please refer to the DAR and its Addendum, and the Review Report (SANCO/4058/2001, rev. 4.4).

Additional storage stability data for mancozeb and ethylene thiourea (ETU) in/on potatoes and grapes were submitted. Mancozeb and ETU residues are stable in potato tubers and grapes for at least up to 12 months, when the crops are stored under frozen conditions (at/below -18 °C).

Residue studies with valifenalate on grapes conducted according to the GAP have already been evaluated during the Annex I inclusion. Two additional trials are submitted with this product registration. The studies are acceptable and support the use of Valis M on grapes in northern Europe. The current MRL for valifenalate in grapes is 0.2 mg/kg. Based on the OECD MRL calculator an MRL of 0.3 mg/kg would be required (unrounded: 0.236 mg/kg). At the time of MRL setting, however, the 'old' MRL-calculator was still in use resulting in an MRL of 0.2 mg/kg based on the same residue data. Therefore it is concluded that the submitted trials are acceptable. Trials on wine grapes can be extrapolated to table grapes and vice versa. The cGAP for table grapes is identical to the cGAP for wine grapes, except for the PHI. Since the PHI for the use on wine grapes is more critical than the PHI for the use on table grapes, residue data for wine grapes are concluded to cover table grapes.

Additional residue studies with valifenalate were submitted to support the use of Valis M on potatoes. Sufficient residue trials are available for the proposed use on potatoes. The trials confirm the observation in the metabolism study that translocation of valifenalate into the potato tubers is negligible: its content in the harvested tubers is below the LOD (0.01 mg/kg). Although MRL calculations are normally performed with the LOQ (0.015 mg/kg), based upon expert judgement, it is concluded that the existing MRL of valifenalate in potatoes (0.01 mg/kg) is not expected to be exceeded and that a no-residue situation is demonstrated.

With regard to residues of mancozeb in grapes, reference is made to the 14 residue trials on grapes in northern Europe evaluated in the DAR and the addendum 1. The trials are concluded to cover the use

of Valis M on grapes in northern Europe. Two additional decline curve residue trials and two harvest trials conducted on grapes during the growing season 2007 were submitted. The trial results confirm the existing MRL 5 mg/kg of mancozeb in grapes.

Residue studies with mancozeb on potatoes have already been evaluated during the 91/414/EEC procedure and are described in the DAR, Addendum 1. These data can be used to support the intended GAP on potatoes. The residue data indicate that mancozeb residues expressed as CS2 are expected to be below the LOQ (= 0.03 mg/kg) when applied according to the proposed GAP. Four additional trials were presented as well. In all trials, no residues of mancozeb or ETU were detected in the treated field specimens of potato at the intended PHI. The existing MRL of mancozeb in potatoes (0.3 mg/kg) is not expected to be exceeded.

Four trials including grape wine processing were submitted. Two trials were performed as balance studies and two trials as follow-up study. The supplementary submitted processing studies on grapes show following results:

- 1. Transfer factor for mancozeb (expressed as CS2) during wine processing is 0.03 (median of transfer factor of young wine, not heated).
- 2. Transfer factor for the conversion of mancozeb (expressed as CS2) to ETU during wine processing is 0.01 (median of transfer factor of young wine, not heated).

No livestock feeding studies are required for valifenalate as animal exposure is negligible. The exposure of mancozeb in animals was addressed in the inclusion process and additional data are not considered necessary.

Although not required due to the low persistence of mancozeb, a metabolism study in rotational crops was evaluated in the DAR. No additional study relating to rotational crops is deemed necessary. In contrast, residues of valifenalate in rotational crops were not investigated in the Annex I inclusion process, however, due to its low persistence this is not considered necessary either.

#### 3.1.4.2 Consumer exposure

The consumer risk assessment of valifenalate and mancozeb was performed with revision 2 of the EFSA Residues Intake Model (PRIMO). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2007).

For the chronic risk assessment of valifenalate calculations are based on conservative assumptions using the MRL values for all crops (including MRLs at the LOQ). No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMO.

For the chronic risk assessment of mancozeb reference is made to EFSA Journal 2011;9(3):2108 and EFSA Journal 2015;13(7):4208. The uses considered in these previous assessments and supporting the existing MRLs published under Regulation (EC) No 396/2005 cover those related to the intended uses of Valis M on potatoes and grapes and include all other uses in the EU and CXLs. Again, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMO.

ETU is a relevant metabolite for mancozeb, formed from the parent during heating and, therefore, is relevant to consumer intake from processed commodities only. There are no MRLs in the EU or at Codex for ETU residues. As processing data and STMR values are available for only a few processed commodities, a comprehensive calculation of the Theoretical Maximum Daily Intake (TMDI) cannot be performed. In previous reasoned opinions on the modification of existing MRLs for dithiocarbamates EFSA only performed an indicative risk assessment for those crops for which

modification of the MRL was requested. A comprehensive consumer exposure assessment for ETU residues based on a full data set on the formation of ETU in processed products from various dithiocarbamates is to be performed during review of the existing maximum residue levels for dithiocarbamates according to Article 12 of Regulation (EC) No 396/2005. In the current application, only input data for the uses under consideration were used in order to estimate the chronic dietary risk arising from ETU residues produced during processing. The calculation of the chronic consumer exposure to ETU residues using EFSA PRIMo rev. 2.0 indicates that consumer exposure to ETU residues not results in a consumer exposure exceeding the ADI derived for ETU.

The setting of the acute reference dose for valifenalate is considered as not necessary. Therefore, an acute dietary risk assessment is not needed for valifenalate and will consequently not be presented.

For mancozeb and ETU the acute risk assessment was calculated with the current EFSA model using the highest residue levels (HR) from supervised residue trials for RACs for mancozeb and for the highest obtainable ETU concentration in processed products. The calculations show an acceptable risk.

Based on the different calculations made to estimate the risk for consumer through diet and other means, it can be concluded that the use of product Valis M does not lead to an unacceptable risk for consumer when applied according to the recommendations.

#### **3.1.5** Environmental fate and behaviour (Part B, Section 5, Point 9)

Based on LoEP data established in the EU review and new data provided in this submission, appropriate endpoints were used to calculate PEC values for Valis M with its active substances Valifenalate and Mancozeb and their metabolites in soil, surface water, groundwater and air for the intended use patterns. Please note that the original GAP was amended in order to demonstrate safe use. The worst-case conditions (i.e. the highest application rates, lowest interception rates for each application) were chosen for each crop and cover the intended uses listed in the GAP.

# 3.1.5.1 Predicted Environmental Concentration in Soil (PECsoil) (Part B, Section 5, Points 9.4 and 9.5)

The PEC of Valis M with its active substances Valifenalate and Mancozeb in soil has been assessed with the FOCUS model and the FOCUS groundwater interception values and the  $DT_{50}$  values established in the EU review or agreed in the assessment, based on new data provided. The PECsoil calculations of the core assessment are relevant for The Netherlands as there are no special requirements for The Netherlands, and the results of PECsoil are summarised in the following.

#### Valifenalate

Based on the recommended use rate of  $6 \times 0.150$  kg a.s./ha in potatoes and  $3 \times 0.120$  kg a.s./ha in grapes the maximum initial predicted environmental concentration in soil (PIECsoil) of Valifenalate will be 0.170 mg/kg in potatoes early after 1<sup>st</sup> application. Due to the short worst-case half-life of 0.37 days for Valifenalate, it was not necessary to calculate plateau concentrations.

For the metabolites IR5839 and PCBA the proposed use pattern will lead to maximum initial PECsoil of 0.122 mg/kg in potatoes early after 1<sup>st</sup> application and 0.057 mg/kg in potatoes early after 5<sup>th</sup> application, respectively, which is acceptable according to the uniform principles. Due to the short worst-case half-lives of 0.63 and 9.52 days for IR-5839 and PCBA, it was not necessary to calculate plateau concentrations.

The results for PECsoil for the active substance and its metabolites were used for the eco-toxicological risk assessment.

#### Mancozeb

Based on the recommended use rate of 6 x 1.5 kg a.s./ha in potatoes and 3 x 1.2 kg a.s./ha in grapes the maximum initial predicted environmental concentration in soil (PECsoil) of Mancozeb will be 1.70 mg/kg in potatoes early after  $1^{st}$  application. Due to the short worst-case half-life of 0.125 days for Mancozeb, it was not necessary to calculate plateau concentrations.

For the metabolites EBIS, ETU and EU the proposed use pattern will lead to maximum initial PECsoil of 0.321 mg/kg in potatoes early after 1<sup>st</sup> application, 0.362 mg/kg and 0.151 mg/kg in potatoes early after 5<sup>th</sup> application, respectively, which is acceptable according to the uniform principles. Due to the short worst-case half-lives of 0.58, 18.2 and 7.6 days for EBIS, ETU and EU, it was not necessary to calculate plateau concentrations.

The results for PECsoil for the active substance and its metabolites were used for the eco-toxicological risk assessment.

# 3.1.5.2 Predicted Environmental Concentration in Groundwater (PECgw) (Part B, Section 5, Point 9.6)

The PEC of Valifenalate and Mancozeb and their metabolites in groundwater have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models and the Koc values established in the EU review or agreed in the assessment based on new data provided. Additionally, the simulation model GeoPEARL 3.3.3 was used to estimate the concentrations of Mancozeb and its metabolite ETU in the leachate at one metre soil depth. No additional GeoPEARL calculations for Valifenalate and its metabolites were necessary since all PECgw values were below 0.001  $\mu$ g/L. Metabolite S5 should be recalculated with GeoPEARL, because the DT50 and Kom are below 10 days and 10 L/kg respectively. However, considering the S5 concentrations are smaller than 0.001  $\mu$ g/L for all scenario's and all applications, the risk of S5 PECgw levels reaching >0.01  $\mu$ g/L in the GeoPEARL recalculation is considered low.

#### Valifenalate

Valifenalate has a low mobility in soil and therefore the risk to groundwater is expected to be minimal. The predicted environmental concentrations (PECgw) at 1 m depth for Valifenalate and its metabolites IR5839, PCBA and S5 following yearly use on potatoes at 6 x 0.150 kg a.s./ha with 15-50-50-50-80 % foliar interception for early and 80-80-80-80-80-90 % foliar interception for late use at the respective applications, were 0.001  $\mu$ g/L or less in all scenarios using FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models. PECgw for the use on grapes at 3 x 0.150 kg a.s./ha and foliar interception of 50-60-60 % for early and 70-85-85 % for late use were also calculated to be 0.001  $\mu$ g/L or less.

The models predict that Valifenalate and its metabolites will not be found in groundwater at concentrations greater than 0.001  $\mu$ g/L. Based on the assessment, Valifenalate is not expected to lead to leaching into groundwater at levels that would be unacceptable when applied according to the recommended use pattern.

#### Mancozeb

PECgw values are below the trigger of  $0.01 \ \mu g/L$  for Mancozeb and metabolites EBIS for the scenario Kremsmünster relevant for The Netherlands using both models. The simulation model GeoPEARL 3.3.3 was used to estimate the concentrations of Mancozeb and its metabolites ETU and

EU in the leachate at one metre soil depth, because the DT50 and Kom of these metabolites are below 10 days and 10 L/kg. For Mancozeb and its metabolites, the substance parameters were the same as used for the PEARL 4.4.4 calculations in the core dossier. For potatoes and grapes, for the early applications, the first application was set at the  $25^{\text{th}}$  of May, which is the default Ctgb application date for spring applications. The last application for the late application is assumed to take place at September  $30^{\text{th}}$ .

Results are presented in Table 3.1.5.2-1 and 3.1.5.2-2.

# Table 3.1.5.2-1:PECgw at 1 m soil depth for Mancozeb and its metabolites using the<br/>FOCUS model PEARL 4.4.4 after the use on potatoes and grapes (80<sup>th</sup><br/>percentile)

Scenario	Сгор	Mancozeb	EBIS
Kremsmünster	potatoes early	< 0.001	< 0.001
Kremsmünster	potatoes late	< 0.001	< 0.001
Kremsmünster	grapes early	< 0.001	< 0.001
Kremsmünster	grapes late	< 0.001	< 0.001

# Table 3.1.5.2-2:PECgw at 1 m soil depth for Mancozeb and its metabolites using the<br/>model GeoPEARL 3.3.3 after the use on potatoes for 250 plots (90<sup>th</sup><br/>percentile)

Сгор	Mancozeb	EBIS	ETU	EU
Potatoes early	< 0.001	< 0.001	< 0.001	< 0.001
Potatoes late	< 0.001	< 0.001	<u>0.013</u>	<u>0.03</u>
Grapes early	< 0.001	< 0.001	< 0.001	< 0.001
Grapes late	< 0.001	< 0.001	0.003	<u>0.0102</u>

The predicted concentration for the Mancozeb metabolites ETU and EU are larger than  $0.01 \,\mu g/L$  when autumn simulations are performed. Therefore a restriction on the use in groundwater protection areas should be placed on the label.

*Om het grondwater te beschermen mag dit product niet worden gebruikt in grondwaterbeschermingsgebieden in de periode 1 september tot 1 maart.* 

#### Monitoring data groundwater

There are no data available regarding the presence of the substance Valifenalate or the substance Mancozeb in groundwater.

Mancozeb metabolite ETU was found in the groundwater at monitoring of shallow groundwater under potato and flower bulb fields. There appears to be a relation with soil type, however, this could not be clearly demonstrated because of the limited number of fields per soil type. In shallow groundwater the 90th percentile concentrations exceeded 0.1  $\mu$ g/L. Moreover, in a TNO study ETU was detected in concentrations > 0.1  $\mu$ g/L in groundwater below clay soils at two locations in the 'Flevopolders' [Minnema et al., 2000].

In a monitoring study for deep groundwater in regions with flower bulbs or potatoes, the overall 90th percentile of the measured concentrations in the total area of use is <0.1  $\mu$ g/L (0.08  $\mu$ g/L), [Kerkdijk, 2001]. If the results are distinguished by crop it can be stated that the 90th percentile concentration for flower bulbs in 'Noord- en Zuid-Holland' is >0.1  $\mu$ g/L (34 sample points). A closer look at the dataset shows that the 90th percentile of locations in 'Zuid-Holland' exceeds the standard of 0.1  $\mu$ g/L (90th percentile 3.1  $\mu$ g/L). The 90th percentile for the remaining 28 sample points in flower bulbs in 'Noord-Holland' is <0.1  $\mu$ g/L (0.09  $\mu$ g/L).

Hence, the standard of 0.1  $\mu$ g/L is not exceeded for potatoes in 'Noord-Holland'. ETU complies with the requirements concerning leaching in soil. Basic assumption is that the selection of monitoring wells include wells in the 25 years zone of groundwater protection areas.

# 3.1.5.3 Predicted Environmental Concentration in Surface Water (PECsw) (Part B, Section 5, Points 9.7 and 9.8)

The calculation of the predicted environmental concentrations of Valifenalate and Mancozeb in surface water is based on the recommendations given in the procedures given in the Evaluation Manual for the authorisation of plant protection products and biocides (Ctgb, 2014). Calculations were performed using the model TOXSWA 1.2. Dutch procedures only consider entry into surface water via drift. Additionally, according to the Dutch requirements for active substances authorised < 3 years in Netherland, an assessment was made with the surface water models FOCUS Step 3 and the Dutch drinking water tool DROPLET 1.1 in order to obtain valifenalate concentrations for the Dutch surface water water abstraction points for drinking water production. Dutch procedures consider entry into surface water water via spray drift.

Calculations were performed using a standard spray drift of 1 % for the use in potatoes (standard value for downward spraying at field crops) and 8.6 % in grapes (standard drift value for fruit crops, large and soft fruit, with 3 m crop free zone. Grapes are always considered as the 'full leaf' stadium.). Additional calculations were performed for Mancozeb in grapes for full leave stage, crop free zones of 3 m and varying drift values for fruit crops (including soft fruit) according to the Evaluation Manual for the authorisation of plant protection products and biocides (Ctgb, 2014), e.g. of 1.3 % (reduced drift for tunnel sprayer), 0.41 % (Wanner equipment with reflection shield and 90 % drift reducing nozzles (Lechler ID 90-015C)), 0.36 % (Venturi nozzle (90 % drift reduction) + one-sided spraying last tree row and reduced air fan setting) and 0.05 % (KWH k1500-3R2 VLOS 3-row sprayer with variable air support system and 90 % drift reducing nozzles and low air setting (400 rpm pto)). The pesticide mass of drift was calculated according to Ctgb (2014) for the model TOXSWA v1.2. Additional calculations of 7-day TWA values were performed using the xls-sheet from Ctgb "PECsw\_twa\_different\_from\_4\_21\_28.xls" for grapes and potatoes from the ec080.out-files. Differences in the two data sets (7-day TWA values and TWA data from TOXSWA NL) are most likely attributed to the shorter time interval of 0.007 d requested for the 7-day TWA value calculations (0.5 d interval in TOXSWA NL).

The proposed use pattern that was assessed is summarised in the following Table according to the GAP (see Appendix 2).

## Table 3.1.5.3-1:Proposed use pattern of Valis M (critical GAP) and derived worst-case<br/>application dates used in the model TOXSWA v1.2

Crop scenario	Covered crops	Use	Maximum individual application rate <sup>*</sup> [kg a.s./ha]	Minimum application interval [days]	Application timing
Potatoes early	Potatoes	F	1.5 Mancozeb 0.15 Valifenalate	5	Spring scenario
Potatoes late	Potatoes	F	1.5 Mancozeb 0.15 Valifenalate	5	Autumn scenario
Grapes early	Grapes	F	1.2 Mancozeb 0.12 Valifenalate	10	Spring scenario
Grapes late	Grapes	F	1.2 Mancozeb 0.12 Valifenalate	10	Autumn scenario

<sup>\*</sup> VALIS M M is applied with 6 applications in potatoes and 3 applications in grapes. Early: from May until July, late from July until September

The maximum initial concentrations of Valifenalate in surface water were calculated to be 12.1  $\mu$ g/L for grapes after spring application. The respective value in sediment was calculated to be 0.666 mg/kg based on a density of 80 kg/m<sup>3</sup> in grapes after spring application. The highest PEC-TWA for grapes, no mitigation, are 11.48 (4 day), 9.267 (21 day) and 8.835 (28 days)  $\mu$ g/L.

The maximum initial concentrations of Mancozeb in surface water were calculated to be 49.1  $\mu$ g/L. The respective values in sediment were calculated to be 0.499 mg/kg based on a density of 80 kg/m<sup>3</sup> in grapes after spring application. For calculations using drift reducing nozzles or other special equipment maximum PECsw ranged from 0.284  $\mu$ g/L to 7.41  $\mu$ g/L. The respective PECsed ranged from 0.006 to 0.097 mg/kg based on a density of 80 kg/m<sup>3</sup>.

The highest PEC Time Weight Average (TWA) for grapes, no mitigation, are 7.716 (4 day), 4.464 (7 day), 4.131 (21 day) and 3.345 (28 day)  $\mu$ g/L.

The results for PEC surface water for the active substance and its metabolites were used for the ecotoxicological risk assessment.

#### Monitoring data surface water

#### Mancozeb

For the active substance Mancozeb there are no recent data available in the pesticide atlas regarding the presence of the substance.

#### Metabolite ETU

The metabolite ETU was observed in the surface water (most recent data from 2014). The authorisation threshold for ETU equals 200  $\mu$ g a.s./L (consisting of first or higher tier acute or chronic ecotoxicological threshold value, including relevant safety factors, which is used for risk assessment, in this case 0.1 \* NOEC daphnia). The relevant EQS for this substance (ETU) is the MPC and equals 0.005  $\mu$ g/L.

Eight observations > MPC (ad-hoc/indicative) were observed. As the exceedances of ETU concern a non-harmonised threshold, no consequences can be drawn from the observed exceedances at this moment.

#### Valifenalate

For the active substance valifenalate there are no recent data available in the pesticide atlas regarding the presence of the substance. The substance is not considered in the current monitoring as it is a new substance.

#### Drinking water criterion

#### Mancozeb

Active substance mancozeb has been on the Dutch market for > 3 years (authorised since 01-01-1986). This period is sufficiently large to consider the market share to be established. From the general scientific knowledge collected by the Ctgb about the product and its active substance, the Ctgb concludes that there are in this case no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. The Ctgb does under this approach expect no exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water are met.

#### Valifenalate

In line with the Dutch requirements for active substances authorised < 3 years in Netherland, an assessment was made with the surface water models FOCUS Step 3 and the Dutch drinking water tool DROPLET 1.1 in order to obtain concentrations for the Dutch surface water abstraction points for drinking water production.

The results are presented in the following table.

Table 3.1.5.3-2:	Predicted concentrations at drinking water abstraction points in The
Netherlands as calcula	ited by DROPLET 1.1 after use in potatoes early and potatoes late, and
grapes late (combined	output summary)

Drinking water	FOCUS D3 crop	$\mathbf{f}_{\text{useintensity}}$	Relative	PEC <sub>drinking</sub> water abstraction
abstraction point		(-)	Cropped Area	point
			(-)	$(\mu g/L)$
De Punt	Potatoes	0.019577	0.097886	0.005
	Pome/stone fruit,	-	-	< 0.001
	late application			
Andijk	Potatoes	0.008607	0.043036	< 0.001
	Pome/stone fruit,	0.000286	0.001428	< 0.001
	late application			
Nieuwegein	Potatoes	0.001492	0.007459	< 0.001
	Pome/stone fruit,	0.006277	0.031384	0.003
	late application			
Heel	Potatoes	0.005546	0.027731	0.001
	Pome/stone fruit,	0.002592	0.012962	0.001
	late application			
A'dam Rijnkanaal	Potatoes	0.001155	0.005776	< 0.001
	Pome/stone fruit,	0.004845	0.024224	0.002
	late application			
Brakel	Potatoes	0.005666	0.028332	0.001
	Pome/stone fruit,	0.000920	0.004600	< 0.001
	late application			
Petrusplaat	Potatoes	0.005413	0.027067	0.001
	Pome/stone fruit,	0.000882	0.004410	< 0.001
	late application			
Twentekanaal	Potatoes	0.000279	0.001393	< 0.001
	Pome/stone fruit,	0.000010	0.000050	< 0.001
	late application			
Scheelhoek	Potatoes	0.005590	0.027950	0.001
	Pome/stone fruit,	0.001933	0.009664	0.001
	late application			
Bommelerwaard	Potatoes	0.001506	0.007531	< 0.001
(subarea of Brakel)	Pome/stone fruit,	0.005395	0.026975	0.003
	late application			

The maximum initial concentrations of Valifenalate do not exceed the 0.1  $\mu$ g/l standard in the Dutch surface water abstraction points for drinking water production. The standards for surface water destined for the production of drinking water are met.

# **3.1.5.4** Predicted Environmental Concentration in Air (PEC<sub>Air</sub>) (Part B, Section 5, Point 9.9)

Valis M BCP382F

#### Valifenalate

The fate and behaviour in air of Valifenalate was evaluated during the Annex I Inclusion procedure. From the vapour pressure of Valifenalate (9.6 x  $10^{-8}$  Pa at  $20^{\circ}$ C), the compound was determined as non-volatile. The DT<sub>50</sub> in air according to Atkinson (photochemical oxidative degradation) is below the trigger of 2 days (7.5 h).

No additional studies with the formulated product were performed and no studies are deemed necessary.

Short-range transport

- due to the vapour pressure of  $9.6 \times 10^{-8}$  Pa (at 20 °C) no consideration of the deposition of volatilised Valifenalate by the use of the model EVA 2.1 is required
- risk assessments for terrestrial organisms are covered by in field-risk assessments
- for risk assessment for aquatic organisms transport of Valifenalate via volatilisation and successive deposition has only to be taken into account at FOCUS Step 4. As an acceptable risk for aquatic organisms can be demonstrated via FOCUS Step 3 PEC values, it is not necessary to consider short-range transport into surface water in aquatic risk assessments

Long-range transport potential and adverse effects to the environment

- as the  $DT_{50}$  in air according to Atkinson is below the trigger of 2 days, no long-range transport potential or adverse effects to the environment are expected for Valifenalate

#### Mancozeb

The fate and behaviour in air of Mancozeb was evaluated during the Annex I Inclusion procedure. From the vapour pressure of Mancozeb ( $6.9 \times 10^{-6}$  Pa at  $20^{\circ}$ C), the compound was determined as non-volatile (EU endpoint list). No photochemical oxidative degradation data were considered necessary for Mancozeb.

No additional studies with the formulated product were performed and no studies are deemed necessary.

Short and long-range transport potential and adverse effects to the environment

- as the vapour pressure for Mancozeb is  $< 1 \times 10^{-5}$  Pa, no short and long-range transport potential or adverse effects to the environment are expected for Mancozeb

#### 3.1.6 Ecotoxicology (Part B, Section 6, Point 10)

#### 3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)

Birds

#### Dietary exposure

Based on the screening step, the TER values for Valifenalate and the TER for Mancozeb, and the combination TER of Mancozeb and Valifenalate in grapes were above the Annex VI trigger of 10, indicating an acceptable acute risk to birds from this use. The acute TER values for Mancozeb and the combination in potatoes and the product Valis M for both uses were below the Annex VI trigger of 10. Tier 1 assessment for use in potato indicated acceptable acute risk with regard to the active substance Mancozeb, Valifenlate, the combination of Mancozeb and Valifenalate, and the product Valis M.

Based on the screening step, the TER values for Valifenalate were above the Annex VI trigger of 5, indicating a low long-term risk to birds from Valifenalate. The TER values for Mancozeb, and combination of Mancozeb and Valifenalate were below the Annex VI trigger of 5 (between 0.12 and 0.42). Therefore, a Tier 1 risk assessment for the active substance Mancozeb and combination of Mancozeb and Valifenalate was required for both uses in potatoes and grapes.

When assuming the presumptions of the Tier 1 risk assessment for all generic focal species in potatoes, the TER values for Mancozeb were below the Annex VI trigger of 5 for insectivorous and omnivorous birds. Furthermore, the TER for redstart (insectivore) was below the trigger of 5 for use in grapes. The applicant was thus requiested to further address the reproductive risk from exposure to Mancozeb.

Based on the information provided it is expected that actually the long-term combination toxicology of mancozeb and valifenalate is not relevant in case of birds and it can be concluded that the toxicity to birds is driven by mancozeb only.

#### Higher tier reproductive risk assessment for birds

During the commenting round for the dRR, the applicant and some MSs have expressed that zRMS should leave the refinements for mammals at MS level. The zRMS is of the opinion that Central Zone should aim at a harmonized approach to risk evaluations and refers to the DCG agreement (d.d. june 2017). that the core should be complete and conclusive. A national addendum should be restricted to climatological or agricultural elements as is mentioned in the Regulation (art 36.3).

#### Potato

<u>Insectivorous birds:</u> the risk was refined with a DT50 (moving time window). The refined risk assessment resulted in acceptable reproductive risk to insectivorous birds.

<u>Omnivorous birds:</u> the risk was refined with the focal species skylark (*Alauda arvensis*), PD, PT, FIR, deposition factor, and DT50s (moving time window). The refined risk assessment resulted in acceptable reproductive risk to omnivorous birds.

#### Vineyards

<u>Insectivorous birds:</u> the risk was refined with a DT50 (moving time window). The refined risk assessment resulted in acceptable reproductive risk to insectivorous birds.

Overall, the acute and reproductive risk to birds from exposure to Valis M is considered acceptable.

#### Drinking water risk assessment

As the ratios of application rate/endpoint do not exceed the value of 3000 for Valifenalate (Koc = 753 L/kg) and for Mancozeb (Koc = 997.5 L/kg), it is not necessary to conduct a drinking water risk assessment for birds.

Food chain behaviour

Mancozeb, its metabolites EU and ETU, and metabolites IR5839 and PCBA of Valifenalate have a log  $P_{OW}$  of <3, hence their risk for bioaccumulation in fish-eating and worm-eating birds is negligible. Valifenalate has a log  $P_{OW}$  value of 3.05 and a detailed assessment was conducted, indicating a low risk for fish-eating and earthworm-eating birds when exposed to Valifenalate. Valifenalate has no potential for biomagnification in terrestrial food chains.

#### **Terrestrial vertebrates (other than birds)**

Based on the screening step, the TER values for Valifenalate and Mancozeb were above the trigger of 10, indicating an acceptable acute risk to mammals from Valifenalate and Mancozeb. However, the TER of the product Valis M for the use in potatoes was below the trigger of 10 (> 7.7). Therefore, a Tier 1 risk assessment for the product Valis M for the use in potatoes is performed and considered acceptable.

In the reproductive Tier 1 assessment TER values for all generic focal species were above the trigger of 5 for valifenalate, indicating an acceptable long-term risk to mammals.

An acceptable risk for Mancozeb was shown only for small insectivorous mammals in potatoes and grapes in the Tier 1 assessment. The risk from Mancozeb was also acceptable for large herbivorous mammals and small omnivorous mammals for the use in grapes in the Tier 1 assessment.

For small and large herbivorous mammals and small omnivorous mammals in potatoes and for small herbivorous mammals in grapes, further refinement of the risk assessment was conducted.

A risk from combitox is not expected.

#### Higher tier reproductive risk assessment for mammals

During the commenting round for the dRR, the applicant and some MSs have expressed that zRMS should leave the refinements for mammals at MS level. The zRMS is of the opinion that Central Zone should aim at a harmonized approach to risk evaluations and refers to the DCG agreement (d.d. june 2017). that the core should be complete and conclusive. A national addendum should be restricted to climatological or agricultural elements as is mentioned in the Regulation (art 36.3). The Netherlands conducted the following risk assessment.

#### Potato

<u>Small herbivorous mammal:</u> the risk to the vole was refined with RUDs, PD, FIR, DT50s (moving time window), and a deposition factor. The refined reproductive risk assessment for voles resulted in a TER of 1.69, indicating unacceptable reproductive risk to small herbivorous mammals in potato. Further refinement was provided by the applicant as well as a lowering of the frequency of the application, which resulted in an acceptable reproductive risk to small herbivorous mammals in potatoes. Note that the reproductive risk to small herbivorous mammals in potatoes. Note that the reproductive risk to small herbivorous mammals in potatoes. Note that the reproductive risk to small herbivorous mammals in potatoes is acceptable under the condition of the GAP change – only 3 applications in total are allowed in potato, all at BBCH  $\geq$  40. Member states should consider a restriction sentence or similar to be placed on the label to reflect the conditions of safe use in potato. To protect mammals in the Netherlands, a restriction on applications has been added in the WG.

<u>Large herbivorous mammal</u>: the risk to the European rabbit was refined with RUDs, DT50s (moving time window), and a deposition facto. The refined risk assessment resulted in an acceptable reproductive risk to large herbivorous mammals.

<u>Small omnivorous mammal:</u> the risk to the wood mouse was refined with RUDs, DT50s (moving time window), and a deposition factor. The refined risk assessment resulted in an acceptable reproductive

risk to small omnivorous mammals.

#### Vineyards

<u>Small herbivorous mammal:</u> the risk to vole was refined with RUDs, PD, FIR, DT50s (moving time window), and deposition factor. The refined higher tier risk assessment resulted in a TER of 2.66, indicating unacceptable reproductive risk to voles in vineyards.

#### Drinking water risk assessment

As the ratios of application rate/endpoint do not exceed the value of 3000 for Valifenalate (Koc = 753 L/kg) and for Mancozeb (Koc = 997.5 L/kg), it is not necessary to conduct a drinking water risk assessment for mammals. Food chain behaviour

Mancozeb, its metabolites EU and ETU, and metabolites IR5839 and PCBA of Valifenalate have a log  $P_{OW}$  of <3, hence their risk for bioaccumulation in fish-eating and worm-eating mammals is negligible. Valifenalate has a log  $P_{OW}$  value of 3.05 and a detailed assessment was conducted, indicating a low risk for fish-eating and earthworm-eating mammals when exposed to Valifenalate. Valifenalate has no potential for biomagnification in terrestrial food chains.

#### **3.1.6.2** Effects on Aquatic Species (Part B, Section 6, Point 10.2)

#### Core assessment:

An acceptable risk by the intended uses of Valis M to aquatic organisms is demonstrated when the following mitigation measures are applied:

- early grapes, a drift buffer zone of 5 m with at least 75% drift reduction;
- late grapes, a drift buffer zone of 5 m with at least 90 % drift reduction is needed to achieve an acceptable risk for acute toxicity to invertebrates;
- potatoes, a drift buffer zone of 5 m with at least 75 % drift reduction

Furthermore, he risk assessment for fish was refined with a 7d-twa PECsw. The zRMS agrees with the use of the default 7-day twa, as the criteria of ELINK or EFSA (2013) are met. This is also in line with the worst case DT90 of 6.6 days (158 hours, EFSA conclusion on mancozeb). Since not all MSs might accept the 7d TWA approach, it can be reconsidered in the national assessments.

#### NL addendum:

The risk to aquatic organisms was considered acceptable when appropriate drift mitigation measures are applied. Of note, the long term risk to fish was refined with a 7d TWA PECsw.

# 3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)

#### Bees

The honey bee risk assessment was performed in accordance with the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002). Effects on bees of Valis M were not evaluated as part of the EU review of Valifenalate and Mancozeb. Therefore, all relevant data and assessments are

provided here and are considered adequate. Further details regarding the tests with the active substances and the formulation are provided in the core dossier in chapter MIIIA1 10.4.2. Hazard quotients were calculated for oral ( $Q_{HO}$ ) and contact exposure ( $Q_{HC}$ ) to Valifenalate, Mancozeb and the product Valis M. A hazard quotient of less than 50 indicates a low risk to bees in the field.

The acute and oral hazard quotients are below 50 indicating that the active substances and the product pose a low risk to bees.

#### **Other non-target arthropods**

The Dutch risk assessment scheme is in line with the European risk assessment methodology for non-target arthropods according to ESCORT 2. However, for the off-field scenario, a drift factor of 10 % for field crops (potatoes) and 15.9 % for grapes is considered according to the specific Dutch requirements (CTGB, 2014).

For the in-field risk assessment of non-target arthropods, please refer to the core registration report.

#### Off-field risk assessment according to the Dutch requirements

With regard to the risk to non-target arthropods, an acceptable off-field risk with a HQ below the trigger of 1 was achieved with a drift of 5.5 % (Conventional DG11004+end nozzle or a Conventional ID12002+end nozzle, 50% and 75% DRN respectively) and for all other conventional spray techniques with an equal or lower drift value, for the use in potatoes. Sprayer types, indicating an acceptable risk are:

Low boom DG80015 + end nozzle (50 % DRN), Low boom ID90015 + end nozzle (50 % DRN), Släpduk XR110015 (0 % DRN), Släpduk AI110015 (50 % DRN), Tunnel XR11004 + UB8504 (0 % DRN).

The applicant proposed to use 90% drift reducing nozzles in potatoes, with drift percentage 9.7%, and no mitigation in grapes. With the revised MAF, this does not lead to acceptable risk. Therefore, the Ctgb has used different mitigation measures in the table below. The Ctgb notes that the measured drift values for 90% drift-reducing nozzles are higher than those for 50 and 75% drift-reducing nozzles, which seems contradictory. It may be a result of the fact that fewer measurements were performed for 90% drift-reducing nozzles. That said, it may also be a result of the fact that the reduction percentiles are defined based on their reduction of drift into surface water, which is further from the use area (field). Thus, nozzles with a high reduction percentage for water bodies bordering a field may actually have higher drift in the non-crop vicinity closer to the edge of the field. If an end nozzle is used in conjunction with the drift-reducing nozzle, this situation can be improved (as end nozzles ensure that there is less spray drift off the field area).

Since it would be difficult for the end-user and general public to understand why the use of a 50% drift-reducing nozzle is acceptable but a 90% drift-reducing nozzle is not acceptable, the instructions for use will contain only the lowest acceptable drift-reduction percentage and the words "at least", indicating that nozzles with a higher reduction percentage are also acceptable. The use of an end nozzle will be universally prescribed.

For the use in grapes, an acceptable risk was determined with a drift % of 11.2 for a 90% drift reducing nozzle and on-sided spraying of the last tree row (before May 1) or of 7.2 for a 50% drift reducing nozzle and on-sided spraying of the last tree row (May 1 and after). Other measures are also acceptable.

# 3.1.6.4 Effects on Earthworms and Other Soil Marco-organisms (Part B, Section 6, Point 10.6)

#### Earthworms

The earthworm risk assessment was performed in accordance with the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002). The exposure to soil organisms was estimated by calculating the maximum initial predicted environmental concentrations in soil (PEC<sub>Soil</sub>) (please refer to Part B, Section 5) and by comparing these concentrations with the toxicity endpoints.

All TER values for the active substances, the product Valis M and the major soil metabolites were greater than the required triggers for acute toxicity (> 10) and chronic toxicity (> 5). Considering the fact that the above calculations represent worst-case scenarios, the risk of acute and chronic effects on earthworms is considered to be low.

As the combined TER values are above the respective trigger values, an acceptable acute risk for earthworms simulataneously exposed to Valifenalate and Mancozeb after application of Valis M to potatoes and grapes is indicated.

The acute and chronic combination toxicity of Valifenalate and Mancozeb to earthworms based on the toxicity endpoints derived from the Valis M product studies indicates an acceptable risk, as the calculated Trigger/TER values are below 1

#### Effects on other soil non-target macro-organisms

A test for assessing the effects on Collembola or soil mite reproduction is required where the  $DT_{90f}$  lies between 100 and 365 days **and** the standard HQ for (*Typhlodromus* and *Aphidius*) > 2.

No tests are required considering the persistence trigger in accordance with the EU Guidance Document, since the  $DT_{90lab}$  values are < 100 days for Valifenalate (0.19 - 1.22 days; Valifenalate EFSA Conclusion 2013; 11(6):3253) and between 2 - 25 h for Mancozeb (Mancozeb Review Report, 2009), indicating that there will be no accumulation of residues.

#### **3.1.6.5** Effects on organic matter breakdown (Part B, Section 6, Point 10.6)

No tests are required considering the persistence trigger in accordance with the EU Guidance Document, since the  $DT_{90lab}$  values are < 100 days for Valifenalate (0.19 - 1.22 days; Valifenalate EFSA Conclusion 2013; 11(6):3253) and between 2 - 25 h for Mancozeb (Mancozeb Review Report, 2009) (Trigger  $DT_{90field} > 365$  days).

#### **3.1.6.6** Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)

The risk assessment for soil non-target macro-organisms was performed in accordance with the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002). Effects on soil microbial activity of Valis M were not evaluated as part of the EU review of Valifenalate or Mancozeb.

Throughout the respiration study the difference to the control for carbon transformation rate at a dose level of 8.33 mg prod./kg soil was less than 25 %. Throughout the nitrogen transformation study the difference to the control for nitrogen transformation rate at a dose level of 8.33 mg prod./kg soil was less than 25 %. Therefore, the risk to soil non-target micro-organisms is considered to be low.

# 3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

#### Non-Target Plants

As spray drift is the key exposure route for non-target plants, the drift values and MAF (multiple application factors) were based on the default values for potatoes and grapes according to BBA (2000) (in ESCORT 2) (worst case assumption). The maximum application rate both in the vegetative vigour and seedling emergence study (KIIIA1 10.8.1.2/01 and KIIIA1 10.8.1.3/01) was 10000 g prod./ha. Based on the test data for all 10 test species, the ER<sub>50</sub> for biomass change and phytotoxicity was > 10000 g prod./ha.

An acceptable in-field risk to non-target plants has already been determined in the core registration report and thus, the risk assessment for in-field effects on non-target plants is covered by the risk assessment presented in the core registration report.

The off-field exposure is at maximum 236.25 g product/ha. This is lower than the  $ER_{50}$  values and it can be concluded that there is an acceptable risk for non-target plants.

#### Other non-target species (Flora and Fauna)

Tests on other non-target species are not required.

#### Implications for labelling resulting from ecotoxicological assessment:

Om de zoogdieren te beschermen is toepassing van het middel in de teelt van aardappels uitsluitend toegestaan indien vanaf het moment dat het bladerdek gesloten is (BBCH 40, 90% van de planten raakt elkaar in de rij), maximaal 3 toepassingen plaatsvinden.

Om in het water levende organismen te beschermen is de toepassing van het middel in de teelt van aardappels op perceelsranden die grenzen aan oppervlaktewater uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 90% driftreducerende spuitdoppen.

Om in het water levende organismen te beschermen is de toepassing van het middel in de teelt van druiven op perceelsranden die grenzen aan oppervlaktewater uitsluitend toegestaan indien gebruik wordt gemaakt van de KWH k1500-3R2 VLOS 3-rijenspuit met variabele luchtondersteuning en 90% driftreducerende doppen en ventilatorstand "laag".

Om niet tot de doelsoorten behorende geleedpotigen te beschermen is toepassing van het middel in de teelt van aardappels uitsluitend toegestaan wanneer gebruik gemaakt wordt van minimaal 75% drift reducerende spuitdoppen.

#### Voor 1 mei:

Om niet tot de doelsoorten behorende geleedpotigen te beschermen is toepassing van het middel in de teelt van druiven uitsluitend toegestaan wanneer gebruik gemaakt wordt van minimaal 90% drift reducerende spuitdoppen en eenzijdige bespuiting van de laatste 3 rijen.

#### <u>Na 1 mei:</u>

Om niet tot de doelsoorten behorende geleedpotigen te beschermen is toepassing van het middel in de teelt van druiven uitsluitend toegestaan wanneer gebruik gemaakt wordt van minimaal 50% drift reducerende spuitdoppen en eenzijdige bespuiting van de laatste 3 rijen.

#### 3.1.7 Efficacy (Part B, Section 7, Point 8)

This dossier concerns the zonal (re-)registration of Valis M, however in the Netherlands Valis M has no uses authorized yet. Therefore, within this application authorization is being sought for the control of *Phytophthora infestans* in potato and for the control of *Plasmopara viticola* in grapevine which are new uses for the Netherlands.

Valis M is a fungicide formulated as a Water dispersible Granule (WG-formulation) and contains the active substances valifenalate (60 g a.s./kg) & mancozeb (600 g a.s/kg). Valis M is initially claimed for the control of *Phytophthora infestans* in potato at a dose rate of 2.5 kg/ha with a maximum of 6 applications per season applied in minimum interval of 5 days and for the control of *Plasmopara viticola* in grapevine at a rate of 2.0 kg/ha with a maximum of 3 applications per season applied in a minimum interval of 10 days.

Yet, during the evaluation an adjusted GAP has been submitted by the applicant which has restricted the use in potato to a maximum of 4 applications of 2.5 kg/ha per season applied with a minimum interval of 7 days instead of 5 days. Furthermore the application period was restricted to April – August and/or BBCH 21 to 89 with the additional restriction that only one application is allowed before the crop reaches BBCH 40. Based on the risk assessment for mammals performed by ecotoxicology the adjusted GAP the use in potato was even further restricted to a maximum of three applications per season to be applied not before the crop reached BBCH 40 and with a minimum interval of 7 days.

In, the by applicant submitted, adjusted GAP also the use in grapevine was further restricted to a maximum of 2 applications of 2.0 kg/ha per season in the period April - August and/or BBCH 53 to 79 instead of 3 applications per season in the period April – July and/or BBCH 15 to 83.

The restrictions as given in the adjusted GAP did not affect the efficacy evaluation as it is common that efficacy trials targeting *P. infestans* in potato and *P. viticola* in grapevine are set up preventatively with continuous sprayings of the intended dose rates to cover a complete growing season. Therefore the adjusted GAP is accepted and conclusions regarding efficacy are based on a maximum of 4 applications in potato and 2 applications in grapevine.

#### **Preliminary trials – Benefit of the co-formulation**

Valis M is a combination of 2 active substances; valifenalate and mancozeb. The active substances have a different mode of action, minimizing the risk of resistance and offering a broader spectrum of control.

The benefit of the co-formulation on effectiveness was demonstrated in 22 efficacy trials in which Valis M was compared to a product containing only mancozeb.

In 13 trials the effectiveness of Valis M in the control of potato late blight in potato was compared to reference product (P1) containing mancozeb solo. The trials were conducted in the Maritime EPPO Zone (11) and the Mediterranean EPPO Zone (2).

Valis M was applied at 2.5 kg/ha (corresponding to 150 g valifenalate/ha and 1500 g mancozeb/ha) and reference product P1 was applied at 2-2.1 kg/ha (corresponding to 1500-1575 g mancozeb/ha). Over the trials, especially under conditions of high disease pressure, Valis M was more effective than the reference product P1.

In 9 trials the effectiveness of Valis M in the control of downy mildew in grape was compared to reference products V5 and V11 containing mancozeb solo. The trials were conducted in the Maritime EPPO Zone (4), Mediterranean EPPO Zone (1) and South East EPPO Zone (4).

Valis M was applied at 2.0 kg/ha (corresponding to 120 g valifenalate/ha and 1200 g mancozeb/ha), reference product V5 was applied at 1.6 kg/ha (corresponding to 1200 g mancozeb/ha) and reference product V11 was applied at 1.5 kg/ha (corresponding to 1200 g mancozeb/ha).

Over the trials infection on leaves and bunches was generally more effectively controlled by Valis M than by both the reference products containing mancozeb solo. This was especially pronounced in the trials conducted in the South East EPPO Zone.

Considering the improved effectiveness of the combination of mancozeb and valifenalate as compared to mancozeb solo, as observed in the efficacy trials, and the minimization of the resistance risk due to the different modes of action of the two active substances, the benefit of the co-formulation is considered sufficiently substantiated.

#### Minimum effective dose

#### Potato late blight (Phytophthora infestans, PHYTIN) in potato

A total of 31 trials is available from the Maritime (23), North East (4) and Mediterranean EPPO Zone (4) to determine the minimum effective dose for the control of Phytophthora infestans in potato.

Trials from the Maritime EPPO Zone are available from Austria (3), Belgium (3), Czech Republic (2), Germany (6) France (2), Ireland (4), the Netherlands (2) & the United Kingdom (1). In these trials generally a dose related effect on control was observed as the higher dose rates of 2.0 and 2.5 kg/ha achieved substantially higher control than lower dose rates 1.2-1.25 and 1.5 kg/ha. The control achieved at the proposed dose rate of 2.5 kg/ha was comparably to slightly higher than that achieved at a dose rate of 2.0 kg/ha.

Favorable conditions for the development of *Phytophthora infestans* are temperatures between 10-25°C and high humidity. The climates in the Netherlands, Ireland and United Kingdom are especially favorable for the development of *Phytophthora infestans*. Trials conducted in these countries are available. In the trials conducted in Ireland no clear dose related effect was observed, as all dose rates generally achieved high control up towards the end of the trial. In the trials conducted in the Netherlands and United Kingdom the higher dose rates of 2.0 and 2.5 kg/ha were more effective as compared to the lower rate of 1.5 kg/ha and it was observed that the higher dose rate held control longer towards the end of the trial as compared to the lower rates.

Considering that the climate in the Netherlands, Ireland and United Kingdom represent more challenging conditions, it is considered that Minimum Effective Dose is sufficiently justified and that the proposed dose rate of 2.5 kg/ha Valis M can be considered as the appropriate Minimum Effective Dose for good and acceptable control of *Phytophthora infestans* in potato under challenging conditions.

#### Downy mildew of grape (Plasmopara viticola, PLASVI) in grape

A total of 13 trials is available from the Maritime (9) and South East EPPO Zone (4) to determine the minimum effective dose for the control of *Plasmopara viticola* in grape.

In the trials from the Maritime EPPO Zone (Czech Republic [7 trials] & France [2 trials]) only in both the French trials a dose related effect on control was observed as the high dose rate of 2.0 kg/ha achieved substantially higher control than the lower dose rates 1.0 and 1.5 kg/ha. In the Czech Republic trials disease pressure was too low for reliable assessments. In addition to the Maritime trials a dose related effect on the control of *Plasmopara viticola* was observed in all four South-East trials (2 Hungarian trials & 2 Romanian trials) as in these trials the high dose rate of 2.0 kg/ha achieved substantially higher control than the lower dose rates 1.0 and 1.5 kg/ha.
Although supportive MED trials conducted in the Maritime EPPO Climatic Zone were limited, MED-justification was fully supported by 4 South-East trials, the dose rate of 2.0 kg/ha is considered as the appropriate Minimum Effective Dose to achieve sufficiently control *Plasmopara viticola* in grapes.

#### Effectiveness

A total of 111 efficacy trials are available in which the effectiveness of Valis M against potato late blight in potato (63 trials) and downy mildew in grape (48 trials) was tested. Trials are available from the Maritime, South East, North East and Mediterranean EPPO Zone.

#### Potato late blight (Phytophthora infestans, PHYTIN) in potato

The effectiveness of Valis M in the control of *Phytophthora infestans* in potato was tested in a total of 40 efficacy trials conducted in the Maritime EPPO Zone. Assessments were made on disease severity on leaves.

Trials are available from Austria (3), Belgium (3), Czech Republic (2), Germany (8), Northern-France (15), the Netherlands (2) and the United Kingdom (2) from the period of 2005 to 2013. Under conditions of moderate to high disease pressure, Valis M achieved useful control on infection on leaves and was generally comparably effective to a range of (authorized) reference products containing (combinations of) the following active substances: mancozeb, benthiavalicarbe-isopropyle, dimethomorph and/or mefenoxam.

Favorable conditions for the development of *Phytophthora infestans* are temperatures between 10-25°C and high humidity. The climates in the Netherlands, Ireland and United Kingdom are especially favorable for the development of *Phytophthora infestans*. However the *Phytophthora infestans* populations differ between the member states. Due to these country-specific situations, specific trials are required the individual member states.

Three (relevant) trials are available from the Netherlands. Valis M achieved high control of infection on leaves and was comparably effective to the reference product containing benthiavalicarbeisopropyle + mancozeb and comparably to more effective than the reference product containing mancozeb solo. Additionally a trial conducted in Germany, close to the Dutch border, is available, in which Valis M achieved high control and was comparable to the reference product containing benthiavalicarbe-isopropyle + mancozeb.

Overall, and in comparison with a range of reference products, Valis M applied at a rate of 2.5 kg/ha was effective in the control of *Phytophthora infestans* in potato. Considering the specific data generated under conditions favorable for the development of *Phytophthora infestans*, from trials conducted in the Netherlands, Ireland and United Kingdom, it is concluded that also sufficiently control of *Phytophthora infestans* under challenging conditions might expected by the application of Valis M at a rate of 2.5 kg/ha.

As the proposed GAP does restrict the application period the following restrictions / instructions of use will be placed on the Dutch label under the table of uses:

\*Maximaal 1 toepassing voor het sluiten van het gewas en maximaal 3 toepassingen na het sluiten van het gewas (BBCH 40)

## Downy mildew (Plasmopara viticola, PLASVI) in grape

The effectiveness of Valis M in the control of *Plasmopara viticola* (PLASVI) in grapevine was tested in a total of 15 efficacy trials conducted in the Maritime EPPO Zone. Trials are available from

Northern France (5) and the Czech Republic (8) from the period between 2006 and 2008 and two additional French trials conducted in 2013.

Disease severity was assessed only in the French trials. Disease severity in the untreated objects was sufficient. Valis M achieved good control of infection on leaves and bunches and was generally comparably effective to a range of reference products containing (combinations of) the following active substances: mancozeb, iprovalicarb, cymoxanil and dimethomorph.

Disease incidence was assessed in all trials. Disease incidence in the Czech trials was, as subsequence of insufficient disease pressure, too low for reliable assessments. Nevertheless, it was observed that Valis M provided a slight effect on diseases incidence which was fully comparable to the effect achieved with a reference product containing mancozeb + dimethomorph. Under high disease pressure (French trials) Valis M achieved variable yet on average sufficient control on *Plasmopara viticola* which was in general similar to the control achieved with the range of reference products containing (combinations of) the following active substances: mancozeb, iprovalicarb, cymoxanil and dimethomorph.

In conclusion, disease pressure in the French trials (5) was high and therefore trials were fully supportive to the claimed use on *Plasmopara viticola* (PLASVI) in grapevine, yet in the Czech trials (8) disease pressure was low and not sufficient. As for the Netherlands claimed use concerns a new use, ideally more trials should be made available and the trials should be better distributed over the climatic zone. However, when taken into consideration that the provided efficacy data are excepted for reregistration of the current authorization of Valis M in member state Czech Republic and that fully supportive efficacy data are available from the South-East and Mediterranean EPPO Climatic zone, it is concluded that the claimed use of 2.0 kg/ha Valis M to control *Plasmopara viticola* (PLASVI) in grapevine is sufficiently justified.

As the spray volume range of 200 to 800 L/ha in the proposed GAP differs from the commonly used spray volume range (200 to 1200 L/ha) for NL grapevine cultivation the following instruction of use regarding spray volume will be placed on the Dutch label:

In de teelt van tafeldruif en wijndruif het middel toepassen in 200-800 liter water per ha.

### Quality

The effects of treatment with Valis M on quality were assessed in 22 efficacy trials in potato. The trials were conducted in the Maritime (14 trials) and North East EPPO Zone (8 trials) in the period between 2005 and 2010. Additionally 1 processing trial was carried out in France in 2006.

Tubers harvested from efficacy trials were assessed for starch content (5 trials) and were graded to size (21 trials). Tubers in the processing trial were assessed on color after frying, disintegration and darkening after boiling and taste after boiling. No negative effects on quality of treatment with Valis M at a dose rate of 2.5 kg/ha were observed.

No assessments on quality were made in the efficacy trials conducted in grapevine. However as neither symptoms of phytotoxicity nor effects on the processing procedure were observed, Valis M applied at the proposed dose rate is not expected to have negative effects on quality.

### Processing

In 4 processing trials in grapevine, the effects of treatment with Valis M on wine processing and taste were assessed. Grapes of grapevines treated with Valis M at the proposed dose rate of 2.0 kg/ha were

tested and compared to grapes of grapevines treated with reference product V2 containing cymoxanil + mancozeb.

Some slight differences in the maturity of the must were observed between samples from grapevine treated with Valis M and grapevine treated with the reference product, yet no differences were recorded on wine tasting after bottling.

Based on the presented results it is not expected that Valis M applied at the proposed dose rate of 2.0 kg/ha will have negative effects on the processing procedure.

### Yield

In a total of efficacy 30 trials in potato conducted in the Maritime (21 trials) and North East EPPO Zone (9 trials) in the period between 2005 and 2010, tubers were harvested and taken to yield. Overall, treatment with Valis M at the proposed dose rate of 2.5 kg/ha resulted in a positive effect on yield in relation to the untreated objects, due to the control of *Phytophthora infestans*. The effect on yield of Valis M was comparable to that of the reference products.

Based on the presented data, treatment with Valis M is expected to have a positive effect on yield due to the control of *Phytophthora infestans*.

In 1 efficacy trial in grapevine conducted in Greece in 2006, grapes were harvested and taken to yield. Treatment with Valis M at the proposed dose rate of 2.0 kg/ha resulted in a positive effect on yield in relation the untreated objects, due to the control of *Plasmopara viticola*. The effect on yield of Valis M was comparable to that of the reference product containing mancozeb + benalaxyl.

Based on the presented data, combined with the fact that no symptoms of phytotoxicity were observed in the efficacy trials, treatment with Valis M is expected to have a positive effect on yield due to the control of *Plasmopara viticola*.

### **Crop safety**

In 64 efficacy trials in potato against potato late blight, conducted in the Maritime (41), South East (4), North East (9) and Mediterranean EPPO Zones (10) in the period between 2005 and 2015, no symptoms of phytotoxicity were observed after treatment with Valis M in 4-12 applications at a dose rate of 2.5 kg/ha.

In 45 efficacy trials in grapevine against downy mildew, conducted in the Maritime (13), South East (7) and Mediterranean EPPO Zone (25) in the period between 2005 and 2013, no symptoms of phytotoxicity were observed after treatment with Valis M in 5-10 applications at a dose rate of 2.0 kg/ha.

Based on the presented data it is concluded that Valis M, when used as proposed, is safe to the crop.

#### Adverse effects

In 1 trial conducted in Northern France in 2006-2007, the germinating capacity of potato tubers treated with Valis M was tested. No significant differences between tubers treated with Valis M and tubers treated with the reference product were observed.

Based on the presented data and the fact that no symptoms of phytotoxicity were observed over the course of the efficacy trials, adverse effects on parts of plant of potato used for propagating purposes after treatment with Valis M are considered unlikely.

No specific trials were carried out on the effects of Valis M on parts of plants of grapevine used for propagating purposes. However, no symptoms of phytotoxicity were observed over the course of the efficacy trials. Therefore adverse effects on parts of plant of grapevine used for propagating purposes after treatment with Valis M are considered unlikely.

No specific trials on the impact of Valis M on succeeding crops were conducted. However no phytotoxicity or negative effects on yield or quality were observed in the efficacy trials in potato and grapevine.

Based on the above, negative effects on succeeding crops are considered unlikely. Based on a vegetative vigour and a seedling emergence test conducted in 10 species of higher plants, no negative effects of Valis M on adjacent plants are expected.

### Resistance

Valis M is a fungicide formulated as a water dispersible granule (WG) formulation containing 6% valifenalate and 60% mancozeb.

- Valifenalate belongs to the family of Carboxylic Acid Amides fungicides (FRAC code H5), and is classed as low to medium risk for resistance.

- Mancozeb belongs to the family of Dithiocarbamates (FRAC code M3), and is classed as low risk for resistance.

According to the FRAC Pathogen risk list (December 2013) *Phytophthora infestans* is accepted as showing a medium risk to development of resistance to fungicides. However it is known that there are aggressive populations of *Phytophthora infestans* especially in the Netherlands for which the resistance risk is considered high. *Plasmopara viticola* is accepted as showing a high risk to development of resistance to fungicides.

Cases of fungicide resistance of *Phytophthora infestans* in potato are reported for Phenylamide fungicides and CAA fungicides (dimethomorph). Monitoring programs conducted in 2013 did not highlight cases of resistance regarding *Phytophthora infestans* on potato and tomato.

There are known cases of fungicide resistance of *Plasmopara viticola* in grapevine for Phenylamide fungicides, Qol fungicides, CAA fungicides, cyanoacetamide oxines and phosphonates.

Valis M is applied with a maximum of 4 applications in potato against potato late blight and with a maximum of 2 applications in grapevine against downy mildew. Resistance management on the national label is required, therefore the following warning sentence is placed on the label:

Dit middel bevat de werkzame stoffen valifenalate en mancozeb. Valifenalate behoort tot de Carboxylic Acid Amides. De FRAC code is 40. Mancozeb behoort tot de dithiocarbamaten fungiciden. De FRAC code is M3. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen.

### **Overall conclusion**

Based on the presented data it can be concluded that Valis M, when applied in accordance with good agricultural practices, is at the proposed dose rate of 2.5 kg/ha effective against *Phytophthora infestans* in potato and is at the proposed dose rate of 2.0 kg/ha effective against *Plasmopara viticola* in grapevine without occurrence of unacceptable and unintended side-effects.

# 3.2 Conclusions

An authorisation can be granted for potatoes, An authorisation cannot be granted for the application in graphes, due to risks for the vole..

# **3.3** Substances of concern for national monitoring

Not applicable

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

Not applicable

# Appendix 1: Provisional label

## Wettelijk Gebruiksvoorschrift

Toegestaan is uitsluitend het professionele gebruik als schimmelbestrijdingsmiddel door middel van een gewasbehandeling in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0, Ctgb juni 2011) onder de vermelde toepassingsvoorwaarden

Toepassingsgebi ed	Te bestrijden organisme	Dosering (middel) per toepassin g	Maximaal aantal toepassing en per teeltcyclus	Minimum interval tussen toepassing en in dagen	Veiligheidsterm ijn in dagen
Aardappelen	Aardappelziekt e <sup>1</sup>	2,5 kg/ha	4*	7	7

\*Maximaal 1 toepassing voor het sluiten van het gewas en maximaal 3 toepassingen na het sluiten van het gewas (BBCH 40)

<sup>1</sup> Aardappelziekte (*Phytophthora infestans*)

## Toepassingsvoorwaarden

De spuitvloeistof dient continu geroerd te worden.

Draag geschikte handschoenen bij werkzaamheden aan behandeld gewas.

Om in het water levende organismen te beschermen is de toepassing van het middel in de teelt van aardappelen op perceelsranden die grenzen aan oppervlaktewater uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 90% driftreducerende spuitdoppen.

Om niet tot de doelsoorten behorende geleedpotigen te beschermen is toepassing van het middel in de teelt van aardappelen uitsluitend toegestaan wanneer gebruik gemaakt wordt van minimaal 75% drift reducerende spuitdoppen.

### Resistentiemanagement

Dit middel bevat de werkzame stoffen valifenalate en mancozeb. Valifenalate behoort tot de Carboxylic Acid Amides. De FRAC code is 40. Mancozeb behoort tot de dithiocarbamaten fungiciden. De FRAC code is M3. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen.

Valis M BCP382F

# Appendix 2: Letter of Access

Applicant has provided a letter of access to Ctgb.

# **Appendix 3:** Glossary

There are no abbreviations in this chapter which are not listed in Appendix 1 "Standard terms and abbreviations" of "Guidelines and Criteria for Industry for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for Plant Protection Products and their Active Substances in Support of Regulatory Decision in OECD Countries", Revision 2, May 2005.

# Appendix 4: List of data submitted in support of the evaluation

Section 1 – Identity, physic-chemical properties and further informatio	Section 1	– identity.	physic-chemical	properties and	further information
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Annex Point /	Year	Title	Data	Relied on	Data	Owner
reference		Source (where different from company)	protection	Y/N	protection	
number		Company, Report No.	claimed		granted	
		GLP or GEP status (where relevant)	Y/N		Y/N	
		Published or unpublished				
IIIA1 2.1/01,	2008	IR5885 M : PHYSICAL AND CHEMICAL	Y	Y	Y	Belchim
IIIA1 2.4.2/01,		CHARACTERISATION - DETERMINATION				Crop
IIIA1 2.7.5/01		OF SHELF LIFE AT AMBIENT				Protection
		TEMPERATURE (AFTER 24 MONTHS OF				
		STORAGE)				
		S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy				
		Report No.: 20065003/01-PCRT				
		GLP, unpublished				
IIIA1 2.2.1/01	2006	IR5885 M - BATCH NO.: G 005/06 -	Y	Y	Y	Belchim
		EXPLOSIVE PROPERTIES A.14.				Crop
		Siemens AG, Prozess Sicherheit, Frankfurt,				Protection
		Germany				
		Report No.: 20060578.01				
		GLP, unpublished				
IIIA1 2.2.2/01	2006	IR5885 M : OXIDISING PROPERTIES	Y	Y	Y	Belchim
		S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy				Crop
		Report No.: 20065003/01-PCOP				Protection
	<b>2</b> 004	GLP, unpublished				
IIIA1 2.3.2/01	2006a	IR5885 M : DETERMINATION OF	Y	Y	Y	Belchim
		FLAMMABILITY (SOLIDS)				Crop
		S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy				Protection
		Report No.: 20065003/01-PCFS				
	2006-	GLP, unpublished	V	V	V	Dalahim
IIIAI 2.3.3/01	2006a	IK5885 M - BATCH NU.: G 005/00 - AUTO-	ľ	I	r	Gran
		FLAWIWADILITI (SOLIDS -				Drotaction
		ICNITION TEMPEDATURE) A 16				Protection
		Sigmons AG, Brozass Sicharhait Frankfurt				
		Germany				
		Report No : 20060578.02				
		GLP unpublished				
KIIIA1262/01	2012	DETERMINATION OF THE PHYSICAL	v	v	v	Belchim
111111 2.0.2/01	2012	CHEMICAL PROPERTIES OF THE IR 5885	1	1	1	Cron
		MANCOZEB 6-60 WG FORMULATION				Protection
		Renolab S.r.L. Poggio Renatico. Italy				Tiotection
		Report No.: 12020-01C				
		GLP, unpublished				
IIIA1 2.7.1/01	2006b	IR5885 M - DETERMINATION OF ACTIVE	Y	Y	Y	Belchim
		INGREDIENTS CONTENT	_	-	-	Crop
		S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy				Protection
		Report No.: 20065003/01-PCAI				
		GLP, unpublished				

Annex Point /	Vear	Title	Data	Relied on	Data	Owner
reference number	i cai	Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or unpublished	protection claimed Y/N	Y/N	protection granted Y/N	Owner
IIIA1 2.7.1/02	2010	IR5885 + MANCOZEB 6+60 WG - MANCOZEB AND ETHYLENTHIOUREA CONTENT ON FRESH SAMPLE AND AFTER ACCELERATED STABILITY AT +54 °C Sipcam Experimental Service, Salerano Sul Lambro, Italy	Y	Y	Y	Belchim Crop Protection
IIIA1 2.7.1/03	2006c	Report No.: 027/2010 GLP, unpublished IR5885 M : PHYSICAL AND CHEMICAL	Y	Y	Y	Belchim
		CHARACTERISATION - DETERMINATION OF APPEARANCE (PHYSICAL STATE, COLOUR AND ODOUR) S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy Report No.: 20065003/01-PCAP GLP, unpublished	-			Crop Protection
IIIA1 2.7.1/04	2006d	IR5885 M : PHYSICAL AND CHEMICAL CHARACTERISATION - DETERMINATION OF pH (1% DISPERSION) S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy Report No.: 20065003/01-PCPH GLP, unpublished	Y	Y	Y	Belchim Crop Protection
IIIA1 2.7.1/05, IIIA1 2.8.1/01	2006e	IR5885 M : PHYSICAL AND CHEMICAL CHARACTERISATION - DETERMINATION OF WETTABILITY S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy Report No.: 20065003/01-PCWP GLP_unpublished	Y	Y	Y	Belchim Crop Protection
IIIA1 2.7.1/06, IIIA1 2.8.6.2/01	2006f	IR5885 M : PHYSICAL AND CHEMICAL CHARACTERISATION - DETERMINATION OF PARTICLE SIZE DISTRIBUTION S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy Report No.: 20065003/01-PCDD GLP, unpublished	Y	Y	Y	Belchim Crop Protection
IIIA1 2.7.1/07, IIIA1 2.8.5.2/01	2006g	IR5885 M : PHYSICAL AND CHEMICAL CHARACTERISATION - DETERMINATION OF WET SIEVING S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy Report No.: 20065003/01-PCWG GLP. unpublished	Y	Y	Y	Belchim Crop Protection
IIIA1 2.7.1/08, IIIA1 2.8.6.3/01	2006h	IR5885 M : PHYSICAL AND CHEMICAL CHARACTERISATION - DETERMINATION OF DUSTINESS S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy Report No.: 20065003/01-PCDU GLP, unpublished	Y	Y	Y	Belchim Crop Protection
IIIA1 2.7.1/09, IIIA1 2.8.3.1/01	2006i	IR5885 M : PHYSICAL AND CHEMICAL CHARACTERISATION - DETERMINATION OF SUSPENSIBILITY S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy Report No.: 20065003/01-PCSG GLP, unpublished	Y	Y	Y	Belchim Crop Protection

Annex Point /	Vear	Title	Data	Relied on	Data	Owner
reference number	1000	Source (where different from company) Company, Report No. GLP or GEP status (where relevant)	protection claimed Y/N	Y/N	protection granted Y/N	0 wher
IIIA1 2.7.1/10. IIIA1 2.8.3.2/01	2006j	Published or unpublished IR5885 M : PHYSICAL AND CHEMICAL CHARACTERISATION - DETERMINATION OF DISPERSIBILITY	Y	Y	Y	Belchim Crop
		S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy Report No.: 20065003/01-PCDW GLP, unpublished				Tiotection
IIIA1 2.7.1/11, IIIA1 2.8.6.5/01	2006k	IR5885 M : PHYSICAL AND CHEMICAL CHARACTERISATION - DETERMINATION OF ATTRITION RESISTANCE S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy Report No.: 20065003/01-PCAR GLP, unpublished	Y	Y	Y	Belchim Crop Protection
IIIA1 2.7.1/12	20061	IR5885 M : PHYSICAL AND CHEMICAL CHARACTERISATION - DETERMINATION OF PERSISTENT FOAM S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy Report No.: 20065003/01-PCPF GLP, unpublished	Y	Y	Y	Belchim Crop Protection
IIIA1 2.7.5/02	2012	IR5885 + MANCOZEB 6+60 WG - MANCOZEB AND ETHYLENTHIOUREA CONTENT DETERMINATION DURING STORAGE AT ROOM TEMPERATURE FOR TWO YEARS Sipcam Experimental Service, Salerano Sul Lambro, Italy Report No.: 004/2010 GLP, unpublished	Y	Y	Y	Belchim Crop Protection
IIIA1 2.8.2/01	2012	DETERMINATION OF THE PHYSICAL- CHEMICAL PROPERTIES OF THE IR5885 MANCOZEB 6-60 WG FORMULATION Renolab S.r.l., Poggio Renatico, Italy Report No.: 12020-01C GLP, unpublished	Y	Y	Y	Belchim Crop Protection
IIIA1 2.8.2/02, IIIA1 4.2.2/02	2015	<sup>•</sup> BCP382F (as Sulfotechnica)' – Determination of specified physical/chenmical properties before andf after 14 days accelerated storage at 54±2°C Oxford Analytical Ltd, UK Study no. OA02464 GLP, unpublished	Y	Y	Y	Belchim Crop Protection
IIIA1 2.8.8.1/01	2006m	IR5885 M : PHYSICAL AND CHEMICAL CHARACTERISATION - DETERMINATION OF FLOWABILITY S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy Report No.: 20065003/01-PCFL GLP, unpublished	Y	Y	Y	Belchim Crop Protection
IIIA1 2.15/01	2006n	IR5885 M : PHYSICAL AND CHEMICAL CHARACTERISATION - DETERMINATION OF WATER S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy Report No.: 20065003/01-PCWT GLP, unpublished	Y	Y	Y	Belchim Crop Protection

Annex Point / reference number	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or unpublished	Data protection claimed Y/N	Relied on Y/N	Data protection granted Y/N	Owner
IIIA1 4.2.2/01	2003	IR5885 / FOLPET 6-48 WG - EFFECTIVENESS OF THE CLEANING PROCEDURE Isagro Ricerca s.r.l., Vincenzo di Galliera, Italy Report No.: 004/03 IRG - CCF Not GLP, unpublished	Y	Y	Y	Belchim Crop Protection

# Section 2 – analytical methods

Annex Point / reference number	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or unpublished	Data protection claimed Y/N	Data protection granted Y/N	Relied on Y/N	Owner
KIIIA1 5.2.2/01	2007	DEVELOPMENT AND VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF THE CONTENT OF ACTIVE INGREDIENTS IN IR5885 M S.P.F. GAB Italia s.r.l., Poggio Renatico, Italy Report No.: 20065003/01-PCVE GLP, unpublished	Y	Y	Y	Belchim Crop Protection
KIIIA1 5.2.4/01	2012	IR5885 + MANCOZEB 6+60 WG - MANCOZEB AND ETHYLENTHIOUREA CONTENT DETERMINATION DURING STORAGE AT ROOM TEMPERATURE FOR TWO YEARS Sipcam Experimental Service, Salerano Sul Lambro, Italy Report No.: 004/2010 GLP, unpublished	Y	Y	Y	Belchim Crop Protection
KIIIA1 5.4/01	2002	ENFORCEMENT METHOD (INCLUDING VALIDATION) FOR THE DETERMINATION OF RESIDUES OF IR5885 IN SOIL Dr. Specht & Partner Chemische Laboratorien GmbH, Hamburg, Germany Report No.: ISA-0105V G01-0124 GLP, unpublished	Y	Y	Y	Belchim Crop Protection
KIIIA1 5.4/02	2004	SET UP AND VALIDATION OF A METHOD FOR RESIDUE OF IR5839 IN SOILS (THREE TYPES) Isagro Ricerca S.r.l., Novara, Italy Report No.: 2414 GLP, unpublished	Y	Y	Y	Belchim Crop Protection
KIIIA1 5.4/03	2004	SET UP AND VALIDATION OF A METHOD FOR RESIDUE OF PCBA IN SOIL (THREE TYPES) Isagro Ricerca S.r.l., Novara, Italy Report No.: 2416 GLP, unpublished	Y	Y	Y	Belchim Crop Protection
KIIIA1 5.6/01	2002	ENFORCEMENT METHOD (INCLUDING VALIDATION) FOR THE DETERMINATION OF RESIDUES OF IR5885 IN GROUND WATER Dr. Specht & Partner Chemische Laboratorien GmbH, Hamburg, Germany Report No.: ISA-0104V Az. G01-0123 GLP, unpublished	Y	Y	Y	Belchim Crop Protection

Annex Point / reference number	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or unpublished	Data protection claimed Y/N	Data protection granted Y/N	Relied on Y/N	Owner
KIIIA1 5.6/02	2014	VALIDATION OF ANALYTICAL METHODOLOGY FOR THE DETERMINATION OF RESIDUES OF VALIFENALATE AND ITS METABOLITE IR5839 AND PCBA IN SURFACE WATER Laboratorio de Analisis de Residuos de Plaguicidas, Castellón, Spain Report No.: 236-14 GLP, unpublished	Y	Y	Y	Belchim Crop Protection
KIIIA1 5.7/01	2004	VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF IR5885 IN AIR GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Öschelbronn, Germany Report No.: 20041036/01-CMLU GLP, unpublished	Y	Y	Y	Belchim Crop Protection
KIIIA1 5.8/01	2011	VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF RESIDUES OF ETHYLENETHIOUREA (ETU) IN BODY FLUIDS SGS Institut Fresenius GmbH, Taunusstein, Germany Report No.: IF-10/01821490 GLP, unpublished Doc. No.: 433-001	Y	Y	Y	Indofil Industries Limited

# Section 3 Mammalian Toxicology

Annex Point / reference	Year	Title Source (where different from company)	Data protection	Studies relied on	Data protection	Owner
number		Company, Report No.	claimed	Y/N	granted Y/N	
		GLP or GEP status (where relevant)	Y/N			
		Published or unpublished				
KIIIA1	2006	ACUTE ORAL TOXICITY ACUTE TOXIC	Y	Y	Y	Belchim Crop
7.1.1/01		CLASS METHOD WITH IR5885M				Protection
		Report No.: 060728				
		GLP, unpublished				
KIIIA1	2006	ACUTE DERMAL TOXICITY (LIMIT	Y	Y	Y	Belchim Crop
7.1.2/01		TEST) WITH IR5885M				Protection
		Report No.: 060729				
		GLP, unpublished				
KIIIA1	2009	ACUTE INHALATION TOXICITY - IR5885	Y	Y	Y	Belchim Crop
7.1.3/01		M (STATEMENT)				Protection
		Isagro Ricerca S.r.l., Novara, Italy				
		Report No.: ni				
		Not GLP, unpublished				
KIIIA1	2006	ACUTE DERMAL	Y	Y	Y	Belchim Crop
7.1.4/01		IRRITATION/CORROSION WITH IR5885M				Protection
		Report No.: 060730				
		GLP, unpublished				
KIIIA1	2006	ACUTE EYE IRRITATION/CORROSION	Y	Y	Y	Belchim Crop
7.1.5/01		WITH IR5885M				Protection
		Report No.: 060726				
		GLP, unpublished				

KIIIA1	2006	TEST FOR SENSITIZATION (GUINEA-PIG	Y	Y	Y	Belchim Crop
7.1.6/01		MAXIMISATION TEST) WITH IR5885M				Protection
		Report No.: 060727				
		GLP, unpublished				
KIIIA1	2014	VALIS M - IN VITRO ABSORPTION OF	Y	Y	Y	Belchim Crop
7.6.2/01		VALIFENALATE THROUGH HUMAN				Protection
		DERMATOMED SKIN USING [14C]-				
		RADIOLABELLED VALIFENALATE				
		Dermal Technology Laboratory Ltd.,				
		Staffordshire, United Kingdom				
		Report No.: JV2298-REG				
		JV2298				
		QD1019/01				
		GLP, unpublished				
KIIIA1	2014	VALIS M - IN VITRO ABSORPTION OF	Y	Y	Y	Belchim Crop
7.6.2/02		MANCOZEB THROUGH HUMAN				Protection
		DERMATOMED SKIN USING [14C]-				
		RADIOLABELLED MANCOZEB				
		Dermal Technology Laboratory Ltd.,				
		Staffordshire, United Kingdom				
		Report No.: JV2293-REG				
		JV2293				
		QD1019/01				
		GLP, unpublished				

## Section 4 Metabolism and residues

Annex Point / reference number	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or unpublished	Data protection claimed Y/N	Owner	Study relied on Y/N	Data protection granted Y/N
KIIIA1 8.3.1/01	2006	IR5885 RESIDUES IN POTATO AFTER APPLICATIONS OF IR5885 KG. TWO HARVEST AND TWO DECLINE TRIALS IN NORTHERN EUROPE IN 2005 Isagro Ricerca S.r.l., Novara, Italy Report No.: RA.05.07 GLP, unpublished	Y	Belchim Crop Protection	Y	Y
KIIIA1 8.3.1/02	2004	IR5885 RESIDUES IN POTATO TREATED WITH IR5885 + MANCOZEB (6%+60% W/W) WP. MAXIMUM EXPOSURE IN TWO HARVEST AND FOUR DECLINE TRIALS IN ITALY, SPAIN AND GERMANY (2002) Isagro Ricerca S.r.l., Novara, Italy Report No.: 2411 SP00181 GLP, unpublished	Y	Belchim Crop Protection	Y	Y
KIIIA1 8.3.1/03	2003	VALIDATION OF A METHOD FOR RESIDUE OF IR5885 IN POTATO, GRAPE BUNCHES AND WINE Isagro Ricerca S.r.l., Novara, Italy Report No.: 2407 GLP, unpublished	Y	Belchim Crop Protection	Y	Y
KIIIA1 8.3.2/01	2009	IR5885 RESIDUES IN WINE GRAPE AFTER THREE APPLICATIONS OF IR5885 M. TWO HARVEST TRIALS IN NORTHERN EUROPE IN 2007 Isagro Ricerca S.r.l., Novara, Italy Report No.: RA.07.15 GLP, unpublished	Y	Belchim Crop Protection	Y	Y

Annex	Vear	Title	Data	Owner	Study	Data
Point / reference number	i cui	Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or unpublished	protection claimed Y/N	0 wher	relied on Y/N	protection granted Y/N
KIIIA1 8.3.2/02	2003	VALIDATION OF A METHOD FOR RESIDUE OF IR5885 IN POTATO, GRAPE BUNCHES AND WINE Isagro Ricerca S.r.l., Novara, Italy Report No.: 2407 GLP, unpublished	Y	Belchim Crop Protection	Y	Y
KIIIA1 8.3.2/03	2009	SET UP AND VALIDATION OF A METHOD FOR IR5885 IN GRAPE BUNCHES AND RAISINS Isagro Ricerca S.r.l., Novara, Italy Report No.: RA.08.35 GLP, unpublished	Y	Belchim Crop Protection	Y	Y
KIIIA1 8.1.1/01	2011	STORAGE STABILITY OF RESIDUES OF CYMOXANIL, MANCOZEB AND ETU IN POTATO SAMPLES Eurofins Dr. Specht GLP GmbH, Hamburg, Germany Report No.: GAB-0704 G07-0114 S08-02619 GLP, unpublished Doc. No.: 645-004	Y	Indofil Industries Limited Belchim Crop Protection	Y	Y
KIIIA1 8.1.1/02	2008	VALIDATION OF THE ANALYTICAL METHODS FOR THE DETERMINATION OF RESIDUES OF CYMOXANIL, MANCOZEB AND ITS METABOLITE ETU IN POTATO (TUBER) Eurofins Analytik GmbH, Hamburg, Germany Report No.: GAB-0703V GLP, unpublished Doc. No.: 432-018	Y	Indofil Industries Limited Belchim Crop Protection	Y	N Used for previous authorisation in NL
KIIIA1 8.1.1/03	2010	FROZEN STORAGE STABILITY OF MANCOZEB RESIDUES IN GRAPES Anadiag, Haguenau, France Report No.: R A7188 A7188 GLP, unpublished Doc. No.: 645-003	Y	Indofil Industries Limited Belchim Crop Protection	Y	N Used for previous authorisation in NL
KIIIA1 8.1.1/04	2009	VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF MANCOZEB RESIDUES IN GRAPES (RAC AND PROCESSING FRACTIONS) Anadiag, Haguenau, France Report No.: R A7185 A7185 GLP, unpublished Doc. No.: 432-017	Y	Belchim Crop Protection Indofil Industries Limited	Y	N Used for previous authorisation in NL
KIIIA1 8.1.1/05	2010	FROZEN STORAGE STABILITY OF ETU IN GRAPES Anadiag, Haguenau, France Report No.: R A7189 A7189 GLP, unpublished Doc. No.: 645-002	Y	Indofil Industries Limited Belchim Crop Protection	Y	N Used for previous authorisation in NL
KIIIA1 8.1.1/06	2009	VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF ETU RESIDUES IN GRAPES (RAC AND PROCESSING FRACTIONS) Anadiag, Haguenau, France Report No.: R A7186 A7186 GLP, unpublished Doc. No.: 432-016	Y	Belchim Crop Protection Indofil Industries Limited	Y	N Used for previous authorisation in NL

Annex Point /	Yeaı	Title Source (where different from company)	Data protection	Owner	Study relied	Data protection
number		Company, Report No. GLP or GEP status (where relevant) Published or unpublished	Y/N		on Y/N	granted Y/N
KIIIA1 8.3.1/05	2010	DETERMINATION OF RESIDUES OF CYMOXANIL AND MANCOZEB AFTER SIX APPLICATIONS CYMOXANIL/MANCOZEB 4.5/68% W/W WP IN FIELD POTATOES, NORTHERN EUROPE, 2007/2008 Eurofins Agroscience Services GmbH, Niefern- Öschelbronn, Germany Report No.: 20074095/E1-FPPO F07W133R G07W344R PL07W020R S08-02370-01 GLP, unpublished Doc. No.: 634-1105	Y	Belchim Crop Protection Indofil Industries Limited	Y	N Used for previous authorisation in NL
KIIIA1 8.3.1/06 (see also study KIIIA1 8.1.1/02)	2008	VALIDATION OF THE ANALYTICAL METHODS FOR THE DETERMINATION OF RESIDUES OF CYMOXANIL, MANCOZEB AND ITS METABOLITE ETU IN POTATO (TUBER) Eurofins Analytik GmbH, Hamburg, Germany Report No.: GAB-0703V GLP, unpublished Doc. No.: 432-018	Y	Indofil Industries Limited Belchim Crop Protection	Y	N Used for previous authorisation in NL
KIIIA1 8.3.2/04	2009	DETERMINATION OF CYMOXANIL AND MANCOZEB RESIDUES IN WINE GRAPES FOLLOWING TREATMENT WITH WP 4,5/68 OR WP 4/46,5 UNDER OPEN FIELD CONDITIONS IN NORTHERN AND SOUTHERN EUROPE, 2007 Anadiag, Haguenau, France Report No.: R A7115 A7115 GLP, unpublished Doc. No.: 632-4003	Y	Indofil Industries Limited	Y	Y
KIIIA1 8.3.2/05 (see also study KIIIA1 8.1.1/04)	2009	VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF MANCOZEB RESIDUES IN GRAPES (RAC AND PROCESSING FRACTIONS) Anadiag, Haguenau, France Report No.: R A7185 A7185 GLP, unpublished Doc. No.: 432-017	Y	Belchim Crop Protection Indofil Industries Limited	Y	N Used for previous authorisation in NL
KIIIA1 8.5.3/01	2009	DETERMINATION OF CYMOXANIL AND MANCOZEB RESIDUES IN WINE GRAPES FOLLOWING TREATMENT WITH BCP 309F (=MANCOZEB/CYMOXANIL WG) UNDER OPEN FIELD CONDITIONS IN NORTHERN AND SOUTHERN EUROPE, 2007 Anadiag, Haguenau, France Report No.: R A7127 A7127 GLP, unpublished	Y	Belchim Crop Protection	Y	N Used for previous authorisation in NL

Annex Point / reference number	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or unpublished	Data protection claimed Y/N	Owner	Study relied on Y/N	Data protection granted Y/N
KIIIA1 8.5.3/02	2009	DETERMINATION OF CYMOXANIL AND MANCOZEB RESIDUES IN WINE GRAPES FOLLOWING TREATMENT WITH WP 4,5/68 OR WP 4/46,5 UNDER OPEN FIELD CONDITIONS IN NORTHERN AND SOUTHERN EUROPE, 2007 Anadiag, Haguenau, France Report No.: R A7115 A7115 GLP, unpublished Doc. No.: 632-4003	Y	Indofil Industries Limited	Y	Y
KIIIA1 8.5.3/04 (see also study KIIIA1 8.1.1/04)	2009	VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF MANCOZEB RESIDUES IN GRAPES (RAC AND PROCESSING FRACTIONS) Anadiag, Haguenau, France Report No.: R A7185 A7185 GLP, unpublished Doc. No.: 432-017	Y	Belchim Crop Protection Indofil Industries Limited	Y	N Used for previous authorisation in NL
KIIIA1 8.5.3/05 (see also study KIIIA1 8.1.1/06)	2009	VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF ETU RESIDUES IN GRAPES (RAC AND PROCESSING FRACTIONS) Anadiag, Haguenau, France Report No.: R A7186 A7186 GLP, unpublished Doc. No.: 432-016	Y	Belchim Crop Protection Indofil Industries Limited	Y	N Used for previous authorisation in NL

# Section 5 - Fate and behaviour

Core

Annex Point / reference number	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or unpublished	Data protection claimed Y/N	Owner	data protection granted Y/N	studies relied on Y/N
KIIIA1 9.1/02	2002	AEROBIC METABOLISM OF [14C-U- PHENYL]IR5885 IN SOIL Isagro Ricerca S.r.l., Novara, Italy Report No.: MEF.01.08 GLP, unpublished	Y	Belchim Crop Protection	N (claimed in DAR)	Y
KIIIA1 9.1.1/01	2012	ATTEMPTS TO IDENTIFY AN UNKNOWN IR5885 METABOLITE FOUND IN SOIL STUDIES Isagro Ricerca S.r.l., Novara, Italy Report No.: MEF.12.06 GLP, unpublished	Y	Belchim Crop Protection	Y	Y

Annex Point / reference number	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or unpublished	Data protection claimed Y/N	Owner	data protection granted Y/N	studies relied on Y/N
KIIIA1 9.6/01 :	2014	VALIS M - RAW DATA TO PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUNDWATER (PECgw) FOR VALIFENALATE AND ITS METABOLITES USING FOCUS PEARL 4.4.4 AND FOCUS PELMO 5.5.3 RELATED TO THE dRR PART B SECTION 5 OF VALIS M FOR THE CENTRAL ZONE Scientific Consulting Company, Bad Kreuznach, Germany Report No.: PP176-00008_782-005 Not GLP, unpublished	Y	Belchim Crop Protection	Ν	Y
KIIIA1 9.6/02 :	2014	VALIS M - RAW DATA TO PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUNDWATER (PECgw) FOR MANCOZEB AND ITS METABOLITES USING FOCUS PEARL 4.4.4 AND FOCUS PELMO 5.5.3 RELATED TO THE dRR PART B SECTION 5 OF VALIS M FOR THE CENTRAL ZONE Scientific Consulting Company, Bad Kreuznach, Germany Report No.: PP176-00008_782-010 Not GLP, unpublished	Y	Belchim Crop Protection	N	Y

# NL addendum

Annex Point / reference number	Year	CitleDataOvCource (where different from company)protectionCompany, Report No.claimedGLP or GEP status (where relevant)Y/NPublished or unpublishedY/NVALIS M - RAW DATA TO PREDICTEDY			data protection granted y/n	studies relied on y/n
KIIIA1 9.7/01 (NL)	2014	VALIS M - RAW DATA TO PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER (PECsw) FOR THE PARENT COMPOUND VALIFENALATE USING TOXSWA v 2.1 RELATED TO THE dRR PART B SECTION 5 OF VALIS M FOR THE NATIONAL ADDENDUM - THE NETHERLANDS Scientific Consulting Company, Bad Kreuznach, Germany Report No.: PP176-00008_782-008 Not GLP, unpublished	Y	Belchim Crop Protection	Ν	Y
KIIIA1 9.7/02 (NL)	2014	VALIS M - RAW DATA TO PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER (PECsw) FOR THE PARENT COMPOUND MANCOZEB USING TOXSWA v 2.1 RELATED TO THE dRR PART B SECTION 5 OF VALIS M FOR THE NATIONAL ADDENDUM - THE NETHERLANDS Scientific Consulting Company, Bad Kreuznach, Germany Report No.: PP176-00008_782-013 Not GLP, unpublished	Y	Belchim Crop Protection	Ν	Y
KIIIA1 9.7/03	2016	Predicted environmental concentrations of MANCOZEB in surface water and sediment following application to POTATOES – a modelling assessment for the Netherlands using TOXSWA Dr. Knoell Consult GmbH, Germany Report No. 104290-3 Not GLP, unpublished	Y	Belchim Crop Protection	N	Y
KIIIA 9.7	2017	Predicted environmental concentrations of Mancozeb in surface water and sediment following use in Potatoes and Vines Excelra Knowledge Solutions Pvt Ltd Regulatory Science Project ID: BCP-16-0021 Non-GLP unpublished	Y	Belchim Crop Protection NV/SA	N	Y
KIIIA1 9.8/01 (NL)	2014	VALIS M - RAW DATA TO PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER (PECsw) FOR THE METABOLITES OF VALIFENALATE USING TOXSWA v 2.1 RELATED TO THE dRR PART B SECTION 5 OF VALIS M FOR THE NATIONAL ADDENDUM - THE NETHERLANDS Scientific Consulting Company, Bad Kreuznach, Germany Report No.: PP176-00008_782-009 Not GLP, unpublished	Y	Belchim Crop Protection	Ν	Y

KIIIA1 9.8/02	2014	VALIS M - RAW DATA TO PREDICTED	Y	Belchim	N	Y
(NL)		ENVIRONMENTAL CONCENTRATIONS IN		Crop		
		SURFACE WATER (PECsw) FOR THE		Protection		
		METABOLITES OF MANCOZEB USING				
		TOXSWA v 2.1 RELATED TO THE dRR PART B				
		SECTION 5 OF VALIS M FOR THE NATIONAL				
		ADDENDUM - THE NETHERLANDS				
		Scientific Consulting Company, Bad Kreuznach,				
		Germany				
		Report No.: PP176-00008_782-014				
		Not GLP, unpublished				

# Section 6 – Ecotoxicology

Core

#### Valifenalate

Annex Point /	Year	Title	Data	Owner	Data	Studies	
reference		Source (where different from company)	protection		protection	relied	
number		Company, Report No.	claimed		granted Y/N	on Y/N	
		GLP or GEP status (where relevant)	Y/N		0		
		Published or unpublished					
KIIIA1	2006	IR5885 M: AN ACUTE ORAL TOXICITY STUDY	Y	Belchim	Y	Y	
10.1.6/01		WITH THE NORTHERN BOBWHITE		Crop			
		Wildlife International Ltd., Easton, Maryland, USA		Protection			
		Report No.: 544-115					
		GLP, unpublished					
KIIIA1	2006	ACUTE ORAL TOXICITY ACUTE TOXIC CLASS	Y	Belchim	Y	Y	
10.3.2.1		METHOD WITH IR5885M		Crop			
		BSL Bioservice Scientific Laboratories, Planegg, Germany		Protection			
		Report No.: 060728					
		GLP, unpublished					
KIIIA1	2006	IR5885 M: ACUTE ORAL TOXICITY TEST WITH THE	Y	Belchim	Y	Y	
10.4.2.1/01		HONEYBEE, APIS MELLIFERA		Crop			
		ABC Laboratories, Columbia, USA		Protection			
		Report No.: 50460					
		GLP, unpublished					
KIIIA1	2006	IR5885 M: ACUTE CONTACT TOXICITY TEST WITH	Y	Belchim	Y	Y	
10.4.2.2/01		THE HONEYBEE, APIS MELLIIFERA		Crop			
		ABC Laboratories, Columbia, USA		Protection			
		Report No.: 50459					
		GLP, unpublished					
KIIIA1	2006	A RATE-RESPONSE LABORATORY TEST TO	Y	Belchim	Y	Y	
10.5.1/01		DETERMINE THE EFFECTS OF IR5885 M ON THE		Crop			
		PREDATORY MITE, TYPHLODROMUS PYRI (ACARI:		Protection			
		PHYTOSEIIDAE)					
		Mambo-Tox Ltd., Southampton, United Kingdom					
		Report No.: ISA-06-1					
		GLP, unpublished					
KIIIA1	2006	A RATE-RESPONSE LABORATORY TEST TO	Y	Belchim	Y	Y	
10.5.1/02		DETERMINE THE EFFECTS OF IR5885 M ON THE		Crop			
		PARASITIC WASP, APHIDIUS RHOPALOSIPHI		Protection			
		(HYMENOPTERA, BRACONIDAE)					
		Mambo-Tox Ltd., Southampton, United Kingdom					
		Report No.: ISA-06-3					
		GLP, unpublished					

Annex Point	Year	Title	Data	Owner	Data	Studies
reference	I cui	Source (where different from company)	protection	0 wher	protection	relied
number		Company, Report No.			granted Y/N	on Y/N
		GLP of GEP status (where relevant) Published or uppublished	1/1			
KIIIA1	2006	A RATE-RESPONSE LABORATORY TEST TO	Y	Belchim	Y	Y
10.5.1/03	2000	DETERMINE THE EFFECTS OF 'IR5885 M	-	Crop	-	-
		MANCOZEB-FREE' ON THE PREDATORY MITE.		Protection		
		TYPHLODROMUS PYRI (ACARI: PHYTOSEIIDAE)				
		Mambo-Tox Ltd., Southampton, United Kingdom				
		Report No.: ISA-06-2				
		GLP, unpublished				
KIIIA1 10.5.1/04	2006	A RATE-RESPONSE LABORATORY TEST TO DETERMINE THE EFFECTS OF 'IR5885 M	Y	Belchim Crop	Y	Y
		MANCOZEB-FREE' ON THE PARASITIC WASP,		Protection		
		APHIDIUS RHOPALOSIPHI (HYMENOPTERA,				
		BRACONIDAE)				
		Mambo-Tox Ltd., Southampton, United Kingdom				
		Report No.: ISA-06-4				
		GLP, unpublished				
KIIIA1	2006	A RATE-RESPONSE EXTENDED LABORATORY	Y	Belchim	Y	Y
10.5.2/01		TEST TO DETERMINE THE EFFECTS OF IR5885 M		Crop		
		ON THE PREDATORY MITE, TYPHLODROMUS PYRI		Protection		
		(ACARI: PHY IOSEIIDAE) Member Tey I td. Southematen, United Kingdom				
		Mambo-10x Ltd., Southampton, United Kingdom				
		GLP unpublished				
KIIIA1	2014	BCP 382E - AN EXTENDED I ABORATORY TEST TO	v	Belchim	v	v
10.5.2/02	2014	EVALUATE THE EFFECTS OF FRESH RESIDUES ON	1	Crop	1	1
		THE GREEN LACEWING, CHRYSOPERLA CARNEA		Protection		
		(NEUROPTERA, CHRYSOPIDAE)				
		Mambo-Tox Ltd., Southampton, United Kingdom				
		Report No.: BEL-14-1				
		GLP, unpublished				
KIIIA1	2014	BCP 382F - AN EXTENDED LABORATORY TEST TO	Y	Belchim	Y	Y
10.5.2/03		DETERMINE EFFECTS ON THE LADY BIRD BEETLE,		Crop		
		COCCINELLA SEPTEMPUNCTATA (COLEOPTERA:		Protection		
		COCCINELLIDAE) Mamba Tay I td. Southampton United Kingdom				
		Report No · BEL -14-2				
		GLP. unpublished				
KIIIA1	2007	EFFECTS OF THE TEST SUBSTANCES IR 5885 F. IR	Y	Belchim	Y	Y
10.5.4/01		5885 M ON PHYTOSEIDS IN VINEYARDS		Crop		
		ENIGMA, Beaumes de Venise, France		Protection		
		Report No.: EPA-JTM-01-07				
		FISA075735				
		GLP, unpublished				
KIIIA1	2006	ACUTE TOXICITY (14 DAYS) OF IR5885 M TO THE	Y	Belchim	Y	Y
10.6.2/01		EARTHWORM EISENIA FEITDA IN ARTIFICIAL		Crop		
		DOIL WITH 5% PEAT Institut für Biologische Analytik und Consulting IBACON		Protection		
		GmbH Rossdorf Germany				
		Report No · 29851021				
		GLP. unpublished				
KIIIA1	2006	EFFECTS OF IR5885 M ON REPRODUCTION AND	Y	Belchim	Y	Y
10.6.3/01		GROWTH OF EARTHWORMS EISENIA FETIDA IN		Crop		
	1	ARTIFICIAL SOIL WITH 5% PEAT		Protection		
	1	Institut für Biologische Analytik und Consulting IBACON				
	1	GmbH, Rossdorf, Germany				
	1	Report No.: 29852022				
		GLP, unpublished				

Annex Point	Year	Title	Data	Owner	Data	Studies
reference		Source (where different from company)	protection		protection	relied
number		Company, Report No.	claimed		granted Y/N	on Y/N
		GLP or GEP status (where relevant)	Y/N			
		Published or unpublished				
KIIIA1	2006	EFFECTS OF IR5885M ON THE ACTIVITY OF THE	Y	Belchim	Y	Y
10.7.1/01		SOIL MICROFLORA IN THE LABORATORY		Crop		
		Institut für Biologische Analytik und Consulting IBACON		Protection		
		GmbH, Rossdorf, Germany				
		Report No.: 29853080				
		GLP, unpublished				
KIIIA1	2006	IR5885M: A TOXICITY TEST TO DETERMINE THE	Y	Belchim	Y	Y
10.8.1.2/01		EFFECTS ON VEGETATIVE VIGOUR OF TEN		Crop		
		SPECIES OF PLANTS		Protection		
		Wildlife International Ltd., Easton, Maryland, USA				
		Report No.: 544-117				
		GLP, unpublished				
KIIIA1	2006	IR5885M: A TOXICITY TEST TO DETERMINE THE	Y	Belchim	Y	Y
10.8.1.3/01		EFFECTS ON SEEDLING EMERGENCE OF TEN		Crop		
		SPECIES OF PLANTS		Protection		
		Wildlife International Ltd., Easton, Maryland, USA				
		Report No.: 544-116				
		GLP, unpublished				

Mancozeb

Annex Point /	Author	Year	Title	Data	Owner	Data	Studies
reference			Source (where different from company)	protection		protection	relied
number			Company, Report No.	claimed		granted Y/N	on Y/N
			GLP or GEP status (where relevant)	Y/N		-	
			Published or unpublished				
KIIIA1	Hicks, S.L.	2003	MANCOZEB: PROLONGED TOXICITY	Y	Indofil	Y	Ν
10.2.5.1/02			TEST WITH THE RAINBOW TROUT,		Industries		
			ONCORHYNCHUS MYKISS, IN A		Limited		
			STATIC SEDIMENT-WATER SYSTEM				
			ABC Laboratories, Columbia, USA				
			Report No.: 47955				
			DN0008929				
			ER 111.05				
			GLP, unpublished				
			Doc. No.: 826-001				
KIIIA1	Nienstedt,	2002	A FIELD TEST ON THREE	Y	Indofil	Y	Y
10.5.4/02	K.M.		LOCATIONS TO DETERMINE THE		Industries		
			POTENTIAL EFFECT OF DITHANE®		Limited		
			M-45 APPLIED ON VINEYARDS TO				
			PREDATORY MITE POPULATIONS				
			(ACARI: PHYDOSEIIDAE)				
			Springborn Smithers Laboratories Europe,				
			Horn, Switzerland				
			Report No.: 1007.075.668				
			01RC-0135				
			GHE-P-10098				
			ER 121.05				
			GLP, unpublished				
17111 4 1		2005		37	T 1 C1	37	37
KIIIAI	Bakker, F.	2006	EVALUATING EFFECTS OF GF-999	Y	Indofil	Ŷ	Ŷ
10.5.4/03			APPLICATIONS ON MITE FAUNA		Industries		
			(ACARI) AND OTHER LEAF		Linned		
			EIELD (CRADE VINES ERANCE)				
			MITOX Stichting Bevordering Duurzame				
			Plaaghestrijding Amsterdam				
			Report No : $DA032AFG$				
			050287				
			ER 121.08				
			GLP, unpublished				
			Doc. No.: 834-028				
KIIIA1	Aldershof	2006	EVALUATING EFFECTS OF GF-999	Y	Indofil	Y	Y
10.5.4/04	S.	_000	APPLICATIONS ON MITE FAUNA	-	Industries	-	-
			(ACARI) AND OTHER LEAF		Limited		
			DWELLING ARTHROPODS IN THE				
			FIELD (GRAPE VINES, FRANCE)				
			MITOX Stichting Bevordering Duurzame				
			Plaagbestrijding, Amsterdam				
			Report No.: DA031AFG				
			050286				
			PTR 1000947				
			ER 121.06				
			GLP, unpublished				
			Doc. No.: 834-027				

KIIIA1	Buerge, I.	2000	DITHANE M-45: ACTIVATED	Y	Indofil	Y	Y
10.10.1/01			SLUDGE, RESPIRATION INHIBITION		Industries		
			TEST		Limited		
			Springborn Laboratories (Europe) AG,				
			Switzerland				
			Report No.: 99RC-0234				
			1007.056.790				
			99P-234				
			ER 92.7				
			GLP, unpublished				
			Doc. No.: 842-002				

## NL addendum

Please refer to the above references submitted for the core dossier.

# Section 7 – Efficacy

Annex point	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished GEP status	Data protection claimed Y/N	Owner	Data protection granted Y/N	Studies relied upon Y/N
IIIA1 6.1/1	NA	2009	Efficacy of IRF102 and IR5885 M against PHYTIN in potato REDEBEL R150-09F (Z2280) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/2	NA	2009	Efficacy of IRF102 and IR5885 M against PHYTIN in potato REDEBEL R151-09F (Z2281) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/3	F. Varret B. Willocq	2005	Evaluation of the efficacy of IR 5885M, IRF 028 and other experimental compounds against artificially inoculated <i>Phytophthora</i> <i>infestans</i> in a potato crop in 2005 at Achery (02800), France STAPHYT F 05 057 104 01 (Z097N) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/4	I. Könings C. Ertus	2006	Efficacy of FANTIC M, IR5885- M, IR585-CTL and IR6141 experimental mixture against <i>Phytophthora infestans</i> on potato ASTRIA PHYTO ANADIAG APA06-092-BP1 (Z124Q) GEP Unpublished	Y	Belchim Crop Protection	Y	Y

Annex point	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished GEP status	Data protection claimed Y/N	Owner	Data protection granted Y/N	Studies relied upon Y/N
IIIA1 6.1/5	F. Varret O. Bedu	2006	Evaluation of the efficacy of a new fungicide product against <i>Phytophthora infestans</i> on potato crop STAPHYT FVT-06-2239-02 (Z124W) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/6	F. Varret B. Willocq	2006	Evaluation of the efficacy of a new fungicide product against <i>Phytophthora infestans</i> on potato crop STAPHYT FVT-06-2239-01 (Z124V) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/7	F. Varret B. Willocq	2006	Evaluation of the efficacy new fungicide products against <i>Phytophthora infestans</i> on potato crop STAPHYT FVT-06-2241-00 (Z1250) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/8	F. Varret B. Willocq	2006	Evaluation of the efficacy a new fungicide product against <i>Phytophthora infestans</i> on potato crop STAPHYT FVT-06-2239-00 (Z124T) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/9	C. Valentin C. Aubin	2006	Impact study of FANTIC M WP 4- 65, IR5885 M 6-60 WG and IR5885 A on sensorial properties and culinary aptitudes of potatoes. Selectivity in field and sampling BIOTEK Agriculture BPE06/139/FGC (Z124Z) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/10	J. Waples P. Diagouraga	2006	Efficacy of fungicide programmes based on FANTIC M 4-65, VALBON, IR5885 M 6-60WG, R6141 50WP and IR5885 40WP against potato late blight ( <i>Phytophthora infestans</i> ) under artificial inoculation conditions. BIOTEK Agriculture BPE06/136/FGC (Z125Z) GEP Unpublished	Y	Belchim Crop Protection	Y	Y

Annex point	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished GEP status	Data protection claimed Y/N	Owner	Data protection granted Y/N	Studies relied upon Y/N
IIIA1 6.1/11	C. Ertus P. Doublier	2007	Efficacy of different fungicides against <i>Phytophthora infestans</i> on potato ASTRIA PHYTO ANADIAG APA07-109-BP1 (Z1628) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/12	F. Varret B. Willocq	2007	Evaluation of the efficacy of IR 5885 M 6-60 WG and IR 5885 CTL against <i>Phytophthora</i> <i>infestans</i> on potato crop. Trial set up in France at Achery (02800) in 2007, and realized under artificial conditions. STAPHYT FVT-07-3138-00 (Z1626) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/13	JL. Paratte	2007	Efficacité sur le mildiou de la pomme de terre (dû à <i>Phytophthora</i> <i>infestans</i> ). Suivant la méthode CEB06 selon une cadence d'application de 7 jours, en 2007. PROMO-VERT 07 F PT IG 01 (Z1627) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/14	E. Guillard	2008	Determination of Efficacy of formulations containing IR5885 and IR6141 against <i>Phytophthora</i> <i>infestans</i> in Potato, La Boisse (01) in South of France 2008. EUROFINS Agroscience service S08-01656 (Z209B) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/15	L. Plantecoste	2008	Efficacy against potato late blight (due to <i>Phytophthora infestans</i> ). According to CEB method n°06 and according to a rhythm of application of 7 days. PROMO-VERT 08 F PT IG 05 (Z2055) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/16	L. Culiez	2008	Compte rendu d'essai en date du 30-08-08. Essai situé à AUCHY LES MINES (62138). Essais conduit sous irrigation FREDON PHYTEUROP_30/10/2008 GEP Unpublished	Y	Belchim Crop Protection	Y	Y

Annex point	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished GEP status	Data protection claimed Y/N	Owner	Data protection granted Y/N	Studies relied upon Y/N
IIIA1 6.1/17	J. Ridgway	2008	Determination of Efficacy of a range of experimental formulations against Late blight ( <i>Phytophthora</i> <i>infestans</i> ) in field crop potato, 1 site in Marloes, UK, 2008. EUROFINS Agroscience service S08-02007 (Z206U) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/18	O. Scrimshaw	2013	Evaluation of the efficacy of BCP382F (valifenalate + mancozeb, 60+600 g ai/kg, WG) and different tank mixtures with BCP385F (valifenalate, 200 g ai/l, SC) in a preventive spraying schedule on <i>Phytophthora infestans</i> in ware potato. Central zone, 2013 EUROFINS F13-SOLTU-17B-UK01 (S13- 03296-01) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/19	M. Hilweg	2007	ASU03021F (60 g/kg IR5885 + 600 g/kg Mancozeb) for control of Late blight ( <i>Phytophthora</i> <i>infestans</i> ) in potato STAHLER 07KF07 (5 trials: 07KF07-A1, 07KF07-A2, 07KF07D35, 07KF07D36, 07KF07D37) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/20	NA	2008	Prufbericht des Dienstleistungszentrums Landlichter Raum (DLR) Rheinhessen-Nahe-Hunsruck, 55545 Kreuznach DLR RNH, KH ASU03021F_08KF109_D101 GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/21	NA	2008	Landwirtschaftskammer Niedersachsen - Pflanzenschutzamt LWK Niedersachsen ASU03021F_08KF109_D102 GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/22	NA	2008	Pflanzenschutzdienst – Dienstselle Bonn, Siebengebirgsstr. 200, 53229 Bonn LWK NRW ASU03021F_08KF109_D103 GEP Unpublished	Y	Belchim Crop Protection	Y	Y

Annex point	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished GEP status	Data protection claimed Y/N	Owner	Data protection granted Y/N	Studies relied upon Y/N
IIIA1 6.1/23	M. Funfkirchen	2008	ASU03021F for control of Late blight ( <i>Phytophthora infestans</i> ) in potatoes STAHLER 08KF109-A1 GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/24	Р. Маав	2008	ASU03021F against <i>Phytophthora</i> <i>infestans</i> in potatoes STAHLER 08KF109D36 GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/25	Р. Маав	2008	ASU03021F against <i>Phytophthora</i> <i>infestans</i> in potatoes STAHLER 08KF109D37 GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/26	Р. Маав	2008	ASU03021F against <i>Phytophthora</i> <i>infestans</i> in potatoes STAHLER 08KF109D38 GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/27	J. Subr	2007	Trial report of Plant Protection Products ZS Trutnov AATRUF07/02 (Z159G) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/28	P. Dana	2007	Trial report of Plant Protection Products ZZS Kujavy Z2/4-2007 (Z159J) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/29	T. Agoston C. Sandor	2006	Report on Fungicide trial 2006 Plant Protection and Soil Conservation Service of country BAZ, Miskolc F-105/1/2006 (Z1231) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/31	T. Agoston Z. Simon	2006	Report on Fungicide trial 2006 Plant Protection and Soil Conservation Service of country Szabolcs-Szatmar-Bereg F-105/3/2006 (Z1233) GEP Unpublished	Y	Belchim Crop Protection	Y	Y

Annex point	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished GEP status	Data protection claimed Y/N	Owner	Data protection granted Y/N	Studies relied upon Y/N
IIIA1 6.1/32	N. Csaba	2007	Report on Fungicide trial 2007 Agricultural office of Somogy country. Plant protection and soil conservation directorate Kaposvar F-60/1/2007 (Z170P) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/33	Z. Simon	2007	Report on Fungicide trial 2007 Agricultural office of Szabolcs- Szatmar-Bereg country Plant protection and soil conservation directorate F-60/2/2007 (Z170Q) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/34	J. Kapsa	2005	Ocena skutecznosci fungicydu IT 5885 MZ 6-60 WG w zwalczaniu zarazy ( <i>Phytophthora infestans</i> ) w uprawach ziemniaka (Bonin) IHAR Fz/05/BON/014-1 (Z0994a) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/35	J. Kapsa	2005	Ocena skutecznosci fungicydu IT 5885 MZ 6-60 WG w zwalczaniu zarazy ( <i>Phytophthora infestans</i> ) w uprawach ziemniaka (Stare Olesno) IHAR Fz/05/BON/014-2 (Z0995a) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/36	J. Kapsa	2006	Ocena skutecznosci fungicydu DPX-QGC 45 (66% WG) w zwalczaniu zarazy ( <i>Phytophthora</i> <i>infestans</i> ) w ziemniaku (Bonin) IHAR Fz/06/BON/u-z/5-1 (Z130A) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/37	J. Kapsa	2006	Ocena skutecznosci fungicydu DPX-QGC 45 (66% WG) w zwalczaniu zarazy ( <i>Phytophthora</i> <i>infestans</i> ) w ziemniaku (Mierzym) IHAR Fz/06/BON/u-z/5-3 (Z130B) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/38	J. Kapsa	2006	Evaluation of biological efficacy of IR 5885 MZ 6-60 WG in control of late blight ( <i>Phytophthora infestans</i> ) in potato crop (Bonin) IHAR Fz/06/BON/010-1 (Z121X) GEP Unpublished	Y	Belchim Crop Protection	Y	Y

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IIIA1 6.1/40	C. Touche K. Kaminska	2010	Evaluation of the efficacy of IR5885-mancozeb & IRF112 against <i>Phytophthora infestans</i> on potato. Trial set up in Poland at Zalesie (Jaraczewo) in 2010. STAPHYT CTE 7891 PL01 (ZV003)	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/41	C. Touche K. Kaminska	2010	GEP Unpublished Evaluation of the efficacy of IR5885-mancozeb & IRF112 against <i>Phytophthora infestans</i> on potato. Trial set up in Poland at Chludowo (Dabrowa) in 2010. STAPHYT CTE-7891-PL02 (ZV004) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/42	I. Raacke	2010	Determination of Efficacy of VALIS M Formulation against <i>Phytophthora infestans</i> in Potatoes, 2 sites in Poland 2010 EUROFINS Agroscience service S10-01617-01 (ZV005) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/43	I. Raacke	2010	Determination of Efficacy of VALIS M Formulation against <i>Phytophthora infestans</i> in Potatoes, 2 sites in Poland 2010 EUROFINS Agroscience service S10-01617-02 (ZV006) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/44	S. Bergalio M. Landini	2005	Efficacy evaluation of different products against Late blight ( <i>Phytophthora infestans</i> ) on potato ANADIAG Italia R 5011 BO1 (Z098X) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/45	R. Bucchi	2006	Efficacy of IR5885 M 6-60WP, IR5885-CTL 10-65WP, FANTIC M WG 4-64, FANTIC M WP 4-65 and FANTIC CTL sv. <i>Phytophthora infestans</i> on potato in Bologna district, Italy 2006 AGRI 2000 SRI06-086-59FE (Z125B) GEP Unpublished	Y	Belchim Crop Protection	Y	Y

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IIIA1 6.1/46	A. Pandolfi	2007	Field evaluation of efficacy and Phytotoxicity of ISAGRO RICERCA for control of <i>Phytophthora</i> infestans (late blight) on Potato located in Alba Adriatica – Abruzzo region – Teramo district – Italy. RES AGRIARIA RA 07 016 IT 01 (Z1571) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/47	NA	2007	Efficacy of IR5885 & NEORAM in the control of downy mildew ( <i>Phytophthora infestans</i> ) in potato SYNTECH Research SRS06-127-59FE (Z1291) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/49	M. Chianella	2007	Efficacy of IR5885 M for late blight ( <i>Phytophthora infestans</i> PHYTIN) control on potato in Greece, 2007 SPF GAB Italia GR07I097E (Z170V) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/50	M. Chianella	2007	Efficacy of IR5885 M for late blight ( <i>Phytophthora infestans</i> PHYTIN) control on potato in Greece, 2007 SPF GAB Italia GR07I098E (Z170W) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/51	M. Panzeres André G. Correia	2006	Potato / Fungicides 2006 SAPEC AGRO 07/031/06 (Z122Fa) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/52	M. Panzeres André G. Correia	2006	Potato / Fungicides 2006 SAPEC AGRO 07/022/06 (Z122Fb) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/64	F.W.G Van Tilburg	2011	Control of <i>Phytophthora infestans</i> in ware potatoes De Bredelaar B.V. F-11-6002 (ZV042) GEP Unpublished	Y	Belchim Crop Protection	Y	Y

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IIIA1 6.1/65	F. Wallart	2013	Efficacy evaluation of BCP382F and different tank mixes with BCP385F against late blight of potato EPHYDIA F13-SOLTU-17-A-FR01 (FRB-13- F04) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/66	P. Decarsin	2013	Evaluation of the efficacy of BCP382F (valifenalate + mancozeb, 60 + 600 g ai/ka, WG) and different tank mixtures with BCP358F (valifenalate, 200 g ai/l, SC) in a preventive spraying schedule on <i>Phytophthora infestans</i> in ware potato. Southern zone, 2013. DECARSIN F13-SOLTU-17-A-FR02 (FBEL135732) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/67	R. Bucchi	2013	Evaluation of the efficacy of BCP382F (valifenalate + mancozeb, 60 + 600 g ai/ka, WG) and different tank mixtures with BCP358F (valifenalate, 200 g ai/l, SC) in a preventive spraying schedule on <i>Phytophthora infestans</i> in ware potato. Southern zone, 2013. AGRI 2000 F13-SOLTU-17-A-IT01 (A13-328- 45FE) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/68	R. Bucchi	2013	Evaluation of the efficacy of BCP382F (valifenalate + mancozeb, 60 + 600 g ai/ka, WG) and different tank mixtures with BCP358F (valifenalate, 200 g ai/l, SC) in a preventive spraying schedule on <i>Phytophthora infestans</i> in ware potato. Southern zone, 2013. AGRI 2000 F13-SOLTU-17-A-IT02 (A13-329- 45FE) GEP Unpublished	Y	Belchim Crop Protection	Y	Y

Annex point	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished GEP status	Data protection claimed Y/N	Owner	Data protection granted Y/N	Studies relied upon Y/N
IIIA1 6.1/69	P. Reynens	2013	Efficacy of BCP382F and different tank mixtures with BCP385F in a preventive spraying schedule on <i>Phytophthora infestans</i> in ware potato REDEBEL F13-SOLTU-17-B-BE01 (R137- 13F) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/70	F.W.G. van Tilburg	2013	Evaluation of the efficacy of BCP382F (valifenalate + mancozeb, 60 + 600 g ai/kg, WG) and different tank mixtures with BCP385F (valifenalate, 200 g ai/l, SC) in a preventive schedule on <i>Phytophthora infestans</i> in ware potato (Central zone), 2013 De Bredelaar B.V. F13-SOLTU-17-B-NL01 (F-13- 2604) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/71	N Person	2006	Evaluation sensorielle de "Pomme de terre" CAPINOV ES068501 Non GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/72	F Varret	2007	Evaluation of the germinative capacity of tubers coming from mate blight trial FVT-06-2239-00 (Z124T) set up in 2006. Trial set up in Inchy en Artois. FVT-07-2243-00 (Z124Y) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/73	Corinne Ertus	2006	Efficacy of preparations 1 40283 00 and 1 40284 00 against Downy mildew (Plasmopara viticola) on vine at the rate of 1 treatment every 10 days ASTRIA PHYTO ANADIAG FIELD NETWORK APA06-080-AL1 (Z121K) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/74	Christian Touche	2006	Evaluation de la performance des preparations 14028300 et 14028400 à la cadence de 10 jours contre le mildiou de la vigne (Plasmopara viticola) sur la vigne fructifère en conditions controlées STAPHYT CTE-02-2061-00 (Z121G) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y

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IIIA1 6.1/75	Iris Kônings	2006	Efficacy of IR5885-F, IR588M, IR588-A and IR6141+copper derivates, applied at 10-day intervals, against Plasmopara viticola on grapes under natural conditions ASTRIA PHYTO ANADIAG FIRLS NETWORK APA06-091-DR1 (Z124H) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/76	Promo-vert	2006	Efficacité de IR5885-F, IR5885-M, IR5885A et IR6141 en mélange experimental sur le mildiou de la vigne (Plasmopara viticola) PROMO-VERT 06 F VI IG 03 (Z124G) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/77	Promo-vert	2006	Efficacité sur le mildiou de la vigne (dû à Plasmopara viticola) PROMO-VERT 06 F VI IG 04 (Z124L) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/78	Christian Touche	2006	Evaluation of the efficacy of IR5885-F, IR5885-M, IR5885-A and IR6141 in an experimental association (applied every days) against Plasmopara viticola on vineyard under controlled conditions in the Valley of Loire – France (37), 2006 season. STAPHYT CTE-06-2154-01 (Z214K) GEP. Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/79	Christian Touche	2006	Evaluation of the efficacy of IR5885-F, IR5885-M, IR5885-A and IR6141 in an association with Airone (applied every 10 days) against Plasmopara viticola on vineyard under controlled conditions in South east of France (34), 2006 season. STAPHYT CTE-06-2154-00 (Z214J) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/80	Christophe Narboux	2007	Final report on project AR/12002/IR AGRISEARCH FRANCE AR/12002/IR (Z1622) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y

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IIIA1 6.1/81	Fabrice Comte	2007	Efficacy of IR5885 in association with folpet, mancozeb or copper on the downy mildiou of the wine (due to Plasmopara viticola) according to the CEB method n°07 and according to a rhythm of application of 10 days, in 2007 PROMO-VERT 07 F VI IG 02 (Z1620) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/82	David Lemoine	2007	Evaluation of the efficacy of products against Plasmopara viticola on vineyard at 10 days interval under controlled conditions at Boisseron in the South east – France (34), 2007 season STAPHYT CET-07-3142-00 (Z1624) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/83	Jean Christophe Imbert	2008	Efficacy trial carried out against Plasmopara viticola on vine grape, in Montfrin-France during 2008 season, testing IR5885-M 6-60WG and IR5885A at 2 Kg/ha at 10 days schedule. AGROLIS Consulting 81908045 (Z2053) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/84	Hubert Galy	2008	Efficacy of different fungicides containing Folpet and Mancozeb, against Plasmopara viticola on vine trial carried out at Duras (47), France in 2008 ASTRIA PHYTO ANADIAG FIELD NETWORK APA08-012-DR1 (Z204T) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/85	Hubert Galy	2008	Efficacy of different fungicides containing Mancozeb, against Plasmopara viticola on vine trial carried out at Duras (47), France in 2008 ASTRIA PHYTO ANADIAG FIELD NETWORK APA08-012-DR2 (Z2054) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
Annex point	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished GEP status	Data protection claimed Y/N	Owner	Data protection granted Y/N	Studies relied upon Y/N
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IIIA1 6.1/86	Emilie Guillard	2008	Determination of efficacy of products containing IR5885 against Plasmopara viticola in grape, Perrones (71), France (North), 2008 EUROFINS S08-01655-01 (Z2050) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/87	Fabrice Comte	2008	Efficacy of IR5885 in association with mancozeb or copper on the downy mildiou of the vine (due to Plasmopara viticola) PROMO-VERT 08 F VI IG 01 (Z204Z) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/88	Christian Touche	2008	Evaluation of the efficacy of IR5885-M and IR5885-A against Plasmopara viticola on vineyard under controlled conditions at Merceuil in the Burgundy area – France (21), 2008 season STAPHYT CTE-08-4281-FR01 (Z204X) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/89	INRA	2008	Evaluation de l'efficacité vis-à-vis du mildiou de la vigne des formulations expérimentales IR 5885 F et IR 5885 M – Essai d'efficacité INRA GM6/16/08 Non GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/90	Renzo Bucchi	2005	Grapes – Plasmopara viticola – Efficacy evaluation AGRI 2000 0548E (Z103V) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/91	Renzo Bucchi	2006	Efficacy of IR5885-F, IR5885 M 6- 60WG, IR5885 M 6-60WP, IR5885 A 6-30 WG, AIRONE 28 WG, IR6141 50 WP, ODENA UD, ZEMIX R vs Plasmopara viticola on grape in Bologna district, Italy 2006. AGRI 2000 SRI06-082-59FE (Z123U) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y

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YIIIA1 6Y.1/92	Lorenzo Granchelli	2006	Field evaluation of different IR5885 coformulations, of Zemix R and of other experimental, in comparison with standard products, applied at 10 days intervals, to control Downy mildew on grapevine in Italy, Abruzzo region, Teramo district RESAGRARIA RA 06 010 IT 01 (Z123V) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIYIA1 6.1Y/93	Salvador Moreno García	2006	Comparative study of efficacy and selectivity of several fungicides formulated from Isagro (IR6141 – IR5885) for the control of Plasmopara viticola in the grapevine crop. AGRICULTURA Y ENSAYO S.L. F-06-Z128-M01.0-ESC-125 (Z128M) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIAY1 6.1/94Y	Lidon Avinent PhD	2006	Efficacy of IR6141 and IR5885 for Plasmopara viticola on grapes SYNTECH RESEARCH SRS06-123-59FE (Z128K) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/95	Joaquín Soler Álvarez	2007	To evaluate the efficacy and selectivity of IR6141 and IR5885 against Plasmopara viticola in grapes AGRO SOLER AS 09107 F 01 (Z153U) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/96	Joaquín Soler Álvarez	2007	To evaluate the efficacy and selectivity of IR6141 and IR5885 against Plasmopara viticola in grapes AGRO SOLER AS 09107 F 01 (Z153T) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/97	Massimo Chianella	2006	Efficacy of IR6141 (Fantic M 4-65 WP) and Fantic M 4-65 WG) and IR5885 (JAVA M 6-60) for downy mildew (Plasmopara viticola PLASVI) control on grapevine. GAB ITALIA GR06I068E (Z1319) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y

Annex point	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished GEP status	Data protection claimed Y/N	Owner	Data protection granted Y/N	Studies relied upon Y/N
IIIA1 6.1/98	Massimo Chianella	2007	Efficacy of IR5885 M for downy mildew (Plasmopara viticola) control on grapevine, trial located at Piperia, Aridea – Pella region, in Greece 2007. GAB ITALIA GR07I093E (Z1597) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/99	Massimo Chianella	2007	Efficacy of IR5885 M for downy mildew (Plasmopara viticola) control on grapevine, Kalokastro, Serres, Greece 2007 GAB ITALIA GR07I094E (Z1598) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/100	Plant protection and Soil conservation service of county Borsod- Abauj- Zemplén, Miskolc	2006	Report on fungicide trial 2006 Plant protection and Soil conservation service of county Borsod-Abauj-Zemplén, Miskolc F-104/1/2006 (Z122Y) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/101	Plant protection and Soil conservation service of county Heves	2006	Report on fungicide trial 2006 Plant protection and Soil conservation service of county Heves F-104/2/2006 (Z122Z) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/102	Plant protection and Soil conservation service of county Komarom- Esztergom- Tata	2006	Report on fungicide trial 2006 Plant protection and Soil conservation service of county Komarom-Esztergom-Tata F-104/3/2006 (Z1230) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/103	Government office of Komarom- Esztergom County	2013	Report on fungicide trial 2013 Government office of Komarom- Esztergom County F13-VITVI-24B-HU01 (F- 89/1/2013) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y

Annex point	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished GEP status	Data protection claimed Y/N	Owner	Data protection granted Y/N	Studies relied upon Y/N
IIIA1 6.1/104	D. Blasko	2013	Evaluation of the efficacy of BCP381F (valifenalate/folpet, 60/480 g ai/kg, WG) and BCP382F (valifenalate/mancozeb, 60/600 gai/kg) on Plasmopara viticola in European grapevine. Central zone (South east EPPO zone). 2013 ANADIAG Hungary F13-VITVI-24B-HU02 (HU 13 064 KO1)	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/105	B. Binhold	2013	GEP, Unpublished Evaluation of the efficacy of BCP381F (valifenalate/folpet, 60/480 g ai/kg, WG) and BCP382F (valifenalate/mancozeb, 60/600 gai/kg) on Plasmopara viticola in European grapevine. Central zone (South east EPPO zone). 2013 EUROFINS F13-VITVI-24B-RO01 (S13- 02656-01) F13-VITVI-24B-RO02 (S13- 02656-02) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/106	Rosa Pérez	2005	Evaluar la eficacia y la selectividad de los productos fungicidas IR6141 y IR5885 en el control de Plasmopara viticola en el cultivo de la vid Agricultura y ensayo F-05-Z106-Q-02.0-ESA-130 (Z106R) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/107	José Ramon Viruega	2005	Evaluar la eficacia y la selectividad de los productos fungicidas IR6141 y IR5885 en el control de Plasmopara viticola en el cultivo de la vid Agricultura y ensayo F-05-Z106-Q-02.0-ESC-103 (Z106O) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/108	L Avirent	2005	Field trial report : Efficacy of several mixtures of IR5885 against Plasmopara viticola on grapes in Spain SYNTECH RESEACH Spain 109-05-IS-F (Z106T) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y

Annex point	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished GEP status	Data protection claimed Y/N	Owner	Data protection granted Y/N	Studies relied upon Y/N
IIIA1 6.1/109	Salvador Moreno Garcia	2007	To assess the efficacy and selectivity of the fungicides IR6141 and IR5885 in the control of Plasmopara viticola in grapevine. Agricultura y ensayo F-07-Z153-S03.0-ESC-156 (Z153S) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/110	Lukas Kylian	2006	Protokol o pokusu s pripravky na ochranu rostlin Agro Aliance s.r.o AV/01/06 (Z119S) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/111	Lukas Kylian	2006	Protokol o pokusu s pripravky na ochranu rostlin Agro Aliance s.r.o AV/02/06 (Z119T) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/112	Pavel Lacina	2006	Trial report of plant protection product Agro Aliance s.r.o V/03/06 (Z119U) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/113	Pavel Lacina	2006	Trial report of plant protection product Agro Aliance s.r.o V/04/06 (Z119V) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/114	Lukas Kylian	2007	Protokol o pokusu s pripravky na ochranu rostlin Agro Aliance s.r.o V1/4-2007 (Z159B) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/115	Lukas Kylian	2007	Protokol o pokusu s pripravky na ochranu rostlin Agro Aliance s.r.o V2/4-2007 (Z159C) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/116	Pavel Lacina	2007	Trial report of plant protection product Agro Aliance s.r.o V3/4-2007 (Z159D) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y

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IIIA1 6.1/117	Pavel Lacina	2007	Trial report of plant protection product Agro Aliance s.r.o V4/4-2007 (Z159E) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/118	Richter Tomas	2008	Trial report of plant protection product Agro Aliance s.r.o 2008/1/5/CR/GW-ISA (CZ0801) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/119	Pavel Lacina	2008	Trial report of plant protection product Agro Aliance s.r.o 2008/2/5/CR/GW-ISA (CZ0802) GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/120	M Dardé	2006	Study of unintentional effects of experimental fungicide compounds IR5885M 6-60 WG and IR5885A on production and quality of musts and wines VITI RD Z1621 Z1625 Z1623 Z164W GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/121	D Juan	2007	Effects of the test substances IR 5885 F and IR 5885 M on phytoseids in vineyards ENIGMA Z161V GEP, Unpublished	Y	Belchim Crop Protection	Y	Y
	W van de Ven	2014	Evaluate the efficacy of BCP382F against potato late blight ( <i>Phytophthora infestans</i> ). Dose rate justification of BCP382F De Bredelaar B.V F14-SOLTU-07-NL01 F14-SOLTU-07-NL02 GEP, unpublished	Y	Belchim Crop Protection	Y	Y
	T. McCabe	2015	Evaluation of the efficacy of BCP382F, BCP 309F and BCP393F for potato blight ( <i>Phytophthora infestans</i> ) control in potato cv. Endavour Crop Research Ltd. F15SOLTU14-IE01 GEP, unpublished	Y	Belchim Crop Protection	Y	Y

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	T. McCabe	2015	Evaluation of the efficacy of BCP382F, BCP 309F and BCP393F for potato blight ( <i>Phytophthora infestans</i> ) control in potato cv. Endavour Crop Research Ltd. F15SOLTU14-IE02 GEP, unpublished	Y	Belchim Crop Protection	Y	Y
	J. Packwood	2015	Field study to evaluate the efficacy of BCP382F, BCP309F and BCP393F against late blight ( <i>Phytophthora infestans</i> ) in potatoes under commercial conditions, 1 site in Ireland, 2005 Eurofins Agroscience Services Ltd. F15SOLTU14-IE03 GEP, unpublished	Y	Belchim Crop Protection	Y	Y
	J. Packwood	2015	Field study to evaluate the efficacy of BCP382F, BCP309F and BCP393F against late blight ( <i>Phytophthora infestans</i> ) in potatoes under commercial conditions, 1 site in Ireland, 2005 Eurofins Agroscience Services Ltd. F15SOLTU14-IE04 GEP, unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/a	Pollet N, Aubry E	2013	Evaluate the efficacy and selectivity of [] BCP382F (Valis M, valifenalate/mancozeb 60-600 g/kg) on <i>Plasmopara viticola</i> in European grapevine. SCIENCES AGRO ATLANTIQUE F13VITVI24A-FR01 (13BNV07) GEP Unpublished	Y	Belchim Crop Protection	Y	Y
IIIA1 6.1/b	Perrin E	2013	Evaluate the efficacy and selectivity of [] BCP382F (Valis M, valifenalate/mancozeb 60-600 g/kg) on <i>Plasmopara viticola</i> in European grapevine. SGS Agri Min F13VITVI24A-FR02 (13 WHG F BE AN 901) GEP Unpublished	Y	Belchim Crop Protection	Y	Y