

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: 030-S-3-D**

**Product name(s): Orocide Plus**

**Chemical active substance:**

**Orange oil 58,96 g/L**

**Interzonal**

**Zonal Rapporteur Member State: NL**

**NATIONAL ASSESSMENT Germany  
(authorization)**

**Applicant: Oro Agri**

**Submission date: 12/10/2016 in Germany**

**30 June 2016 in NL**

**MS Finalisation date: 11.08.2020**

## Version history

When	What
August 2009	Draft Assessment report for orange oil, with the recommended use of a plant protection product (insecticide) in greenhouses
November 2012	Draft Assessment report for orange oil, with the recommended use of a plant protection product (insecticide & fungicide) in fields
May 2014	Approval of orange oil in Annex I, Directive 94/414//EC – RMS, France
April 2016	Submission of confirmatory answer according to Commission Implementing Regulation (EU) N° 1165/2013 of 18 November 2013, Annex I – RMS, France
June 2016	OROCIDE PLUS (product code 030-S-3-D) first interzonal submission for greenhouse uses, as an insecticide/araricide on fruiting vegetables and ornamental plants - zRMS, The Netherlands.
16 July 2019	dRR available for comments
28 November 2019	Final RR available from the Netherlands
11 August 2020	Finalisation of authorisation inter-zonal uses and refuses of zonal uses (due to the decision of the ZRMS)

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# PART A

## RISK MANAGEMENT

### 1 Details of the application

This document describes the acceptable use condition under greenhouse conditions required for the registration of OROCID PLUS containing 60 g/L orange oil.

The risk assessment conclusions are based on the information, data and assessment provided in Registration Report, Part B Sections 1 to 10 and Part C of the ZRMS The Netherlands and national addenda B.8 and B.9 for Germany. The information, data and assessments provided in this Draft Registration Report, Part B includes core data supporting the new formulation OROCID PLUS (product code 030-S-3-D). Safe use of OROCID PLUS have been made using end-points agreed in the EU review of orange oil, and part of the confirmatory answers according to Commission implementing regulation (EU) N°1165/2013 of 18 November 2013, Annex I.

The applicant has considered all risk assessment models to cover all requirements in Europe for a greenhouse use.

This document describes the specific conditions of use and labelling required in Germany.

#### 1.1 Application background

This application is submitted by ORO AGRI International Ltd located Bankastraet 75, 9715CJ Groningen in The Netherlands.

The botanical active substance, orange oil, was approved in Annex I of Directive 91/414/EC, with an entry in force on May 2014. The applicant was ORO AGRI International Ltd. The reference formulation was PREV-AM (product code OREU 030), for a use in greenhouse to control whiteflies on tomato and zucchini.

The composition of OROCID PLUS (product code 030-S-3-D) under evaluation is the result of further researches and development on the original recipe of PREV-AM, with the scope of providing farmers with a safer plant protection product, eligible for organic farming. All details on recipe updates are provided in the confidential part of this Draft Registration Report, in Part C.

OROCID PLUS (product code 030-S-3-D), containing a plant extract, orange oil, is a new formulation, with the use of insecticide and acaricide in greenhouse, which has never been registered in Europe. This dossier is submitted in The Netherlands, the zRMS for this interzonal application, and in cMS as listed in Part 0 of this submission dossier.

OROCID PLUS is a micro emulsion formulation with a low surface tension, which enhances a good coverage of target pests, damaging the waxy layer of the exoskeleton of soft bodied insects resulting in immediate effect by desiccation (drying). As an insecticide/acaricide orange oil is active on *Trialeurodes vaporariorum*, *Bemisia tabaci*, *Tetranychus species* and other sucking insects. Applications to control target insects will be scheduled when pests are present for its effective curative action.

## 1.2 Letters of Access

The applicant presented a LoA dated 23<sup>rd</sup> October 2015 for specific field trials. The remaining data requirements were addressed by own data.

## 1.3 Justification for submission of tests and studies

To obtain approval the product Orocid Plus must meet the conditions of Commission Implementing Regulation (EU) No 1165/2013 of 18 November 2013 approving the active substance orange oil and be supported by a dossier satisfying the requirements of Commission Regulation (EU) No 284/ 2013, with an assessment according to Uniform Principles (Commission Regulation (EU) No 546/2011), using agreed endpoints.

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

The reference list included in Part A Appendix 4 defines the list of studies and reports submitted by the applicant and relied on as well as a list of studies submitted by the applicant but not relied on for the authorisation. Furthermore, Appendix 4 includes studies already evaluated at EU peer re-view and studies necessary but not submitted.

## 1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

# 2 Details of the authorization decision

## 2.1 Product identity

Product code	030-S-3-D
Product name in MS	OROCIDE PLUS
Authorization number	008883-00/00
Function	Acaricide, fungicide, insecticide
Applicant	ORO AGRI International Ltd
Active substance(s) (incl. content)	Orange oil 58,96 g/L
Formulation type	Micro-emulsion (ME)
Packaging	0.12 to 0.2 L, 1L to 20L for professional users (HDPE/PA) 0.12 to 0.2 L for non-professional users (HDPE/PA) 1L to 20L for professional users (HDPE/EVOH)
Coformulants of concern for national authorizations	Not applicable
Restrictions related to identity	Not applicable
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not relevant

## 2.2 Conclusion

With respect to identity, physical, chemical and technical properties, further information and analytical methods for the formulation an authorisation can be granted.

With respect to analytical methods for residues an authorisation can be granted.

With respect to toxicology, residues and consumer protection an authorisation can be granted.

With respect to fate and ecotoxicology assessment, an authorisation can be granted. Considering an application in accordance with the evaluated use pattern and good agricultural practice as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

With respect to efficacy and sustainable use/IPM an authorisation can be granted for all greenhouse uses (use 005 – 016). Annotation: No authorisation can be granted for the field uses (use 001 – 004) because the zRMS did not authorise these uses due to insufficient efficacy information (separate final RR).

**The evaluation of the application for Oricide Plus for interzonal applications resulted in the decision to grant the authorization.**

## 2.3 Substances of concern for national monitoring

## 2.4 Classification and labelling

### 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Eye Irrit. 2
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet.

Hazard pictograms:	
GHS07	exclamation mark
Signal word:	
	Warning
Hazard statement(s):	
H319	Causes serious eye irritation.
Precautionary statement(s):	

P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+313	If eye irritation persists: Get medical advice/attention.
P501	Dispose of contents/container to ...
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208	Contains orange oil. May produce allergic reactions
EUH 208	Contains 1,2-benzisothiazole-3(2H)-one. May produce an allergic reaction.

See Part C for justifications of the classification and labelling proposals.

#### 2.4.2 Standard phrases under Regulation (EU) No 547/2011

EO005-2	SPo 5: Ventilate greenhouses thoroughly before re-entry.
SP1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

#### 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None

### 2.5 Risk management

#### 2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Human health protection:	
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
SB005	If medical advice is needed, have product container or label at hand.
SB010	Keep out of the reach of children.
SB111	Concerning the requirements for personal protective gear for handling the plant protection product the material safety data sheet and the instructions for use of the plant protection product as well as the guideline "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection



	and Food Safety (www.bvl.bund.de) must be observed.
SB166	Do not eat, drink or smoke when using this product.
SE110	Wear tight fitting eye protection when handling the undiluted product.
SF245-02	It must be ensured that treated areas/crops may not be entered until the film of the plant protection product has dried.
SS110-1	Protective gloves (plant protection) must be worn when handling the undiluted product.
SS206	Working clothes (if no specific protective suit is required) and sturdy footwear (e.g. rubber boots) must be worn when applying/handling plant protection products.
SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.
Integrated pest management (IPM)/sustainable use:	
WMIUN	Mode of action (IRAC-group): UN (for orange oil)
WH952	The indication identifying the mode of action must be assigned directly to each corresponding name of the active substance as supplementary information on the packaging and in the instructions for use.
NN2001	The product is classified as slightly harmful for populations of relevant beneficial insects.
NN2002	The product is classified as slightly harmful for populations of relevant beneficial predatory mites and spiders.
Environmental protection	
NW262	The product is toxic for algae.
NW264	The product is toxic for fish and aquatic invertebrates.
NW470	Where applicable, fluids left over from application, granules and their remains as well as cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.
Other specific restrictions	
VA551	Apply spray liquid under permanent agitation. (Spritzflüssigkeit unter ständigem Rühren ausbringen.)
WA607	Protect plant protection product from frost. (Pflanzenschutzmittel vor Frost schützen.)
-	An anti-foam agent (at 0.001%, e.g. dimethyl polysiloxane) should be used when preparing the spraysolution to prevent foaming. (Ein Antischaummittel (0.001%, z. B. Dimethylpolysiloxan) sollte genutzt werden zur Herstellung der Spritzflüssigkeit, um dem Schäumen vorzubeugen.)

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
NB6641	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)

## 2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
WP732	Damage may be caused to crops by the sun after application.	005, 006, 007, 010, 011, 012, 015, 016
WH915	The instructions for use must include a list of species and/or varieties of crops which are compatible with the application rate provided for (positive list).	015, 016
Environmental protection:		Relevant for use no.
Other specific restrictions:		Relevant for use no.
HE110-1	SE110 ("Wear tight fitting eye protection when handling the undiluted product") does not apply to home and garden use.	Use 005 – 007, 016 and 018 (home and garden use)
HS110-1	SS110-1 ("Protective gloves (plant protection) must be worn when handling the undiluted product.") does not apply to home and garden use.	Use 005 – 007, 016 and 018 (home and garden use)
HS206-1	SS206 ("Working clothes (if no specific protective suit is required) and sturdy footwear (e.g. rubber boots) must be worn when applying/handling plant protection products.") does not apply to home and garden use.	Use 005 – 007, 016 and 018 (home and garden use)
HS2101-1	SS2101 ("Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.") does not apply to home and garden use.	Use 005 – 007, 016 and 018 (home and garden use)
SE126	Wear eye protection when applying/handling the product.	Use 005 – 007, 016 and 018 (home and garden use)
SS202	Wear protective gloves when handling the product.	Use 005 – 007, 016 and 018 (home and garden use)
SS205-1	Wear long-sleeved shirt, long trousers and sturdy footwear during handling and applying plant protection products.	Use 005 – 007, 016 and 018 (home and garden use)

## 2.6 Intended uses (only NATIONAL GAP)

Reg.-No. 008883-00/00 GAP rev. 2, date: 2020-05-06  
 PPP (product name/code): OROCIDÉ PLUS Formulation type: ME <sup>(a, b)</sup>  
 Active substance 1: Orange oil Conc. of as 1: 55.80 g/L <sup>(c)</sup>  
 Applicant: ORO AGRÍ International Ltd. Professional use:   
 Zone(s): central <sup>(d)</sup> Non professional use:   
 Verified by MS: yes Field of use: Insecticide, acaricide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val be- tween applica- tions (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
005	DE	tomato (LYPES), sweet pepper (CPSAN)	G	red spider mites (TETRSP) (BBCH EX-IL)	spraying	At beginning of infestation and/or when first symp- toms/harmful organisms be- come visible 2nd leaf on main shoot unfolded to Fully ripe: fruits have typical fully ripe colour for paprika and au- bergine	a) 5 b) 5	treatments must be at least 7 days apart	a) plant height up to 50 cm: 0.20 mL/m <sup>2</sup>	a) 0.1116 kg/ha	plant height up to 50 cm: <del>25</del> 50 mL/m <sup>2</sup>	1	Amateur gardening  Notes on dose rate: spray con- centration: 0,4 %
									a) plant height 50 up to 125 cm: 0.30 mL/m <sup>2</sup>	0.1674 kg/ha	plant height 50 up to 125 cm: <del>37,5</del> 75 mL/m <sup>2</sup>		
									a) plant height more than 125 cm: 0.40 mL/m <sup>2</sup>	0.2232 kg/ha	plant height more than 125 cm: <del>50</del> - 100 mL/m <sup>2</sup>		
									b) 2.00 mL/m <sup>2</sup>	b) 1.116 kg/ha			
006	DE	tomato (LYPES), sweet pepper (CPSAN)	G	Whiteflies (ALEUSP) (BBCH EX-IL)	spraying	At beginning of infestation and/or when first symp- toms/harmful organisms be- come visible 2nd leaf on main shoot unfolded to Fully ripe: fruits	a) 6 b) 6	treatments must be at least 7 days apart	a) plant height up to 50 cm: 0.20 mL/m <sup>2</sup>	a) 0.1116 kg/ha	plant height up to 50 cm: <del>25</del> 50 mL/m <sup>2</sup>	1	Amateur gardening  Notes on dose rate: spray con- centration: 0,4 %
									a) plant height 50 up to 125 cm: 0.30 mL/m <sup>2</sup>	0.1674 kg/ha	plant height 50 up to 125 cm: <del>37,5</del> 75 mL/m <sup>2</sup>		
									a) plant height	0.2232 kg/ha	plant height		

					have typical fully ripe colour for paprika and aubergine				more than 125 cm: 0.40 mL/m <sup>2</sup>		more than 125 cm: <del>50</del> -100 mL/m <sup>2</sup>		
									b) 2.40 mL/m <sup>2</sup>	b) 1.3392 kg/ha			
007	DE	giant pumpkin (CUUMX), musky gourd (CUUMO), pumpkin (CUUPE), bottle gourd (LGNSI)	G	Whiteflies (ALEUSP) (BBCH EX-IL)	spraying	At beginning of infestation and/or when first symptoms/harmful organisms become visible 2 true leaves, leaf pairs or whorls unfolded to Fully ripe: fruit shows fully-ripe colour, beginning of fruit abscission	a) 6 b) 6	treatments must be at least 7 days apart	a) plant height up to 50 cm: 0.20 mL/m <sup>2</sup>	a) 0.1116 kg/ha	plant height up to 50 cm: <del>25</del> -50 mL/m <sup>2</sup>	1	Amateur gardening  Notes on dose rate: spray concentration: 0,4 %
									a) plant height 50 up to 125 cm: 0.30 mL/m <sup>2</sup>	0.1674 kg/ha	plant height 50 up to 125 cm: <del>37,5</del> -75 mL/m <sup>2</sup>		
									a) plant height more than 125 cm: 0.40 mL/m <sup>2</sup>	0.2232 kg/ha	plant height more than 125 cm: <del>50</del> -100 mL/m <sup>2</sup>		
									b) 2.40 mL/m <sup>2</sup>	b) 1.3392 kg/ha			
010	DE	tomato (LYPES), sweet pepper (CPSAN)	G	red spider mites (TETRSP) (BBCH EX-IL)	spraying	At beginning of infestation and/or when first symptoms/harmful organisms become visible 12 to 89	a) 5 b) 5	treatments must be at least 7 days apart	a) plant height up to 50 cm: 2.00 L/ha	a) 0.1116 kg/ha	plant height up to 50 cm: <del>250</del> -500 L/ha	1	Notes on dose rate: spray concentration: 0,4 %
									a) plant height 50 up to 125 cm: 3.00 L/ha	0.1674 kg/ha	plant height 50 up to 125 cm: <del>375</del> -750 L/ha		
									a) plant height more than 125 cm: 4.00 L/ha	0.2232 kg/ha	plant height more than 125 cm: <del>500</del> -1000 L/ha		
									b) 20.00 L/ha	b) 1.116 kg/ha			
011	DE	tomato (LYPES), sweet pepper (CPSAN)	G	Whiteflies (ALEUSP) (BBCH EX-IL)	spraying	At beginning of infestation and/or when first symptoms/harmful organisms become visible 12 to 89	a) 6 b) 6	treatments must be at least 7 days apart	a) plant height up to 50 cm: 2.00 L/ha	a) 0.1116 kg/ha	plant height up to 50 cm: <del>250</del> -500 L/ha	1	Notes on dose rate: spray concentration: 0,4 %
									a) plant height 50 up to 125 cm: 3.00 L/ha	0.1674 kg/ha	plant height 50 up to 125 cm: <del>375</del> -750 L/ha		
									a) plant height more than 125 cm: 4.00 L/ha	0.2232 kg/ha	plant height more than 125 cm: <del>500</del> -1000 L/ha		

012	DE	giant pumpkin (CUUMX), bottle gourd (LGNSI), pumpkin (CUUPE), musky gourd (CUUMO)	G	Whiteflies (ALEUSP) (BBCH EX-IL)	spraying	At beginning of infestation and/or when first symptoms/harmful organisms become visible 12 to 89	a) 6 b) 6	treatments must be at least 7 days apart	b) 24.00 L/ha	b) 1.3392 kg/ha		1	Notes on dose rate: spray concentration: 0,4 %
									a) plant height up to 50 cm: 2.00 L/ha	a) 0.1116 kg/ha	plant height up to 50 cm: <del>250</del> 500 L/ha		
									a) plant height 50 up to 125 cm: 3.00 L/ha	0.1674 kg/ha	plant height 50 up to 125 cm: <del>375</del> 750 L/ha		
									a) plant height more than 125 cm: 4.00 L/ha	0.2232 kg/ha	plant height more than 125 cm: <del>500</del> 1000 L/ha		
								b) 24.00 L/ha	b) 1.3392 kg/ha				
015	DE	ornamentals (NNNZZ)  production of cutting flowers	G	sucking insects (4SXXXXX) Aphids (APXXSP), Whiteflies (ALEUSP) (except: Bemisia (BEMISI)) (BBCH EX-IL)	spraying	At beginning of infestation and/or when first symptoms/harmful organisms become visible 12 to 89	a) 5 b) 5	treatments must be at least 7 days apart	a) 2.00 L/ha b) 10.00 L/ha	a) 0.1116 kg/ha b) 0.558 kg/ha	<del>100</del> 500 L/ha	N *	Notes on dose rate: spray concentration: 0,4 %
016	DE	ornamentals (NNNZZ)  production of cutting flowers	G	sucking insects (4SXXXXX) Aphids (APXXSP), Whiteflies (ALEUSP) (except: Bemisia (BEMISI)) (BBCH EX-IL)	spraying	At beginning of infestation and/or when first symptoms/harmful organisms become visible 2 true leaves, leaf pairs or whorls unfolded to Fully ripe: fruit shows fully-ripe colour, beginning of fruit abscission	a) 5 b) 5	treatments must be at least 7 days apart	a) 0.20 mL/m <sup>2</sup> b) 1.00 mL/m <sup>2</sup>	a) 0.1116 kg/ha b) 0.558 kg/ha	<del>100</del> 500 mL/m <sup>2</sup>	N *	Amateur gardening  Notes on dose rate: spray concentration: 0,4 %
017	DE	ornamentals (NNNZZ)  production of cutting flowers	G	sucking insects (4SXXXXX) red spider mites (TETRSP) (BBCH EX-IL)	spraying	At beginning of infestation and/or when first symptoms/harmful organisms become visible 12 to 89	a) 5 b) 5	treatments must be at least 7 days apart	a) 2.00 L/ha b) 10.00 L/ha	a) 0.1116 kg/ha b) 0.558 kg/ha	<del>100</del> 500 L/ha	N *	Notes on dose rate: spray concentration: 0,4 %
018	DE	ornamentals (NNNZZ)  production of cutting flowers	G	sucking insects (4SXXXXX) red spider mites (TETRSP) (BBCH EX-IL)	spraying	At beginning of infestation and/or when first symptoms/harmful organisms be-	a) 5 b) 5	treatments must be at least 7 days apart	a) 0.20 mL/m <sup>2</sup> b) 1.00 mL/m <sup>2</sup>	a) 0.1116 kg/ha b) 0.558 kg/ha	<del>100</del> 500 mL/m <sup>2</sup>	N *	Amateur gardening  Notes on dose rate: spray con-

						come visible 2 true leaves, leaf pairs or whorls unfolded to Fully ripe: fruit shows fully-ripe colour, beginning of fruit abscission							centration: 0,4 %
--	--	--	--	--	--	--	--	--	--	--	--	--	-------------------

\*The setting of a PHI is without any relevance

**Remarks table heading:**

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
 (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008  
 (c) g/kg or g/l

(d) Select relevant  
 (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  
 (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

**Remarks columns:**

1 Numeration necessary to allow references  
 2 Use official codes/nomenclatures of EU Member States  
 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)  
 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  
 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  
 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  
 Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application  
 8 The maximum number of application possible under practical conditions of use must be provided.  
 9 Minimum interval (in days) between applications of the same product  
 10 For specific uses other specifications might be possible, e.g.: g/m<sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  
 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  
 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".  
 13 PHI - minimum pre-harvest interval  
 14 Remarks may include: Extent of use/economic importance/restrictions

## 3 Background of authorization decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of liquid, with a citrus odour. It is not explosive, and it has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 448°C + 5°C. In a 1% aqueous solution, it has a pH value of 7 at 21 °C and the neat formulation has a pH of 7.34. The kinematic viscosity at 40°C is 55.6 mm<sup>2</sup>/s. The surface tension of the neat formulation at 20°C is 27.1 mN/m and therefore the formulation is considered to be surface active. The relative density of the formulation is 1.017. There is no effect of low, ambient and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C and 2 year at ambient temperature tested in HDPE, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in original packaging coex-HDPE/PA and coex-HDPE/EVOH. The results of the HDPE packaging can be extrapolated to coex-HDPE/PA and coex-HDPE/EVOH packaging, as HDPE is considered worst-case to coex-HDPE/PA and coex-HDPE/EVOH packaging. However, based on the low temperature study, the label should include the phrase "Protect from frost". Its technical characteristics are acceptable for a micro emulsion formulation. However, based on the results of the emulsion characteristics before and after storage the phrase "continuous agitation during application" should be included on the product label. Additionally, based on the results of the persistence of foaming an anti-foam agent (at 0.001%, e.g. dimethyl polysiloxane) should be used when preparing the spraysolution to prevent foaming.

Label instructions: The following information should be included on the product label, "Protect from frost" (*In German: "Vor Frost schützen."*) and "continuous agitation during application" (*In German: "Spritzflüssigkeit unter ständigem Rühren ausbringen."*) and an anti-foam agent (at 0.001%, e.g. dimethyl polysiloxane) should be used when preparing the spraysolution to prevent foaming (*In German: "Ein Antischaummittel (0.001%, z. B. Dimethylpolysiloxan) sollte genutzt werden zur Herstellung der Spritzflüssigkeit, um dem Schäumen vorzubeugen."*).

The intended concentration of use is between 0.4%-0.8% for a pesticidal action, for a standalone use in greenhouse uses.

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

Please refer to the registration report of the zonal RMS NL.

### 3.3 Efficacy data

Please refer to the registration report of the zonal RMS NL.

Ultimately, all efficacy studies are based on different concentrations. The ZRMS NL determines that there is sufficient efficacy at a concentration of 0.4%. For this reason, the requested application rates are extrapolated from a concentration of 0.4%. In addition, the application rates are staggered in Germany in relation to the plant heights.

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

Please refer to the registration report of the zonal RMS NL.

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

Please refer to the registration report of the zonal RMS NL.

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

Please refer to the registration report of the zonal RMS NL.

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

Analytical methods and their validation were already evaluated during the European approval process of the active substance, orange oil.

All data were considered as adequate during the Annex I review.

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

An analytical method for the determination of orange oil (D-limonene) in the formulation has been provided and is fully validated according SANCO/3030/99 rev. 4.

There are no relevant impurities in technical orange oil and will not be formed during manufacturing or storage of the formulation and therefore no analytical method is provided and required.

There is no CIPAC method available for the determination of neither for the botanical substance, orange oil nor its lead compound, D-limonene.

### **3.4.2 Analytical methods for residues**

Orange oil is a natural occurring substance and listed in Annex IV of Reg. (EU) No. 396/2005. Residue definitions for monitoring in soil, water and air do currently not exist. Analytical methods for monitoring of orange oil residues are therefore not required. A method for residues in body fluids and tissues is not required as the active substance is not classified as very toxic.

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

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

As a result of the German assessment no additional evaluation is regarded necessary to cover the national situation. For further details please refer to the registration report of the zonal RMS NL.

### **3.5.1 Acute toxicity**

Please refer to the registration report of the zonal RMS NL.



### **3.5.2 Operator exposure**

Please refer to the registration report of the zonal RMS NL.

### **3.5.3 Worker exposure**

Please refer to the registration report of the zonal RMS NL.

### **3.5.4 Bystander and resident exposure**

Please refer to the registration report of the zonal RMS NL.

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

The intended uses will not result in residues above the MRLs set in Regulation (EC) No 396/2005. A risk for consumers through the consumption of food possibly containing residues of the active substances is not expected.

For further details please refer to the registration report of the zonal RMS NL.

### **3.6.1 Residues**

Please refer to the registration report of the zonal RMS NL.

### **3.6.2 Consumer exposure**

Please refer to the registration report of the zonal RMS NL.

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

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 008883-00/00 according the uniform principles of directive 91/414/EEC.

Special risk mitigation measures to protect the environment are not necessary.

For further details, please refer to the registration report (core assessment) of the zonal RMS NL.

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

PEC<sub>soil</sub> was calculated for the active substance Orange oil considering a soil depth of 1.0 cm. Due to the fast degradation of the active substance Orange oil in soil the accumulation potential of Orange oil was not considered.

The PEC<sub>soil</sub> values for the active substance were used in the ecotoxicological risk assessment for the intended uses of the plant protection product OROCID PLUS in Germany.

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

#### Direct leaching into groundwater

Please refer to registration report (core assessment) of the zonal RMS NL.

Further to DAR evaluation and EFSA conclusion in 2013, a confirmatory data expertise was developed by ORO AGRI International Ltd on environmental fate for the botanical active substance, orange oil.

Physico-chemistry properties of the active substance, orange oil, were also confirmed with further tests to determine the partition coefficient (LogK<sub>ow</sub> = 5.3), to show the low water solubility of the substance (13.8 mg/L at 25°C) and to validate the volatility potential of this natural complex sub-stance (9.88 Pascals at a flow rate of 20 mL/min. at 20°C)

As a conclusion, the natural complex substance, orange oil is not likely to reach nor accumulate in groundwater, therefore it is reasonable to conclude that determination of end points on groundwater contamination are not appropriate for orange oil.

Calculation of predicted environmental concentrations in groundwater (PEC<sub>gw</sub>) is not appropriate for the complex active substance, orange oil.

Ground water contamination is not likely to happen, considering the high volatilisation, the low water solubility and the readily biodegradability of the botanical active substance, orange oil.

Consequences for authorization:

None.

#### Groundwater contamination by bank filtration due to surface water exposure via runoff and drainage

Is not relevant.

Consequences for authorization:

None

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

Risk mitigation measures for the intended uses of plant protection products in Germany due to exposure of surface water consider two routes of entry (i) spray drift and volatilization with subsequent deposition and (ii) runoff, drainage separately.

Surface water exposure including effects of risk mitigation via spray drift and volatilization with subsequent deposition was estimated with the model EVA 3 using drift data by Rautmann and Ganzelmeier.

Surface water exposure including effects of risk mitigation via surface runoff and drainage was estimated using the model EXPOSIT 3.

The results of the specific national exposure assessment for the active substance were used in the ecotoxicological risk assessment.

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

The vapour pressure at 20 °C of the active substance Orange oil is > 10<sup>4</sup> Pa. Hence the active sub-stance Orange oil is regarded as volatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Orange oil due to volatilization with subsequent deposition was not considered.

## **3.8 Ecotoxicology (Part B, Section 9)**

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 008883-00/00 according the uniform principles of directive 91/414/EEC.

For further details, please refer to the registration report (core assessment) of the zonal RMS NL.

The results of the assessment indicate an acceptable risk for terrestrial vertebrates (birds and mammals), aquatic species, bees, non-target arthropods other than bees, soil organisms and non-target terrestrial plants.

### 3.8.1 Effects on terrestrial vertebrates

For the intended uses 005 – 007, 010 – 012 and 015 - 016 no quantitative risk assessment is required as no relevant exposure of birds or mammals is expected for greenhouse uses.

The results of the assessment indicate an acceptable risk for birds and mammals due to the intended use of OROCID PLUS in tomatos, sweet pepper, curcubits and ornamental plants (greenhouse uses) according to the label.

### 3.8.2 Effects on aquatic species

The product Orocid Plus and the active substance Orange oil are toxic to the aquatic environment. Subsequently no additional entries as those according to the evaluated use pattern and good agricultural practise are acceptable, and the labellings and conditions of use NW262, NW264, NW470 and SP1 are assigned.

In agreement with the German modelling scheme TER values are calculated for relevant exposure route: spray drift. The calculation is based on the endpoint of *D. magna* (EC50 = 421 µg a.s./L).

TER values for aquatic organisms were calculated, taking into account the relevant toxicity data for orange oil (d-limonene as lead compound) and calculated exposure levels, according to the intended uses of the product OROCID PLUS in tomatos, sweet pepper, curcubits and ornamental plants. The calculated TER values do achieve the acceptability criterion  $TER \geq 100$  for acute effects on aquatic organisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.2. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of OROCID PLUS in tomatos, sweet pepper, curcubits and ornamental plants according to the label.

Due to the properties of orange oil, i.e considering the high volatilisation, the low water solubility and the readily biodegradability of the active substance orange oil, no relevant exposure via run-off and drainage is expected. As no relevant exposure is expected, the risk via run-off and drainage is considered as acceptable.

## Consequences for authorisation

For the authorisation of the plant protection product OROCID PLUS, labelling and conditions of use are mandatory as follows:

### Labelling requirements according to § 36 (3) PflSchG

NW262	d-limonene as lead compound of orange oil: <i>P. subcapitata</i> NOEC < 1 mg/L (assumed as ErC50 is 0.44 mg/L, hence NOEC must be < 1 mg/L)
NW264	d-limonene as lead compound of orange oil: <i>P. promelas</i> LC <sub>50</sub> = 0.702 mg/L <i>D. magna</i> EC <sub>50</sub> = 0.421 mg/L

**Mandatory conditions of use according to § 36 (1) PflSchG for the protection of aquatic organisms**

NW470	
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**3.8.3 Effects on bees**

Honey bees

Effects on bees for OROCID PLUS were not evaluated as part of the EU review of orange oil. Risk assessments for OROCID PLUS with the proposed use pattern were provided and are considered adequate.

Applications of OROCID PLUS can potentially result in exposure of honeybees either through direct overspray, or by contact with residues on plants whilst bees are foraging for food.

The risks of OROCID PLUS to honey-bees were assessed from hazard quotients between toxicity endpoints, estimated from acute oral and contact studies with the formulated product and a maximum single application rate of 6400 mL formulation/ha (6526.08 g formulation/ha).

**Table 3.8.3-1: First-tier assessment of the risk for bees due to the use of OROCID PLUS in grape (fungicide/vineyard)**

Intended use	Fungicide/vineyards		
Active substance	Orange oil		
Application rate (g/ha)	-		
Test design	LD <sub>50</sub> (lab.) (µg/bee)	Single application rate (g/ha)	Q <sub>HO</sub> , Q <sub>HC</sub> criterion: Q <sub>H</sub> ≤ 50
Oral toxicity	No data on the botanical active substance, orange oil.		
Contact toxicity			
Product	OROCID PLUS (Product code 030-S-3-D)		
Application rate (g/ha)	6.4 L/ha (density OROCID PLUS = 1019.7 g/L at 20°C)		
Test design	LD <sub>50</sub> (lab.) (µg product/bee)	Single application rate (g product/ha)	Q <sub>HO</sub> , Q <sub>HC</sub> criterion: Q <sub>H</sub> ≤ 50
Oral toxicity	326 µg/bee	6526.08 g/ha	20.01
Contact toxicity	155.9 µg/bee		41.86

Q<sub>HO</sub>, Q<sub>HC</sub>: Hazard quotients for oral and contact exposure. Q<sub>H</sub> values shown in bold breach the relevant trigger.

All the hazard quotients are less than 50, indicating that OROCID PLUS poses a low risk to bees when used according to the recommended use pattern.

Because the submitted studies do not cover the direct effect of the application, i.e. when bees are over-sprayed or come in contact with the wet oil spray a higher tier semi field study was also assessed. No adverse effects were observed and the risk to bees is considered acceptable by the zRMS.

Wild bees

Based on the available information for orange oil, overall it is concluded that the risk for wild pollinators can be considered as acceptable.

For further details, please refer to the registration report (core assessment) of the zonal RMS NL.

### **3.8.4 Effects on other arthropod species other than bees**

TER values for non-target arthropods in off-field habitats were calculated, taking into account the relevant toxicity data for orange oil and calculated exposure concentrations in off-field habitats, according to the intended uses of the product OROCID PLUS in tomatos, sweet pepper, curcubits and ornamental plants (greenhouse uses). The calculated TER values do achieve the acceptability criterion  $TER \geq 5$  (extended laboratory database) for effects on non-target arthropods, according to agreed EU Guidance in Document SANCO/10329/2002 rev 2 (as modified by specific German guidance) that overrides the prescriptions of Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.4. The results of the assessment indicate an acceptable risk for non-target arthropods in off-field habitats due to the intended use of OROCID PLUS according to the label.

Consequences for authorisation  
None

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

The TER value for earthworms was calculated, taking into account the relevant toxicity data for OROCID PLUS and calculated exposure concentrations in soil, according to the intended field uses of the product in grapes. The calculated TER value does achieve the acceptability criterion  $TER \geq 10$  for acute effects on earthworms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5. The results of the assessment indicate an acceptable risk for earthworms due to the intended use of OROCID PLUS in grape according to the label. The intended greenhouse uses are covered by this assessment.

As also stated in the core assessment, no relevant exposure of soil organisms has to expected due to the fate characteristics of the active substance orange oil. Thus, the acute and chronic risk for soil organisms is generally considered to be acceptable.

No data were provided for other soil organisms than earthworms. As stated above for earthworms, no relevant exposure of soil organisms has to expected due to the fate characteristics of the active substance orange oil. Thus, the acute and chronic risk for soil organisms is generally considered to be acceptable.

Also no data were provided for soil microorganisms. However, based on qualitative information, D-limonene, the lead compound of orange oil, could be used by soil microorganisms. Hence the active substance rather has a positive than an adverse effect on microorganisms.

Consequences for authorisation  
None

### **3.8.6 Effects on non-target terrestrial plants**

No quantitative risk assessment was performed by zonal RMS NL. Based on the absence of effects in the efficacy studies, it can be concluded that the risk for non-target terrestrial plants is acceptable.

Consequences for authorisation  
None

### **3.8.7 Effects on other terrestrial organisms (Flora and Fauna)**

No data, not required.

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

Please refer to the registration report (core assessment) of the zonal RMS NL. No relevant metabolites.

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

The active substance orange oil is not approved as a candidate of substitution therefore a comparative assessment is not foreseen.

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

None

**Appendix 1 Copy of the product authorization (see Appendix 5)**

## **Appendix 2 Copy of the product label**

The submitted draft product label has been checked by the competent authority. The final version of the label is not displayed in the RR, because the label is the sole responsibility of the applicant and is therefore not finally checked by the competent authority. The applicant is requested to generate the product label in accordance with the authorisation granted by the competent authority.



### **Appendix 3 Letter of Access**

Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

## **Appendix 4 Lists of data considered for national authorization**

No further studies submitted – list of data considered for national authorisation: see ZRMS evaluation

## **Appendix 5 Copy of the product authorization**

See below



Bundesamt für Verbraucherschutz und Lebensmittelsicherheit  
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IHR ZEICHEN  
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.008883-00/00.164145  
(bitte bei Antwort angeben)

DATUM 11. August 2020

**ZV3 008883-00/00**

**OROCIDE PLUS**

**Zulassungsverfahren für Pflanzenschutzmittel**

Bescheid

Das oben genannte Pflanzenschutzmittel

mit dem Wirkstoff: 55,8 g/l Orangenöl

Zulassungsnummer: 008883-00

Versuchsbezeichnungen: ORO-03003-AFI-0-ME

Antrag vom: 3. Oktober 2016

wird auf der Grundlage von Art. 29 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (ABl. L 309 vom 24.11.2009, S. 1), wie folgt zugelassen:

### **Zulassungsende**

Die Zulassung endet am 30. April 2025.

### **Festgesetzte Anwendungsgebiete bzw. Anwendungen**

Es werden folgende Anwendungsgebiete bzw. Anwendungen festgesetzt (siehe Anlage 1):

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008883-00/00-015, 008883-00/00-016	Blattläuse, Weiße Fliegen (ausgenom- men: Bemisia)	Zierpflanzen	
008883-00/00-005, 008883-00/00-010	Spinnmilben	Tomate, Gemüsepa- prika	
008883-00/00-017, 008883-00/00-018	Spinnmilben	Zierpflanzen	
008883-00/00-007, 008883-00/00-012	Weiße Fliegen (aus- genommen: Bem- isia)	Moschus-Kürbis, Rie- senkürbis, Garten-Kür- bis, Flaschenkürbis	
008883-00/00-006, 008883-00/00-011	Weiße Fliegen (aus- genommen: Bem- isia)	Tomate, Gemüsepa- prika	

### Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 4 Absatz 84 des Gesetzes vom 18. Juli 2016 (BGBl. I S. 1666), festgesetzt:

(EO005-2)

SPo 5: Vor dem Wiederbetreten ist das Gewächshaus gründlich zu lüften.

#### Begründung:

Im Ergebnis der Expositionsbewertung für Arbeiter bei Nachfolgearbeiten/Inspektionen ist die Anwendungsbestimmung erforderlich, um den Referenzwert bei bestimmungsgemäßer Anwendung nicht zu überschreiten. Nur in Verbindung mit der Verwendung der zusätzlichen Maßnahmen wird das Risiko als vertretbar beurteilt.

(NW470)

Etwaige Anwendungsflüssigkeiten, Granulate und deren Reste sowie Reinigungs- und Spülflüssigkeiten nicht in Gewässer gelangen lassen. Dies gilt auch für indirekte Einträge über die Kanalisation, Hof- und Straßenabläufe sowie Regen- und Abwasserkanäle.

#### Begründung:

Der im o.g. Pflanzenschutzmittel enthaltene Wirkstoff Orangenöl weist aufgrund seiner Toxizität ein hohes Gefährdungspotenzial für aquatische Organismen auf. Jeder Eintrag von Rückständen in Oberflächengewässer, der den Eintrag als Folge der bestimmungsgemäßen und sachgerechten Anwendung des Mittels entsprechend der guten fachlichen Praxis über-

steigt, würde daher zu einer Gefährdung des Naturhaushaltes aufgrund von nicht akzeptablen Auswirkungen auf Gewässerorganismen führen. Da ein erheblicher Anteil der in Oberflächengewässern nachzuweisenden Pflanzenschutzmittelfrachten auf Einträge aus kommunalen Kläranlagen zurückzuführen ist, muss dieser Gefährdung durch die bußgeldbewehrte Anwendungsbestimmung durchsetzbar begegnet werden.

(SE110)

Dicht abschließende Schutzbrille tragen beim Umgang mit dem unverdünnten Mittel.

Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsaufgaben zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

(SS110-1)

Beim Umgang mit dem unverdünnten Mittel sind Schutzhandschuhe (Pflanzenschutz) zu tragen.

Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsaufgaben zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

(SS2101)

Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen beim Umgang mit dem unverdünnten Mittel.

Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsaufgaben zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

## **Verpackungen**

Gemäß § 36 Abs. 1 S. 2 Nr. 1 PflSchG sind für das Pflanzenschutzmittel die nachfolgend näher beschriebenen Verpackungen für den beruflichen Anwender zugelassen:

Verpackungs- art	Verpackungs- material	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Kanister	HDPE/EVOH	1		1,00	20,00	l
Kanister	HDPE/PA	1		1,00	20,00	l

Die Verpackungen für den beruflichen Anwender sind wie folgt zu kennzeichnen:  
Anwendung nur durch berufliche Anwender zulässig.

Gemäß § 36 Abs. 1 S. 2 Nr. 1 und 2 PflSchG sind für das Pflanzenschutzmittel die nachfolgend näher beschriebenen Verpackungen für die Anwendung durch nichtberufliche Anwender zugelassen:

Verpackungs- art	Verpackungs- material	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Flasche	HDPE/PA	1		0,12	0,20	l

Die Verpackungen für den nichtberuflichen Anwender sind wie folgt zu kennzeichnen:  
Anwendung durch nichtberufliche Anwender zulässig.

## Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:

Kennzeichnungsauflagen:

(EB001-2)

SP 1: Mittel und/oder dessen Behälter nicht in Gewässer gelangen lassen. (Ausbringungsgeräte nicht in unmittelbarer Nähe von Oberflächengewässern reinigen./Indirekte Einträge über Hof- und Straßenabläufe verhindern.)

(NN2001)

Das Mittel wird als schwach schädigend für Populationen relevanter Nutzinsekten eingestuft.

(NN2002)

Das Mittel wird als schwach schädigend für Populationen relevanter Raubmilben und Spinnen eingestuft.

(NW262)

Das Mittel ist giftig für Algen.

(NW264)

Das Mittel ist giftig für Fische und Fischnährtiere.

(SB001)

Jeden unnötigen Kontakt mit dem Mittel vermeiden. Missbrauch kann zu Gesundheitsschäden führen.

(SB005)

Ist ärztlicher Rat erforderlich, Verpackung oder Etikett des Produktes bereithalten.

(SB010)

Für Kinder unzugänglich aufbewahren.

(SB111)

Für die Anforderungen an die persönliche Schutzausrüstung beim Umgang mit dem Pflanzenschutzmittel sind die Angaben im Sicherheitsdatenblatt und in der Gebrauchsanweisung des Pflanzenschutzmittels sowie die BVL-Richtlinie "Persönliche Schutzausrüstung beim Umgang mit Pflanzenschutzmitteln" des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit ([www.bvl.bund.de](http://www.bvl.bund.de)) zu beachten.

(SB166)

Beim Umgang mit dem Produkt nicht essen, trinken oder rauchen.

(SF245-02)

Es ist sicherzustellen, dass behandelte Flächen/Kulturen erst nach dem Abtrocknen des Pflanzenschutzmittelbelages wieder betreten werden.

(SS206)

Arbeitskleidung (wenn keine spezifische Schutzkleidung erforderlich ist) und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln.

(VA551)

Spritzflüssigkeit unter ständigem Rühren ausbringen.

(WA607)

Pflanzenschutzmittel vor Frost schützen.

(WMIUN)



Wirkungsmechanismus (IRAC-Gruppe): unbekannt

Siehe anwendungsbezogene Kennzeichnungsaufgaben in Anlage 1, jeweils unter Nr. 2.

Sonstige Auflagen:

(WH952)

Auf der Verpackung und in der Gebrauchsanleitung ist die Angabe zur Kennzeichnung des Wirkungsmechanismus als zusätzliche Information direkt jedem entsprechenden Wirkstoffnamen zuzuordnen.

### **Vorbehalt**

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

### **Angaben zur Einstufung und Kennzeichnung gemäß Verordnung (EG) Nr. 1272/2008**

Signalwort:

(S1)            Achtung

Gefahrenpiktogramme:

(GHS07)        Ausrufezeichen

(GHS09)        Umwelt

Gefahrenhinweise (H-Sätze):

(H319)

Verursacht schwere Augenreizung.

(H411)

Giftig für Wasserorganismen, mit langfristiger Wirkung.

(EUH 208-0098)

Enthält 1,2-Benzisothiazol-3(2H)-on. Kann allergische Reaktionen hervorrufen.

(EUH 208-0244)

Enthält Orangenöl. Kann allergische Reaktionen hervorrufen.

(EUH 401)

Zur Vermeidung von Risiken für Mensch und Umwelt die Gebrauchsanleitung einhalten.

Sicherheitshinweise (P-Sätze):

(P101)

Ist ärztlicher Rat erforderlich, Verpackung oder Kennzeichnungsetikett bereithalten.

(P102)

Darf nicht in die Hände von Kindern gelangen.

(P280)

Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.

(P305+P351+P338)

BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Eventuell vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen.

(P337+P313)

Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

(P391)

Verschüttete Mengen aufnehmen.

(P501)

Inhalt/Behälter ... zuführen.

### **Abgelehnte Anwendungsgebiete bzw. Anwendungen**

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):

<b>Anwendungsnummer</b>	<b>Schadorganismus/ Zweckbestimmung</b>	<b>Pflanzen/-erzeugnisse/ Objekte</b>	<b>Verwendungszweck</b>
008883-00/00-002, 008883-00/00-004	Botrytis	Weinrebe	Nutzung als Tafel- und Keltertraube
008883-00/00-001, 008883-00/00-003	Echter Mehltau (Uncinula necator)	Weinrebe	Nutzung als Tafel- und Keltertraube

## **Hinweise**

### **Auf dem Etikett und in der Gebrauchsanleitung kann angegeben werden:**

(NB6641)

Das Mittel wird bis zu der höchsten durch die Zulassung festgelegten Aufwandmenge oder Anwendungskonzentration, falls eine Aufwandmenge nicht vorgesehen ist, als nicht bienengefährlich eingestuft (B4).

### **Weitere Hinweise und Bemerkungen**

Zur Verpackung:

Die Verpackungen 0,12 L und 0,2 L mit dem Verpackungsmaterial HDPE/PA wurden in die Datenbank übernommen.

Die weiteren Verpackungen sind unter Vorlage der notwendigen Studien als Verpackungsänderungen zu beantragen.

Vorsorglich weise ich darauf hin, dass bisher mitgeteilte Forderungen bestehen bleiben, soweit sie noch nicht erfüllt sind.

Unterbleibt eine Beanstandung der vorgelegten Gebrauchsanleitung, so ist daraus nicht zu schließen, dass sie als ordnungsgemäß angesehen wird. Die Verantwortung des Zulassungsinhabers für die Übereinstimmung mit dem Zulassungsbescheid bleibt bestehen.

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

## **Rechtsbehelfsbelehrung**

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist beim Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Braunschweig einzulegen.

Mit freundlichen Grüßen  
im Auftrag

gez. Dr. Martin Streloke  
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

## **Anlage**

## Anlage 1 zugelassene Anwendung: 008883-00/00-005

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Spinnmilben

Pflanzen/-erzeugnisse/Objekte: Tomate, Gemüsepaprika

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Gemüsebau
Anwendungsbereich:	Gewächshaus
Anwendung im Haus- und Kleingartenbereich:	Ja
Anwenderkategorie:	Nichtberuflich
Stadium des Schadorganismus:	Ei bis Imago
Stadium der Kultur:	2. Laubblatt am Hauptspross entfaltet bis Vollreife; Paprika- und Auberginenfrüchte haben art-/sortentypische Fruchtausfärbung erreicht
Anwendungszeitpunkt:	Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome/Schadorganismen
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	5
- für die Kultur bzw. je Jahr:	5
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 7 Tage
Anwendungstechnik:	spritzen
Aufwand:	
- Pflanzengröße bis 50 cm	0,2 ml/m <sup>2</sup> in 50 ml Wasser/m <sup>2</sup>
- Pflanzengröße 50 bis 125 cm	0,3 ml/m <sup>2</sup> in 75 ml Wasser/m <sup>2</sup>
- Pflanzengröße über 125 cm	0,4 ml/m <sup>2</sup> in 100 ml Wasser/m <sup>2</sup>
- Erläuterungen:	Konzentration der Spritzbrühe: 0,4 %

#### 2.2 Sonstige Kennzeichnungsauflagen

(HE110-1)

Für den Haus- und Kleingartenbereich entfällt SE110: "Dicht abschließende Schutzbrille tragen beim Umgang mit dem unverdünnten Mittel".

(HS110-1)

Für den Haus- und Kleingartenbereich entfällt SS110-1: "Beim Umgang mit dem unverdünnt-

ten Mittel sind Schutzhandschuhe (Pflanzenschutz) zu tragen."

(HS206-1)

Für den Haus- und Kleingartenbereich entfällt SS206: "Arbeitskleidung (wenn keine spezifische Schutzkleidung erforderlich ist) und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln."

(HS2101-1)

Für den Haus- und Kleingartenbereich entfällt SS2101: "Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen beim Umgang mit dem unverdünnten Mittel".

(WP732)

Bei Sonneneinstrahlung können nach der Anwendung Schäden an den Kulturpflanzen auftreten.

### 2.3 Wartezeiten

1 Tag Gewächshaus: Tomate

1 Tag Gewächshaus: Gemüsepaprika

## 3 Anwendungsbezogene Anwendungsbestimmungen

(SE126)

Schutzbrille tragen bei der Ausbringung/Handhabung des Mittels.

#### Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsaufgaben zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

(SS202)

Schutzhandschuhe tragen beim Umgang mit dem Mittel.

#### Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsaufgaben zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

(SS205-1)

Langärmeliges Hemd, lange Hose und festes Schuhwerk tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln.

#### Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsaufgaben zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Ver-

ordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

## Anlage 1 zugelassene Anwendung: 008883-00/00-006

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Weiße Fliegen (ausgenommen: Bemisia)

Pflanzen/-erzeugnisse/Objekte: Tomate, Gemüsepaprika

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Gemüsebau
Anwendungsbereich:	Gewächshaus
Anwendung im Haus- und Kleingartenbereich:	Ja
Anwenderkategorie:	Nichtberuflich
Stadium des Schadorganismus:	Ei bis Imago
Stadium der Kultur:	2. Laubblatt am Hauptspross entfaltet bis Vollreife; Paprika- und Auberginenfrüchte haben art-/sortentypische Fruchtausfärbung erreicht
Anwendungszeitpunkt:	Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome/Schadorganismen
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	6
- für die Kultur bzw. je Jahr:	6
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 7 Tage
Anwendungstechnik:	spritzen
Aufwand:	
- Pflanzengröße bis 50 cm	0,2 ml/m <sup>2</sup> in 50 ml Wasser/m <sup>2</sup>
- Pflanzengröße 50 bis 125 cm	0,3 ml/m <sup>2</sup> in 75 ml Wasser/m <sup>2</sup>
- Pflanzengröße über 125 cm	0,4 ml/m <sup>2</sup> in 100 ml Wasser/m <sup>2</sup>
- Erläuterungen:	Konzentration der Spritzbrühe: 0,4 %

#### 2.2 Sonstige Kennzeichnungsauflagen

(HE110-1)

Für den Haus- und Kleingartenbereich entfällt SE110: "Dicht abschließende Schutzbrille tragen beim Umgang mit dem unverdünnten Mittel".

(HS110-1)

Für den Haus- und Kleingartenbereich entfällt SS110-1: "Beim Umgang mit dem unverdünnten

ten Mittel sind Schutzhandschuhe (Pflanzenschutz) zu tragen."

(HS206-1)

Für den Haus- und Kleingartenbereich entfällt SS206: "Arbeitskleidung (wenn keine spezifische Schutzkleidung erforderlich ist) und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln."

(HS2101-1)

Für den Haus- und Kleingartenbereich entfällt SS2101: "Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen beim Umgang mit dem unverdünnten Mittel".

(WP732)

Bei Sonneneinstrahlung können nach der Anwendung Schäden an den Kulturpflanzen auftreten.

### 2.3 Wartezeiten

1 Tag Gewächshaus: Tomate

1 Tag Gewächshaus: Gemüsepaprika

## 3 Anwendungsbezogene Anwendungsbestimmungen

(SE126)

Schutzbrille tragen bei der Ausbringung/Handhabung des Mittels.

#### Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsauflagen zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

(SS202)

Schutzhandschuhe tragen beim Umgang mit dem Mittel.

#### Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsauflagen zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

(SS205-1)

Langärmeliges Hemd, lange Hose und festes Schuhwerk tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln.

#### Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsauflagen zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Ver-



ordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

## Anlage 1 zugelassene Anwendung: 008883-00/00-007

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Weiße Fliegen (ausgenommen: Bemisia)

Pflanzen/-erzeugnisse/Objekte: Moschus-Kürbis, Riesenkürbis, Garten-Kürbis, Flaschenkürbis

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Gemüsebau
Anwendungsbereich:	Gewächshaus
Anwendung im Haus- und Kleingartenbereich:	Ja
Anwenderkategorie:	Nichtberuflich
Stadium des Schadorganismus:	Ei bis Imago
Stadium der Kultur:	2. Laubblatt bzw. Blattpaar oder Blattquirl entfaltet bis Vollreife, art-/sortentypische Fruchtausfärbung erreicht. Früchte bzw. Fruchtstände lösen sich relativ leicht
Anwendungszeitpunkt:	Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome/Schadorganismen
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	6
- für die Kultur bzw. je Jahr:	6
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 7 Tage
Anwendungstechnik:	spritzen
Aufwand:	
- Pflanzengröße bis 50 cm	0,2 ml/m <sup>2</sup> in 50 ml Wasser/m <sup>2</sup>
- Pflanzengröße 50 bis 125 cm	0,3 ml/m <sup>2</sup> in 75 ml Wasser/m <sup>2</sup>
- Pflanzengröße über 125 cm	0,4 ml/m <sup>2</sup> in 100 ml Wasser/m <sup>2</sup>
- Erläuterungen:	Konzentration der Spritzbrühe: 0,4 %

#### 2.2 Sonstige Kennzeichnungsauflagen

(HE110-1)

Für den Haus- und Kleingartenbereich entfällt SE110: "Dicht abschließende Schutzbrille tragen beim Umgang mit dem unverdünnten Mittel".

(HS110-1)

Für den Haus- und Kleingartenbereich entfällt SS110-1: "Beim Umgang mit dem unverdünnten Mittel sind Schutzhandschuhe (Pflanzenschutz) zu tragen."

(HS206-1)

Für den Haus- und Kleingartenbereich entfällt SS206: "Arbeitskleidung (wenn keine spezifische Schutzkleidung erforderlich ist) und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln."

(HS2101-1)

Für den Haus- und Kleingartenbereich entfällt SS2101: "Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen beim Umgang mit dem unverdünnten Mittel".

(WP732)

Bei Sonneneinstrahlung können nach der Anwendung Schäden an den Kulturpflanzen auftreten.

### 2.3 Wartezeiten

1 Tag	Gewächshaus: Moschus-Kürbis
1 Tag	Gewächshaus: Flaschenkürbis
1 Tag	Gewächshaus: Garten-Kürbis
1 Tag	Gewächshaus: Riesenkürbis

### 3 Anwendungsbezogene Anwendungsbestimmungen

(SE126)

Schutzbrille tragen bei der Ausbringung/Handhabung des Mittels.

Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsaufgaben zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

(SS202)

Schutzhandschuhe tragen beim Umgang mit dem Mittel.

Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsaufgaben zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

(SS205-1)

Langärmeliges Hemd, lange Hose und festes Schuhwerk tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln.

Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsaufgaben zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

## Anlage 1 zugelassene Anwendung: 008883-00/00-010

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Spinnmilben

Pflanzen/-erzeugnisse/Objekte: Tomate, Gemüsepaprika

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Gemüsebau
Anwendungsbereich:	Gewächshaus
Anwendung im Haus- und Kleingartenbereich:	Nein
Anwenderkategorie:	Beruflich
Stadium des Schadorganismus:	Ei bis Imago
Stadium der Kultur:	12 bis 89
Anwendungszeitpunkt:	Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome/Schadorganismen
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	5
- für die Kultur bzw. je Jahr:	5
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 7 Tage
Anwendungstechnik:	spritzen
Aufwand:	
- Pflanzengröße bis 50 cm	2 l/ha in 500 l Wasser/ha
- Pflanzengröße 50 bis 125 cm	3 l/ha in 750 l Wasser/ha
- Pflanzengröße über 125 cm	4 l/ha in 1000 l Wasser/ha
- Erläuterungen:	Konzentration der Spritzbrühe: 0,4 %

#### 2.2 Sonstige Kennzeichnungsauflagen

(WP732)

Bei Sonneneinstrahlung können nach der Anwendung Schäden an den Kulturpflanzen auftreten.

#### 2.3 Wartezeiten

1 Tag Gewächshaus: Tomate

1 Tag

Gewächshaus: Gemüsepaprika

**3 Anwendungsbezogene Anwendungsbestimmungen**

- keine -

## Anlage 1 zugelassene Anwendung: 008883-00/00-011

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Weiße Fliegen (ausgenommen: Bemisia)

Pflanzen/-erzeugnisse/Objekte: Tomate, Gemüsepaprika

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Gemüsebau
Anwendungsbereich:	Gewächshaus
Anwendung im Haus- und Kleingartenbereich:	Nein
Anwenderkategorie:	Beruflich
Stadium des Schadorganismus:	Ei bis Imago
Stadium der Kultur:	12 bis 89
Anwendungszeitpunkt:	Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome/Schadorganismen
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	6
- für die Kultur bzw. je Jahr:	6
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 7 Tage
Anwendungstechnik:	spritzen
Aufwand:	
- Pflanzengröße bis 50 cm	2 l/ha in 500 l Wasser/ha
- Pflanzengröße 50 bis 125 cm	3 l/ha in 750 l Wasser/ha
- Pflanzengröße über 125 cm	4 l/ha in 1000 l Wasser/ha
- Erläuterungen:	Konzentration der Spritzbrühe: 0,4 %

#### 2.2 Sonstige Kennzeichnungsauflagen

(WP732)

Bei Sonneneinstrahlung können nach der Anwendung Schäden an den Kulturpflanzen auftreten.

#### 2.3 Wartezeiten

1 Tag Gewächshaus: Tomate

1 Tag

Gewächshaus: Gemüsepaprika

**3 Anwendungsbezogene Anwendungsbestimmungen**

- keine -



## Anlage 1 zugelassene Anwendung: 008883-00/00-012

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Weiße Fliegen (ausgenommen: Bemisia)

Pflanzen/-erzeugnisse/Objekte: Moschus-Kürbis, Riesenkürbis, Garten-Kürbis, Flaschenkürbis

Verwendungszweck:

### 2 Kennzeichnungsaufgaben

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Gewächshaus

Anwendung im Haus- und Kleingartenbereich: Nein

Anwenderkategorie: Beruflich

Stadium des Schadorganismus: Ei bis Imago

Stadium der Kultur: 12 bis 89

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome/Schadorganismen

Maximale Zahl der Behandlungen

- in dieser Anwendung: 6
- für die Kultur bzw. je Jahr: 6
- Erläuterungen Anzahl Behandlungen: zeitlicher Abstand der Behandlungen mindestens 7 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße bis 50 cm 2 l/ha in 500 l Wasser/ha
- Pflanzengröße 50 bis 125 cm 3 l/ha in 750 l Wasser/ha
- Pflanzengröße über 125 cm 4 l/ha in 1000 l Wasser/ha
- Erläuterungen: Konzentration der Spritzbrühe: 0,4 %

#### 2.2 Sonstige Kennzeichnungsaufgaben

(WP732)

Bei Sonneneinstrahlung können nach der Anwendung Schäden an den Kulturpflanzen auftreten.

#### 2.3 Wartezeiten

1 Tag Gewächshaus: Moschus-Kürbis

1 Tag Gewächshaus: Flaschenkürbis

1 Tag Gewächshaus: Garten-Kürbis

1 Tag Gewächshaus: Riesenkürbis

### **3 Anwendungsbezogene Anwendungsbestimmungen**

- keine -

## Anlage 1 zugelassene Anwendung: 008883-00/00-015

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Blattläuse, Weiße Fliegen (ausgenommen: Bemisia)

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Gewächshaus

Anwendung im Haus- und  
Kleingartenbereich: Nein

Anwenderkategorie: Beruflich

Stadium des Schadorganismus: Ei bis Imago

Erläuterung zur Kultur: Erzeugung von Schnittware

Stadium der Kultur: 12 bis 89

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten  
Symptome/Schadorganismen

Maximale Zahl der Behandlungen

- in dieser Anwendung: 5

- für die Kultur bzw. je Jahr: 5

- Erläuterungen Anzahl

Behandlungen: zeitlicher Abstand der Behandlungen mindestens 7  
Tage

Anwendungstechnik: spritzen

Aufwand:

- 2 l/ha in 500 l Wasser/ha

- Erläuterungen: Konzentration der Spritzbrühe: 0,4 %

#### 2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WP732)

Bei Sonneneinstrahlung können nach der Anwendung Schäden an den Kulturpflanzen auftreten.

### **2.3 Wartezeiten**

(N)

Gewächshaus: Zierpflanzen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

### **3 Anwendungsbezogene Anwendungsbestimmungen**

- keine -

## Anlage 1 zugelassene Anwendung: 008883-00/00-016

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Blattläuse, Weiße Fliegen (ausgenommen: Bemisia)

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Gewächshaus

Anwendung im Haus- und  
Kleingartenbereich: Ja

Anwenderkategorie: Nichtberuflich

Stadium des Schadorganismus: Ei bis Imago

Erläuterung zur Kultur: Erzeugung von Schnittware

Stadium der Kultur: 2. Laubblatt bzw. Blattpaar oder Blattquirl entfaltet bis  
Vollreife, art-/sortentypische Fruchtausfärbung  
erreicht. Früchte bzw. Fruchtstände lösen sich relativ  
leicht

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten  
Symptome/Schadorganismen

Maximale Zahl der Behandlungen

- in dieser Anwendung: 5

- für die Kultur bzw. je Jahr: 5

Anwendungstechnik: spritzen

Aufwand:

- 0,2 ml/m<sup>2</sup> in 50 ml Wasser/m<sup>2</sup>

- Erläuterungen: Konzentration der Spritzbrühe: 0,4 %

#### 2.2 Sonstige Kennzeichnungsauflagen

(HE110-1)

Für den Haus- und Kleingartenbereich entfällt SE110: "Dicht abschließende Schutzbrille tragen beim Umgang mit dem unverdünnten Mittel".

(HS110-1)

Für den Haus- und Kleingartenbereich entfällt SS110-1: "Beim Umgang mit dem unverdünnten Mittel sind Schutzhandschuhe (Pflanzenschutz) zu tragen."

(HS206-1)

Für den Haus- und Kleingartenbereich entfällt SS206: "Arbeitskleidung (wenn keine spezifi-

sche Schutzkleidung erforderlich ist) und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln."

(HS2101-1)

Für den Haus- und Kleingartenbereich entfällt SS2101: "Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen beim Umgang mit dem unverdünnten Mittel".

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WP732)

Bei Sonneneinstrahlung können nach der Anwendung Schäden an den Kulturpflanzen auftreten.

### 2.3 Wartezeiten

(N)

Gewächshaus: Zierpflanzen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

## 3 Anwendungsbezogene Anwendungsbestimmungen

(SE126)

Schutzbrille tragen bei der Ausbringung/Handhabung des Mittels.

#### Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsaufgaben zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

(SS202)

Schutzhandschuhe tragen beim Umgang mit dem Mittel.

#### Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsaufgaben zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

(SS205-1)

Langärmeliges Hemd, lange Hose und festes Schuhwerk tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln.

#### Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsaufgaben zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

## Anlage 1 zugelassene Anwendung: 008883-00/00-017

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Spinnmilben

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Zierpflanzenbau
Anwendungsbereich:	Gewächshaus
Anwendung im Haus- und Kleingartenbereich:	Nein
Anwenderkategorie:	Beruflich
Stadium des Schadorganismus:	Ei bis Imago
Erläuterung zur Kultur:	Erzeugung von Schnittware
Stadium der Kultur:	12 bis 89
Anwendungszeitpunkt:	Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome/Schadorganismen
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	5
- für die Kultur bzw. je Jahr:	5
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 7 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 500 l Wasser/ha
- Erläuterungen:	Konzentration der Spritzbrühe: 0,4 %

#### 2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WP732)

Bei Sonneneinstrahlung können nach der Anwendung Schäden an den Kulturpflanzen auftreten.

## **2.3 Wartezeiten**

(N)

Gewächshaus: Zierpflanzen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

## **3 Anwendungsbezogene Anwendungsbestimmungen**

- keine -



## Anlage 1 zugelassene Anwendung: 008883-00/00-018

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Spinnmilben

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Gewächshaus

Anwendung im Haus- und  
Kleingartenbereich: Ja

Anwenderkategorie: Nichtberuflich

Stadium des Schadorganismus: Ei bis Imago

Erläuterung zur Kultur: Erzeugung von Schnittware

Stadium der Kultur: 2. Laubblatt bzw. Blattpaar oder Blattquirl entfaltet bis  
Vollreife, art-/sortentypische Fruchtausfärbung  
erreicht. Früchte bzw. Fruchtstände lösen sich relativ  
leicht

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten  
Symptome/Schadorganismen

Maximale Zahl der Behandlungen

- in dieser Anwendung: 5

- für die Kultur bzw. je Jahr: 5

Anwendungstechnik: spritzen

Aufwand:

- 0,2 ml/m<sup>2</sup> in 50 ml Wasser/m<sup>2</sup>

- Erläuterungen: Konzentration der Spritzbrühe: 0,4 %

#### 2.2 Sonstige Kennzeichnungsauflagen

(HE110-1)

Für den Haus- und Kleingartenbereich entfällt SE110: "Dicht abschließende Schutzbrille tragen beim Umgang mit dem unverdünnten Mittel".

(HS110-1)

Für den Haus- und Kleingartenbereich entfällt SS110-1: "Beim Umgang mit dem unverdünnten Mittel sind Schutzhandschuhe (Pflanzenschutz) zu tragen."

(HS206-1)

Für den Haus- und Kleingartenbereich entfällt SS206: "Arbeitskleidung (wenn keine spezifi-

sche Schutzkleidung erforderlich ist) und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln."

(HS2101-1)

Für den Haus- und Kleingartenbereich entfällt SS2101: "Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen beim Umgang mit dem unverdünnten Mittel".

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WP732)

Bei Sonneneinstrahlung können nach der Anwendung Schäden an den Kulturpflanzen auftreten.

### 2.3 Wartezeiten

(N)

Gewächshaus: Zierpflanzen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

## 3 Anwendungsbezogene Anwendungsbestimmungen

(SE126)

Schutzbrille tragen bei der Ausbringung/Handhabung des Mittels.

#### Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsauflagen zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

(SS202)

Schutzhandschuhe tragen beim Umgang mit dem Mittel.

#### Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsauflagen zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

(SS205-1)

Langärmeliges Hemd, lange Hose und festes Schuhwerk tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln.

#### Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsauflagen zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

## Anlage 2 nicht zugelassene Anwendung: 008883-00/00-001

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (*Uncinula necator*)

Pflanzen/-erzeugnisse/Objekte: Weinrebe

Verwendungszweck: Nutzung als Tafel- und Keltertraube

### 2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Weinbau

Anwendungsbereich: Freiland

Anwendung im Haus- und  
Kleingartenbereich: Nein

Anwenderkategorie: Beruflich

Stadium der Kultur: 53 bis 81

Anwendungszeitpunkt: Bei Infektionsgefahr bzw. ab Warndiensthinweis

Maximale Zahl der Behandlungen

- in dieser Anwendung: 9

- für die Kultur bzw. je Jahr: 9

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen oder sprühen

- Erläuterungen: nur zur Behandlung der Traubenzone

Aufwand:

- 6,4 l/ha in 600 bis 1600 l Wasser/ha

- Erläuterungen: Konzentration der Spritzbrühe: 0,4 %

### 3 Begründung

Wirksamkeit und Nachhaltigkeit:

Nach Art. 33 Abs. 3 Buchst. a der Verordnung (EG) Nr. 1107/2009 sind dem Antrag für das Pflanzenschutzmittel ein vollständiges Dossier und eine Kurzfassung davon beizufügen, die jeden Punkt der Datenanforderungen für den Wirkstoff abdecken. Das vollständige Dossier enthält gemäß Art. 8 Abs. 2 S. 1 der Verordnung (EG) Nr. 1107/2009 den Volltext der einzelnen Versuchs- und Studienberichte bezüglich aller unter Art. 8 Abs. 1 Buchst. c der Verordnung (EG) Nr. 1107/2009 genannten Informationen. Hierfür gelten gemäß Art. 1 der Verordnung (EU) Nr. 284/2013 die Datenanforderungen im Anhang dieser Verordnung.

Gemäß Punkt 6.2 im Anhang der Verordnung (EU) Nr. 284/2013 in Verbindung mit EPPO Standard PP 1/241(1) "Guidance on comparable climates" und EPPO Standard PP 1/226 (1) "Number of efficacy trials" sind 10 (6-15) Wirksamkeitsversuche inkl. Grenzaufwandversuche aus möglichst 2 Versuchsjahren je EPPO-Klimazone bei Anwendungen im Freiland vorzulegen. Die zentrale Registrierungszone beinhaltet drei agrarklimatisch relevante EPPO Zonen (maritime, nordöstliche und südöstliche Zone).

Es wurden teils keine oder lediglich wenige Versuchsergebnisse vorgelegt. Die Anzahl und

besonders die Qualität der vorgelegten Studien sind allerdings nicht ausreichend gemäß EPPO Standard PP 1/226 "Number of efficacy trials". Die Wirksamkeit des Mittels gegenüber den beantragten Schadorganismen ist somit nicht belegt.

Da dem zRMS die genannten Unterlagen nicht vorlagen, wurde diese Anwendung vom zRMS negativ bewertet.

## Anlage 2 nicht zugelassene Anwendung: 008883-00/00-002

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Botrytis  
 Pflanzen/-erzeugnisse/Objekte: Weinrebe  
 Verwendungszweck: Nutzung als Tafel- und Keltertraube

### 2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Weinbau  
 Anwendungsbereich: Freiland  
 Anwendung im Haus- und Kleingartenbereich: Nein  
 Anwenderkategorie: Beruflich  
 Stadium der Kultur: 81 bis 89  
 Anwendungszeitpunkt: Bei Infektionsgefahr bzw. ab Warndiensthinweis  
 Maximale Zahl der Behandlungen  
 - in dieser Anwendung: 3  
 - für die Kultur bzw. je Jahr: 9  
 - Abstand: 3 bis 7 Tage  
 Anwendungstechnik: spritzen oder sprühen  
 - Erläuterungen: nur zur Behandlung der Traubenzone  
 Aufwand:  
 - 6 l/ha in 1000 l Wasser/ha  
 - Erläuterungen: Konzentration der Spritzbrühe: 0,6 %

### 3 Begründung

Wirksamkeit und Nachhaltigkeit:

Nach Art. 33 Abs. 3 Buchst. a der Verordnung (EG) Nr. 1107/2009 sind dem Antrag für das Pflanzenschutzmittel ein vollständiges Dossier und eine Kurzfassung davon beizufügen, die jeden Punkt der Datenanforderungen für den Wirkstoff abdecken. Das vollständige Dossier enthält gemäß Art. 8 Abs. 2 S. 1 der Verordnung (EG) Nr. 1107/2009 den Volltext der einzelnen Versuchs- und Studienberichte bezüglich aller unter Art. 8 Abs. 1 Buchst. c der Verordnung (EG) Nr. 1107/2009 genannten Informationen. Hierfür gelten gemäß Art. 1 der Verordnung (EU) Nr. 284/2013 die Datenanforderungen im Anhang dieser Verordnung.

Gemäß Punkt 6.2 im Anhang der Verordnung (EU) Nr. 284/2013 in Verbindung mit EPPO Standard PP 1/241(1) "Guidance on comparable climates" und EPPO Standard PP 1/226 (1) "Number of efficacy trials" sind 10 (6-15) Wirksamkeitsversuche inkl. Grenzaufwandversuche aus möglichst 2 Versuchsjahren je EPPO-Klimazone bei Anwendungen im Freiland vorzulegen. Die zentrale Registrierungszone beinhaltet drei klimatisch relevante EPPO Zonen (maritime, nordöstliche und südöstliche Zone).

Es wurden teils keine oder lediglich wenige Versuchsergebnisse vorgelegt. Die Anzahl und

besonders die Qualität der vorgelegten Studien sind allerdings nicht ausreichend gemäß EPPO Standard PP 1/226 "Number of efficacy trials". Die Wirksamkeit des Mittels gegenüber den beantragten Schadorganismen ist somit nicht belegt.

Da dem zRMS die genannten Unterlagen nicht vorlagen, wurde diese Anwendung vom zRMS negativ bewertet.

## Anlage 2 nicht zugelassene Anwendung: 008883-00/00-003

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (*Uncinula necator*)

Pflanzen/-erzeugnisse/Objekte: Weinrebe

Verwendungszweck: Nutzung als Tafel- und Keltertraube

### 2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Weinbau

Anwendungsbereich: Freiland

Anwendung im Haus- und  
Kleingartenbereich: Ja

Anwenderkategorie: Nichtberuflich

Stadium der Kultur: "Gescheine" (Infloreszenzen) deutlich sichtbar bis  
Beginn der Reife, Beeren beginnen hell zu werden  
(bzw. beginnen sich zu verfärben)

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten  
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 9
- für die Kultur bzw. je Jahr: 9
- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

- Erläuterungen: nur zur Behandlung der Traubenzone

Aufwand:

- 0,64 ml/m<sup>2</sup> in 60 bis 160 ml Wasser/m<sup>2</sup>
- Erläuterungen: Konzentration der Spritzbrühe: 0,4 %

### 3 Begründung

Wirksamkeit und Nachhaltigkeit:

Nach Art. 33 Abs. 3 Buchst. a der Verordnung (EG) Nr. 1107/2009 sind dem Antrag für das Pflanzenschutzmittel ein vollständiges Dossier und eine Kurzfassung davon beizufügen, die jeden Punkt der Datenanforderungen für den Wirkstoff abdecken. Das vollständige Dossier enthält gemäß Art. 8 Abs. 2 S. 1 der Verordnung (EG) Nr. 1107/2009 den Volltext der einzelnen Versuchs- und Studienberichte bezüglich aller unter Art. 8 Abs. 1 Buchst. c der Verordnung (EG) Nr. 1107/2009 genannten Informationen. Hierfür gelten gemäß Art. 1 der Verordnung (EU) Nr. 284/2013 die Datenanforderungen im Anhang dieser Verordnung.

Gemäß Punkt 6.2 im Anhang der Verordnung (EU) Nr. 284/2013 in Verbindung mit EPPO Standard PP 1/241(1) "Guidance on comparable climates" und EPPO Standard PP 1/226 (1) "Number of efficacy trials" sind 10 (6-15) Wirksamkeitsversuche inkl. Grenzaufwandversuche aus möglichst 2 Versuchsjahren je EPPO-Klimazone bei Anwendungen im Freiland vorzule-

gen. Die zentrale Registrierungszone beinhaltet drei klimatisch relevante EPPO Zonen (maritime, nordöstliche und südöstliche Zone).

Es wurden teils keine oder lediglich wenige Versuchsergebnisse vorgelegt. Die Anzahl und besonders die Qualität der vorgelegten Studien sind allerdings nicht ausreichend gemäß EPPO Standard PP 1/226 "Number of efficacy trials". Die Wirksamkeit des Mittels gegenüber den beantragten Schadorganismen ist somit nicht belegt.

Da dem zRMS die genannten Unterlagen nicht vorlagen, wurde diese Anwendung vom zRMS negativ bewertet.



## Anlage 2 nicht zugelassene Anwendung: 008883-00/00-004

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Botrytis

Pflanzen/-erzeugnisse/Objekte: Weinrebe

Verwendungszweck: Nutzung als Tafel- und Keltertraube

### 2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Weinbau

Anwendungsbereich: Freiland

Anwendung im Haus- und  
Kleingartenbereich: Ja

Anwenderkategorie: Nichtberuflich

Stadium der Kultur: Beginn der Reife, Beeren beginnen hell zu werden  
(bzw. beginnen sich zu verfärben) bis Vollreife der  
Beeren (Lesereife)

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten  
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3
- für die Kultur bzw. je Jahr: 9
- Abstand: 3 bis 7 Tage

Anwendungstechnik: spritzen

- Erläuterungen: nur zur Behandlung der Traubenzone

Aufwand:

- 0,64 ml/m<sup>2</sup> in maximal 100 ml Wasser/m<sup>2</sup>
- Erläuterungen: Konzentration der Spritzbrühe: 0,6 %

### 3 Begründung

Wirksamkeit und Nachhaltigkeit:

Nach Art. 33 Abs. 3 Buchst. a der Verordnung (EG) Nr. 1107/2009 sind dem Antrag für das Pflanzenschutzmittel ein vollständiges Dossier und eine Kurzfassung davon beizufügen, die jeden Punkt der Datenanforderungen für den Wirkstoff abdecken. Das vollständige Dossier enthält gemäß Art. 8 Abs. 2 S. 1 der Verordnung (EG) Nr. 1107/2009 den Volltext der einzelnen Versuchs- und Studienberichte bezüglich aller unter Art. 8 Abs. 1 Buchst. c der Verordnung (EG) Nr. 1107/2009 genannten Informationen. Hierfür gelten gemäß Art. 1 der Verordnung (EU) Nr. 284/2013 die Datenanforderungen im Anhang dieser Verordnung.

Gemäß Punkt 6.2 im Anhang der Verordnung (EU) Nr. 284/2013 in Verbindung mit EPPO Standard PP 1/241(1) "Guidance on comparable climates" und EPPO Standard PP 1/226 (1) "Number of efficacy trials" sind 10 (6-15) Wirksamkeitsversuche inkl. Grenzaufwandversuche aus möglichst 2 Versuchsjahren je EPPO-Klimazone bei Anwendungen im Freiland vorzule-

gen. Die zentrale Registrierungszone beinhaltet drei klimatisch relevante EPPO Zonen (maritime, nordöstliche und südöstliche Zone).

Es wurden teils keine oder lediglich wenige Versuchsergebnisse vorgelegt. Die Anzahl und besonders die Qualität der vorgelegten Studien sind allerdings nicht ausreichend gemäß EPPO Standard PP 1/226 "Number of efficacy trials". Die Wirksamkeit des Mittels gegenüber den beantragten Schadorganismen ist somit nicht belegt.

Da dem zRMS die genannten Unterlagen nicht vorlagen, wurde diese Anwendung vom zRMS negativ bewertet.

**REGISTRATION REPORT**

**Part A**

**Risk Management**

**Product code: 030-S-3-D**

**Product name(s): Orocide Plus**

**Chemical active substance:**

**Orange oil 60 g/L**

**Central Zone**

**Zonal Rapporteur Member State: NL**

**NATIONAL ASSESSMENT Germany**

**(refusal)**

**Applicant: Oro Agri**

**Submission date: 12/10/2016 in Germany**

**30 June 2016 in NL**

**MS Finalisation date: 11.08.2020**

## Version history

<b>When</b>	<b>What</b>
August 2009	Draft Assessment report for orange oil, with the recommended use of a plant protection product (insecticide) in greenhouses
November 2012	Draft Assessment report for orange oil, with the recommended use of a plant protection product (insecticide & fungicide) in fields
May 2014	Approval of orange oil in Annex I, Directive 94/414//EC – RMS, France
April 2016	Submission of confirmatory answer according to Commission Implementing Regulation (EU) N° 1165/2013 of 18 November 2013, Annex I – RMS, France
June 2016	OROCIDE PLUS (product code 030-S-3-D) first Central zone submission for field uses, as a fungicide to control fungal diseases on grape - zRMS, The Netherlands.
16 July 2019	dRR available for comments
28 November 2019	Final RR available from the Netherlands
11 August 2020	Finalisation of authorisation inter-zonal uses and refuses of zonal uses (due to the decision of the ZRMS)

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# PART A

## RISK MANAGEMENT

### 1 Details of the application

This document describes the acceptable use condition under field conditions required for the registration of OROCIDE PLUS containing 60 g/L orange oil.

The risk assessment conclusions are based on the information, data and assessment provided in Draft Registration Report, Part B Sections 1 to 10 and Part C of the ZRMS The Netherlands and national addenda B.8 and B.9 for Germany. The information, data and assessments provided in this Draft Registration Report, Part B includes core data supporting the new formulation OROCIDE PLUS (product code 030-S-3-D). Safe use of OROCIDE PLUS have been made using end-points agreed in the EU review of orange oil, and part of the confirmatory answers according to Commission implementing regulation (EU) N°1165/2013 of 18 November 2013, Annex I.

The applicant has considered all risk assessment models to cover all requirements in Europe for a field use.

This document describes the specific conditions of use and labelling required in Germany.

#### 1.1 Application background

This application is submitted by ORO AGRI International Ltd located at Bankastraat 75, 9715CJ Groningen, The Netherlands.

The botanical active substance, orange oil, was approved in Annex I of Directive 91/414/EC, with an entry in force on May 2014, with both modes of action as an insecticide and a fungicide. The applicant was ORO AGRI International Ltd. The reference formulation was PREV-AM (product code OREU 030), for use in field to control whiteflies on tomato and zucchini.

The composition of OROCIDE PLUS (product code 030-S-3-D) under evaluation is a minor revision on the original recipe of PREV-AM, developed to provide farmers with a safer plant protection product, eligible for organic farming. All details on recipe updates are provided in the confidential part of this Draft Registration Report, in Part C.

OROCIDE PLUS (product code 030-S-3-D), containing a plant extract, orange oil, is a new formulation, to be used as a fungicide in field, which has never been registered in Europe. This dossier is submitted in The Netherlands, the zRMS for this Central zone application, and in CMS as listed in Part B.0 of this submission dossier.

OROCIDE PLUS is a micro emulsion formulation with a low surface tension, which enhances a good coverage of target fungal diseases. OROCIDE PLUS is a contact fungicide that wets and breaks down of the layers of fungal mycelia, sporangia, and spores - breaking them down and exposing them to the drying effect of the atmosphere. Drying of the fungal mycelia and the surrounding leaf tissue prevents the spread of further infection.

OROCIDE PLUS solution wets the protective layers of the fungal mycelia, sporangia, and spores - breaking them down and exposing them to the drying effect of the atmosphere. Drying of the fungal mycelia and the surrounding leaf tissue stops the spread of further infection.

Plant tissue damaged by the fungus may also dry out, but healthy tissue will not be affected.

Global target pathogens include: Powdery mildew, botrytis, rots, rusts, downy mildew, foliar blights and more.

Because of its mode of action OROCIDE PLUS has contact activity on botrytis and powdery mildew. OROCIDE PLUS is highly effective as a curative fungicide. The mode of action of OROCIDE PLUS is compared to most commercial products differs due to its physical mode of action. Application is made only when the pest is present.

As OROCIDE PLUS has a physical mode of action product, which primarily targets the outer protective layers of the fungus, the key points for a successful application of OROCIDE PLUS are:

- application of OROCIDE PLUS with quality spray equipment to enhance an even distribution of the product
- application of OROCIDE PLUS at an early stage, at first incidence of disease
- application of OROCIDE PLUS at regular intervals every 7 to 10 days
- application of OROCIDE PLUS observing the minimum dose concentration of 400-600 mL/hL.

## **1.2 Letters of Access**

The applicant presented a LoA dated 23rd October 2015 for specific field trials. The remaining data requirements were addressed by own data.

## **1.3 Justification for submission of tests and studies**

To obtain approval the product Orocide Plus must meet the conditions of Commission Implementing Regulation (EU) No 1165/2013 of 18 November 2013 approving the active substance orange oil and be supported by a dossier satisfying the requirements of Commission Regulation (EU) No 284/ 2013, with an assessment according to Uniform Principles (Commission Regulation (EU) No 546/2011), using agreed endpoints.

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

The reference list included in Part A Appendix 4 defines the list of studies and reports submitted by the applicant and relied on as well as a list of studies submitted by the applicant but not relied on for the authorisation. Furthermore, Appendix 4 includes studies already evaluated at EU peer re-view and studies necessary but not submitted.

## **1.4 Data protection claims**

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.



## 2 Details of the authorization decision

### 2.1 Product identity

Product code	030-S-3-D
Product name in MS	OROCIDE PLUS
Authorization number	008883-00/00
Function	Acaricide, fungicide, insecticide
Applicant	ORO AGRI International Ltd
Active substance(s) (incl. content)	Orange oil 58,96 g/L
Formulation type	Micro-emulsion (ME)
Packaging	0.12 to 0.2 L, 1L to 20L for professional users (HDPE/PA) 0.12 to 0.2 L for non-professional users (HDPE/PA) 1L to 20L for professional users (HDPE/EVOH)
Coformulants of concern for national authorizations	Not applicable
Restrictions related to identity	Not applicable
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not relevant

### 2.2 Conclusion

With respect to identity, physical, chemical and technical properties, further information and analytical methods for the formulation an authorisation can be granted.

With respect to analytical methods for residues an authorisation can be granted.

With respect to toxicology, residues and consumer protection an authorisation can be granted.

With respect to fate and ecotoxicology assessment, an authorisation can be granted. Considering an application in accordance with the evaluated use pattern and good agricultural practice as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

With respect to efficacy and sustainable use/IPM an authorisation cannot be granted for the uses 001, 002, 003 and 004. These uses were not authorised by the zRMS due to insufficient efficacy information. Germany agrees with assessment and conclusion of the zRMS.

**The evaluation of the application for Orocid Plus resulted in the decision to refuse the authorization. These uses were not authorised by the zRMS due to insufficient efficacy information and therefore refused in Germany, too.**

## 2.3 Substances of concern for national monitoring

## 2.4 Classification and labelling

### 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Eye Irrit. 2
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet.

Hazard pictograms:	
GHS07	exclamation mark
GHS09	environment
Signal word:	
	Warning
Hazard statement(s):	
H319	Causes serious eye irritation.
H411	Toxic to aquatic life with long lasting effects.
Precautionary statement(s):	
P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+313	If eye irritation persists: Get medical advice/attention.
P391	Collect spillage.
P501	Dispose of contents/container to ...
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208	Contains orange oil. May produce allergic reactions
EUH 208	Contains 1,2-benzisothiazole-3(2H)-one. May produce an allergic reaction.

See Part C for justifications of the classification and labelling proposals.

## 2.4.2 Standard phrases under Regulation (EU) No 547/2011

EO005-2	SPo 5: Ventilate greenhouses thoroughly before re-entry.
SP1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

## 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Human health protection:	
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
SB005	If medical advice is needed, have product container or label at hand.
SB010	Keep out of the reach of children.
SB111	Concerning the requirements for personal protective gear for handling the plant protection product the material safety data sheet and the instructions for use of the plant protection product as well as the guideline "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety (www.bvl.bund.de) must be observed.
SB166	Do not eat, drink or smoke when using this product.
SE110	Wear tight fitting eye protection when handling the undiluted product.
SF245-02	It must be ensured that treated areas/crops may not be entered until the film of the plant protection product has dried.
SS110-1	Protective gloves (plant protection) must be worn when handling the undiluted product.
SS206	Working clothes (if no specific protective suit is required) and sturdy footwear (e.g. rubber boots) must be worn when applying/handling plant protection products.
SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.
Integrated pest management (IPM)/sustainable use:	
WMFUN	Mode of action (FRAC-group): unknown (for orange oil)
NN2001	The product is classified as slightly harmful for populations of relevant beneficial insects.
NN2002	The product is classified as slightly harmful for populations of relevant beneficial

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	predatory mites and spiders.
Environmental protection	
NW262	The product is toxic for algae.
NW264	The product is toxic for fish and aquatic invertebrates.
NW470	Where applicable, fluids left over from application, granules and their remains as well as cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.
Other specific restrictions	
VA551	Apply spray liquid under permanent agitation. (Spritzflüssigkeit unter ständigem Rühren ausbringen.)
WA607	Protect plant protection product from frost. (Pflanzenschutzmittel vor Frost schützen.)
-	An anti-foam agent (at 0.001%, e.g. dimethyl polysiloxane) should be used when preparing the spraysolution to prevent foaming. (Ein Antischaummittel (0.001%, z. B. Dimethylpolysiloxan) sollte genutzt werden zur Herstellung der Spritzflüssigkeit, um dem Schäumen vorzubeugen.)

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
NB6641	Das Mittel wird bis zu der höchsten durch die Zulassung festgelegten Aufwandmenge oder Anwendungskonzentration, falls eine Aufwandmenge nicht vorgesehen ist, als nicht bienengefährlich eingestuft (B4).

## 2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
None		
Environmental protection:		Relevant for use no.
NW605-1	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*". Drift reduction by 90% 5 m	001

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	<p>75 % 10 m          50% 10 m</p> <p>Drift reduction by          90% * m          75 % 5 m          50% 10 m</p>	002
NW606	<p>The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters - except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro.          Buffer zone of 10 m</p>	001, 002
NW608-1	<p>When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water-bearing surface waters - the product must be applied observing the minimum buffer zone stated below. Irrespective of this, in addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times. Violations may be punished by fines of up to 50 000 EUR.          Buffer zone only: 10 m</p>	003, 004
Other specific restrictions:		Relevant for use no.
HE110-1	SE110 ("Wear tight fitting eye protection when handling the undiluted product") does not apply to home and garden use.	Use 003 - 004 (home and garden use)
HS110-1	SS110-1 ("Protective gloves (plant protection) must be worn when handling the undiluted product.") does not apply to home and garden use.	Use 003 - 004 (home and garden use)
HS206-1	SS206 ("Working clothes (if no specific protective suit is required) and sturdy footwear (e.g. rubber boots) must be worn when applying/handling plant protection products.") does not apply to home and garden use.	Use 003 - 004 (home and garden use)
HS2101-1	SS2101 ("Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.") does not apply to home and garden use.	Use 003 - 004 (home and garden use)
SE126	Wear eye protection when applying/handling the product.	Use 003 - 004 (home and garden use)
SS202	Wear protective gloves when handling the product.	Use 003 - 004 (home and garden use)
SS205-1	Wear long-sleeved shirt, long trousers and sturdy footwear during handling and applying plant protection products.	Use 003 - 004 (home and garden use)

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## 2.6 Intended uses (only NATIONAL GAP)

Reg.-No. 008883-00/00 GAP rev. 2, date: 2020-05-06  
 PPP (product name/code): OROCID PLUS Formulation type: ME <sup>(a, b)</sup>  
 Active substance 1: Orange oil Conc. of as 1: 55.80 g/L <sup>(c)</sup>  
 Applicant: ORO AGRI International Ltd. Professional use:   
 Zone(s): central <sup>(d)</sup> Non professional use:   
 Verified by MS: yes Field of use: Fungicide

1 Use- No. (e)	2 Member state(s)	3 Crop and/ or situation  (crop destination / purpose of crop)	4 F, Fn, Fpn G, Gn, Gpn or I	5 Pests or Group of pests controlled  (additionally: develop- mental stages of the pest or pest group)	6 Application				10 Application rate			13 PHI (days)	14 Remarks:  e.g. g safener/synergist per ha (i)
					6 Method / Kind	7 Timing / Growth stage of crop & season	8 Max. number a) per use b) per crop/ season	9 Min. interval between appli- cations (days)	10 kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	11 g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	12 Water L/ha min / max		
001	DE	grape vine (VITVI) use as table and wine grape	F	powdery mildew of grape (Uncinula necator) (UN- CINE)	spraying or fine spray- ing (low volume spraying) only for treating the grape zone	In case of danger of infection and/or af- ter warn- ing service appeal 53 to 81	a) 9 b) 9	7 to 14 days	a) 6.40 L/ha b) 57.60 L/ha	a) 0.35712 kg/ha b) 3.21408 kg/ha	600 - 1600 L/ha	-	Notes on dose rate: spray con- centration: 0,4 %  Not authorized by zRMS, in- sufficient efficacy data
002	DE	grape vine (VITVI) use as table and wine grape	F	Botrytis (BOTRYT)	spraying or fine spray- ing (low volume spraying) only for treating the grape zone	In case of danger of infection and/or af- ter warn- ing service appeal 81 to 89	a) 3 b) 9	3 to 7 days	a) 6.00 L/ha b) 57.60 L/ha	a) 0.3348 kg/ha b) 3.21408 kg/ha	1000 - 1000 L/ha	-	Notes on dose rate: spray con- centration: 0,6 %  Not authorized by zRMS, in- sufficient efficacy data
003	DE	grape vine (VITVI) use as table and wine grape	F	powdery mildew of grape (Uncinula necator) (UN- CINE)	spraying only for treating the grape zone	At begin- ning of in- festation and/or	a) 9 b) 9	7 to 14 days	a) 0.64 mL/m <sup>2</sup> b) 5.80 mL/m <sup>2</sup>	a) 0.35712 kg/ha b) 3.2364 kg/ha	60 - 160 mL/m <sup>2</sup>	-	Amateur gardening Notes on dose rate: spray con- centration: 0,4 %

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						when first symptoms become visible Inflorescences clearly visible to Beginning of ripening: berries begin to develop variety-specific colour							Not authorized by zRMS, insufficient efficacy data
004	DE	grape vine (VITVI) use as table and wine grape	F	Botrytis (BOTRYT)	spraying only for treating the grape zone	At beginning of infestation and/or when first symptoms become visible Beginning of ripening: berries begin to develop variety-specific colour to Berries ripe for harvest	a) 3 b) 9	3 to 7 days	a) 0.64 mL/m <sup>2</sup> b) 1.80 mL/m <sup>2</sup>	a) 0.35712 kg/ha b) 1.0044 kg/ha	-/100 mL/m <sup>2</sup>	-	Amateur gardening Notes on dose rate: spray concentration: 0,6 %  Not authorized by zRMS, insufficient efficacy data

**Remarks table heading:**

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
 (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008  
 (c) g/kg or g/l

(d) Select relevant  
 (e) Use number(s) in accordance with the list of all intended GAPS in Part B, Section 0 should be given in column 1  
 (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

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



## 3 Background of authorization decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of liquid, with a citrus odour. It is not explosive, and it has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 448°C + 5°C. In a 1% aqueous solution, it has a pH value of 7 at 21 °C and the neat formulation has a pH of 7.34. The kinematic viscosity at 40°C is 55.6 mm<sup>2</sup>/s. The surface tension of the neat formulation at 20°C is 27.1 mN/m and therefore the formulation is considered to be surface active. The relative density of the formulation is 1.017. There is no effect of low, ambient and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C and 2 year at ambient temperature tested in HDPE, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in original packaging coex-HDPE/PA and coex-HDPE/EVOH. The results of the HDPE packaging can be extrapolated to coex-HDPE/PA and coex-HDPE/EVOH packaging, as HDPE is considered worst-case to coex-HDPE/PA and coex-HDPE/EVOH packaging. However, based on the low temperature study, the label should include the phrase “Protect from frost”. Its technical characteristics are acceptable for a micro emulsion formulation. However, based on the results of the emulsion characteristics before and after storage the phrase “continuous agitation during application” should be included on the product label. Additionally, based on the results of the persistence of foaming an anti-foam agent (at 0.001%, e.g. dimethyl polysiloxane) should be used when preparing the spraysolution to prevent foaming.

Label instructions: The following information should be included on the product label, “Protect from frost” (*In German: “Vor Frost schützen.”*) and “continuous agitation during application” (*In German: “Spritzflüssigkeit unter ständigem Rühren ausbringen.”*) and an anti-foam agent (at 0.001%, e.g. dimethyl polysiloxane) should be used when preparing the spraysolution to prevent foaming (*In German: “Ein Antischaummittel (0.001%, z. B. Dimethylpolysiloxan) sollte genutzt werden zur Herstellung der Spritzflüssigkeit, um dem Schäumen vorzubeugen.”*).

The intended concentration of use is between 0.4%-0.6% for a pesticidal action, for a standalone use in field uses.

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

This application is for OROCIDÉ PLUS (containing 60 g/L orange oil) as a fungicide in viticulture. Due to the low number of trials performed and the inconsistent and often low levels of control observed the use of OROCIDÉ PLUS on powdery mildew and grey mould in field is not supported by the available data.

### 3.3 Efficacy data

The applicant submitted four efficacy trials for the maritime zone to determine the minimum effective dose rate against grey mould (*Botrytis cinerea* sny. *Botryotinia fuckeliana*) in grapevine. Since these trials were conducted in the same location and at the same time they cannot be considered as separate trials. Additionally, a dose related effect was not clearly observable. For powdery mildew (*Erysiphe necator*) the applicant submitted three trials for the maritime zone. A significant dose related effect could not be determined. Summarised, the submitted information on the minimum effective dose rate is insufficient for the maritime

zone.

The applicant submitted four efficacy trials for the maritime zone to determine effectiveness against grey mould (*Botrytis cinerea*) in grapevine. Since these trials were conducted in the same location and at the same time they cannot be considered as separate trials. The available information for the maritime zone is insufficient to claim control of the target disease.

To determine effectiveness against Powdery mildew the applicant submitted five trials. Two trials are not considered valid because the product was applied in a tank mixture. At moderate disease severity effectiveness is considered comparable to the reference product with metrafenone and better than the reference product with sulphur. Nevertheless, the available information for the maritime zone is insufficient to claim control of the target disease.

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

Development of resistance can be excluded due to the mode of action of the active substance. Orange oil covers and breaks down the protective outer layers of fungi and thereby prevents the spreading of the infection. No further mitigation measures are considered necessary.

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

The available trials on phytotoxicity demonstrated that the product OROCID PLUS is safe. Only one trial showed low phytotoxic effects which did not have a significant effect on the crop. The data is considered acceptable. Nevertheless, since a negative effect on the quality of the fruits cannot be excluded entirely, risk mitigation measures can be applied.

Negative effects on the transformation process were not observed in the two available trials. The information is nevertheless considered insufficient. The number of trials is insufficient.

Effects on plants or plants products to be used for propagation are not relevant since vineyards are used for production of fruits and not for propagation.

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

Effects on adjacent crops cannot be excluded. OROCID PLUS is also intended for use in greenhouse in fruiting vegetables and ornamental plants which are considered very sensitive to plant protection products. Crop safety is not sufficiently demonstrated for most crops although it is known that the active substance does not specifically target plant tissue.

An impact on other plants including adjacent crops is unlikely and an impact on succeeding crops is not relevant because grapevines are perennial crops.

On the basis of the available information OROCID PLUS is considered to be slightly harmful towards populations of beneficial insects and predatory mites and spiders.

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

Analytical methods and their validation were already evaluated during the European approval process of the active substance, orange oil.

All data were considered as adequate during the Annex I review.

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

An analytical method for the determination of orange oil (D-limonene) in the formulation has been provided and is fully validated according SANCO/3030/99 rev. 4.

There are no relevant impurities in technical orange oil and will not be formed during manufacturing or storage of the formulation and therefore no analytical method is provided and required.

There is no CIPAC method available for the determination of neither for the botanical substance, orange oil nor its lead compound, D-limonene.

### **3.4.2 Analytical methods for residues**

Orange oil is a natural occurring substance and listed in Annex IV of Reg. (EU) No. 396/2005. Residue definitions for monitoring in soil, water and air do currently not exist. Analytical methods for monitoring of orange oil residues are therefore not required. A method for residues in body fluids and tissues is not required as the active substance is not classified as very toxic.

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

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

As a result of the German assessment no additional evaluation is regarded necessary to cover the national situation. For further details please refer to the registration report of the zonal RMS NL.

### **3.5.1 Acute toxicity**

Please refer to the registration report of the zonal RMS NL.

### **3.5.2 Operator exposure**

Please refer to the registration report of the zonal RMS NL.

### **3.5.3 Worker exposure**

Please refer to the registration report of the zonal RMS NL.

### **3.5.4 Bystander and resident exposure**

Please refer to the registration report of the zonal RMS NL.

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

The intended uses will not result in residues above the MRLs set in Regulation (EC) No 396/2005. A risk for consumers through the consumption of food possibly containing residues of the active substances is not expected.

For further details please refer to the registration report of the zonal RMS NL.

#### **3.6.1 Residues**

Please refer to the registration report of the zonal RMS NL.

#### **3.6.2 Consumer exposure**

Please refer to the registration report of the zonal RMS NL.

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

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 008883-00/00 according the uniform principles of directive 91/414/EEC.

For further details, please refer to the registration report (core assessment field) of the zonal RMS NL.

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

PEC<sub>soil</sub> was calculated for the active substance Orange oil considering a soil depth of 1.0 cm. Due to the fast degradation of the active substance Orange oil in soil the accumulation potential of Orange oil was not considered.

The PEC<sub>soil</sub> values for the active substance were used in the ecotoxicological risk assessment for the intended uses of the plant protection product OROCIDÉ PLUS in Germany.

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

##### Direct leaching into groundwater

Please refer to the registration report (core assessment field) of the zonal RMS NL.

Further to DAR evaluation and EFSA conclusion in 2013, a confirmatory data expertise was developed by ORO AGRI International Ltd on environmental fate for the botanical active substance, orange oil.

Physico-chemistry properties of the active substance, orange oil, were also confirmed with further tests to determine the partition coefficient (LogK<sub>ow</sub> = 5.3), to show the low water solubility of the substance (13.8 mg/L at 25°C) and to validate the volatility potential of this natural complex sub-stance (9.88 Pascals at a flow rate of 20 mL/min. at 20°C)

As a conclusion, the natural complex substance, orange oil is not likely to reach nor accumulate in groundwater, therefore it is reasonable to conclude that determination of end points on groundwater contamination are not appropriate for orange oil.

Calculation of predicted environmental concentrations in groundwater (PEC<sub>gw</sub>) is not appropriate for the complex active substance, orange oil.

Ground water contamination is not likely to happen, considering the high volatilisation, the low water solubility and the readily biodegradability of the botanical active substance, orange oil.

Consequences for authorization:  
None.

Groundwater contamination by bank filtration due to surface water exposure via runoff and drainage  
Is not relevant.

Consequences for authorization:  
None

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

Risk mitigation measures for the intended uses of plant protection products in Germany due to exposure of surface water consider two routes of entry (i) spray drift and volatilization with subsequent deposition and (ii) runoff, drainage separately.

Surface water exposure including effects of risk mitigation via spray drift and volatilization with subsequent deposition was estimated with the model EVA 3 using drift data by Rautmann and Ganzelmeier.

Surface water exposure including effects of risk mitigation via surface runoff and drainage was estimated using the model EXPOSIT 3.

The results of the specific national exposure assessment for the active substance were used in the ecotoxicological risk assessment.

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

The vapour pressure at 20 °C of the active substance Orange oil is > 10<sup>-4</sup> Pa. Hence the active substance Orange oil is regarded as volatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Orange oil due to volatilization with subsequent deposition was not considered.

## **3.8 Ecotoxicology (Part B, Section 9)**

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 008883-00/00 according the uniform principles of directive 91/414/EEC.

For further details, please refer to the registration report (core assessment field) of the zonal RMS NL.

The results of the assessment indicate an acceptable risk for terrestrial vertebrates (birds and mammals), bees, non-target arthropods other than bees, soil organisms and non-target terrestrial plants.

Risk mitigation is necessary to protect aquatic organisms.

### **3.8.1 Effects on terrestrial vertebrates**

TER values for birds and mammals were calculated by zRMS in the core assessment, taking into account

the relevant toxicity data for rapeseed oil and calculated exposure levels for dietary exposure, for exposure via drinking water and for exposure via secondary poisoning, according to the intended uses of the product OROCID PLUS in grape vine (use 001 - 004). The calculated TER values presented in this national addendum do achieve the acceptability criterion  $TER \geq 10$  for acute effects on birds and mammals, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.1.

The results of the assessment indicate an acceptable risk for birds and mammals due to the intended use of OROCID PLUS in grape (field use), according to the label.

Consequences for authorisation  
None

### 3.8.2 Effects on aquatic species

The product Orocid Plus and the active substance Orange oil are toxic to the aquatic environment. Subsequently no additional entries as those according to the evaluated use pattern and good agricultural practise are acceptable, and the labellings and conditions of use **NW262**, **NW264**, **NW470** and **SP1** are assigned.

In agreement with the German modelling scheme TER values are calculated for relevant exposure route: spray drift. The calculation is based on the endpoint of *D. magna* ( $EC_{50} = 421 \mu\text{g a.s./L}$ ).

TER values for aquatic organisms were calculated, taking into account the relevant toxicity data for orange oil (d-limonene as lead compound) and calculated exposure levels, according to the intended uses of the product OROCID PLUS in grapes. The calculated TER values do achieve the acceptability criterion  $TER \geq 100$  for acute effects on aquatic organisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.2, provided that risk mitigation measures are applied.

The results of the risk assessment indicate an acceptable risk by spray drift for aquatic organisms according to the intended uses of Orocid Plus according to the label, provided that risk mitigation measures are applied:

NW605-1/NW606:

10 m buffer zone or drift-reduction technique – corresponding buffer zone: 90 % – 5 m; 75 % – 10 m; 50 % – 10 m for professional use 001 and 90 % – \* m; 75 % – 5 m; 50 % – 10 m for professional use 002,

NW608-1: buffer zone only: 10 m for non-professional uses 003, 004.

Due to the properties of orange oil, i.e considering the high volatilisation, the low water solubility and the readily biodegradability of the active substance orange oil, no relevant exposure via run-off and drainage is expected. As no relevant exposure is expected, the risk via run-off and drainage is considered as acceptable.

#### Consequences for authorisation

For the authorisation of the plant protection product OROCID PLUS, labelling and conditions of use are mandatory as follows:

#### Labelling requirements according to § 36 (3) PflSchG

NW262	d-limonene as lead compound of orange oil: <i>P. subcapitata</i> NOEC < 1 mg/L (assumed as ErC50 is 0.44 mg/L, hence NOEC must be < 1 mg/L)
NW264	d-limonene as lead compound of orange oil: <i>P. promelas</i> LC <sub>50</sub> = 0.702 mg/L <i>D. magna</i> EC <sub>50</sub> = 0.421 mg/L

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**Mandatory conditions of use according to § 36 (1) PflSchG for the protection of aquatic organisms**

NW470	
Use 001 (professional use)	
NW605-1/606	Drift-reduction technique– corresponding buffer zone: 90 % – 5 m; 75 % – 10 m; 50 % – 10 m; conv. – 10 m;
Use 002 (professional use)	
NW605-1/606	Drift-reduction technique– corresponding buffer zone: 90 % – * m; 75 % – 5 m; 50 % – 10 m; conv. – 10 m;
Uses 003 and 004 (non-professional uses)	
NW608-1	Buffer zone only: 10 m

**3.8.3 Effects on bees**

Honey bees

Effects on bees for OROCID PLUS were not evaluated as part of the EU review of orange oil. Risk assessments for OROCID PLUS with the proposed use pattern were provided and are considered adequate.

Applications of OROCID PLUS can potentially result in exposure of honeybees either through direct overspray, or by contact with residues on plants whilst bees are foraging for food.

The risks of OROCID PLUS to honey-bees were assessed from hazard quotients between toxicity endpoints, estimated from acute oral and contact studies with the formulated product and a maximum single application rate of 6400 mL formulation/ha (6526.08 g formulation/ha).

**Table 3.8.3-1: First-tier assessment of the risk for bees due to the use of OROCID PLUS in grape (fungicide/vineyard)**

Intended use	Fungicide/vineyards		
Active substance	Orange oil		
Application rate (g/ha)	-		
Test design	LD <sub>50</sub> (lab.) (µg/bee)	Single application rate (g/ha)	Q <sub>HO</sub> , Q <sub>HC</sub> criterion: Q <sub>H</sub> ≤ 50
Oral toxicity	No data on the botanical active substance, orange oil.		
Contact toxicity			
Product	OROCIDE PLUS (Product code 030-S-3-D)		
Application rate (g/ha)	6.4 L/ha (density OROCID PLUS = 1019.7 g/L at 20°C)		
Test design	LD <sub>50</sub> (lab.) (µg product/bee)	Single application rate (g product/ha)	Q <sub>HO</sub> , Q <sub>HC</sub> criterion: Q <sub>H</sub> ≤ 50
Oral toxicity	326 µg/bee	6526.08 g/ha	20.01

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Contact toxicity	155.9 µg/bee		41.86
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Q<sub>HO</sub>, Q<sub>HC</sub>: Hazard quotients for oral and contact exposure. Q<sub>H</sub> values shown in bold breach the relevant trigger.

All the hazard quotients are less than 50, indicating that OROCID PLUS poses a low risk to bees when used according to the recommended use pattern.

Because the submitted studies do not cover the direct effect of the application, i.e. when bees are over-sprayed or come in contact with the wet oil spray a higher tier semi field study was also assessed. No adverse effects were observed and the risk to bees is considered acceptable by the zRMS.

#### Wild bees

Based on the available information for orange oil, overall it is concluded that the risk for wild pollinators can be considered as acceptable.

For further details, please refer to the registration report (core assessment field) of the zonal RMS NL.

### **3.8.4 Effects on other arthropod species other than bees**

TER values for non-target arthropods in off-field habitats were calculated, taking into account the relevant toxicity data for orange oil and calculated exposure concentrations in off-field habitats, according to the intended uses of the product OROCID PLUS in vine (field use). The calculated TER values do achieve the acceptability criterion  $TER \geq 5$  (extended laboratory database) for effects on non-target arthropods, according to agreed EU Guidance in Document SANCO/10329/2002 rev 2 (as modified by specific German guidance) that overrides the prescriptions of Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.4. The results of the assessment indicate an acceptable risk for non-target arthropods in off-field habitats due to the intended use of OROCID PLUS according to the label.

Consequences for authorisation

None

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

The TER value for earthworms was calculated, taking into account the relevant toxicity data for OROCID PLUS and calculated exposure concentrations in soil, according to the intended uses of the product in grapes. The calculated TER value does achieve the acceptability criterion  $TER \geq 10$  for acute effects on earthworms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5. The results of the assessment indicate an acceptable risk for earthworms due to the intended use of OROCID PLUS in grape according to the label. All other intended uses are covered by this assessment.

As also stated in the core assessment, no relevant exposure of soil organisms has to expected due to the fate characteristics of the active substance orange oil. Thus, the acute and chronic risk for soil organisms is generally considered to be acceptable.

No data were provided for other soil organisms than earthworms. As stated above for earthworms, no relevant exposure of soil organisms has to expected due to the fate characteristics of the active substance orange oil. Thus, the acute and chronic risk for soil organisms is generally considered to be acceptable.

Also no data were provided for soil microorganisms. However, based on qualitative information, D-limonene, the lead compound of orange oil, could be used by soil microorganisms. Hence the active substance rather has a positive than an adverse effect on microorganisms.

Consequences for authorisation

None



### **3.8.6 Effects on non-target terrestrial plants**

No quantitative risk assessment was performed by the zRMS. Based on the absence of effects in the efficacy studies, it can be concluded that the risk for non-target terrestrial plants is acceptable.

Consequences for authorisation  
None

### **3.8.7 Effects on other terrestrial organisms (Flora and Fauna)**

No data, not required.

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

No relevant metabolites. For further details, please refer to the registration report of the zonal RMS NL.

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

The active substance orange oil is not approved as a candidate of substitution therefore a comparative assessment is not foreseen.

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

none

**Appendix 1 Copy of the product authorization (refusal = authorisation of indoor uses see Part A of the national authorisation of indoor uses)**

## **Appendix 2 Copy of the product label**

The submitted draft product label has been checked by the competent authority. The final version of the label is not displayed in the RR, because the label is the sole responsibility of the applicant and is therefore not finally checked by the competent authority. The applicant is requested to generate the product label in accordance with the authorisation granted by the competent authority.

### **Appendix 3 Letter of Access**

Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

## **Appendix 4 Lists of data considered for national authorization**

No further studies submitted – list of data considered for national authorisation: see ZRMS evaluation

## **Appendix 5 Copy of the product authorization**

Please see in PART A of national authorisation for the indoor uses. The outdoor uses are refused due to insufficient efficacy data (in parallel to the ZRMS decision).

**DRAFT REGISTRATION REPORT**

**Part B**

**Section 8**

**Environmental Fate**

Detailed summary of the risk assessment

Product code: ZV3 008883-00/00

Product name: OROCIDÉ PLUS

Chemical active substance:

Orange oil 60 g/L

Central Zone

Zonal Rapporteur Member State: NL

**NATIONAL ADDENDUM – GERMANY**  
(authorisation)

Applicant: Oro Agri International Ltd.

Submission date: 03.06.2016

MS Finalisation date: 04/2020

## Version history

<b>When</b>	<b>What</b>
April 2020	National assessment UBA



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## **8 Fate and behaviour in the environment (KCP 9)**

The exposure assessment of the plant protection product OROCIDE PLUS in its intended uses in grape, tomato, sweet pepper, zucchini, cucurbits and ornamental plants is documented in detail in the core assessment of the plant protection product OROCIDE PLUS dated from June 2019 (central zone and interzonal) performed by Niederlande.

This national addendum has been produced to support a national decision on the authorisation of the product OROCIDE PLUS in Germany for the uses listed below. It reflects the impact of specific German environmental or agricultural circumstances on the exposure and risk assessment for OROCIDE PLUS including risk mitigation measures.

## 8.1 Critical GAP and overall conclusions

### 8.1.1 Table of critical GAPs

**Table 8.1-1:** Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gpn or I**	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha	Conclu- sion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L 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			
<b>Intended for uses in Germany</b>														
001	DE	Grape	F	Powdery mildew	Foliar spraying	BBCH 53- 81	a) 9 b) 9	7	a) 6.4 b) 57.6	a) 384 b) 3456	600-1600		Conc. 0.4% spray solution	
002	DE	Grape	F	Botrytis	Foliar spraying	BBCH 81- 89	a) 3 b) 9	3	a) 6 b) 18	a) 340 b) 3060	1000		Conc. 0.6% spray solution	
003	DE	Grape	Fn	Powdery mildew	Foliar spraying	BBCH 53- 81	a) 9 b) 9	7	a) 6.4 b) 57.6	a) 384 b) 3456	600-1600		Conc. 0.4% spray solution	
004	DE	Grape	Fn	Botrytis	Foliar spraying	BBCH 81- 89	a) 3 b) 9	3	a) 6 b) 18	a) 340 b) 3060	1000		Conc. 0.6% Spray solution	
005	DE	Tomato, Sweet pepper	Gn	Spider mite	Foliar spraying	BBCH 12- 89	a) 5 b) 5	7	a) 4 b) 20	a) 240 b) 1200	250-1000		Plant height up to 50 cm: 0.2 mL prod./m <sup>2</sup> in 25 to 50 mL/m <sup>2</sup> water Plant height 50 up to 125 cm: 0.3 mL prod. /m <sup>2</sup> in 37.5 to 75	

													mL/m <sup>2</sup> water Plant height more than 125 cm: 0.4 mL prod./m <sup>2</sup> in 50 to 100 mL/m <sup>2</sup> Conc. 0.4% Spritzbrühe	
006	DE	Tomato, Sweet pepper	Gn	Whitefly	Foliar spraying	BBCH 12-89	a) 6 b) 6	7	a) 4 b) 24	a) 240 b) 1440	250-1000		Plant height up to 50 cm: 0.2 mL prod./m <sup>2</sup> in 25 to 50 mL/m <sup>2</sup> water Plant height 50 up to 125 cm: 0.3 mL prod. /ha in 37.5 to 75 mL/m <sup>2</sup> water Plant height more than 125 cm: 0.4 mL prod./m <sup>2</sup> in 50 to 100 mL/m <sup>2</sup> Conc. 0.4% Spritzbrühe	
007	DE	Cucurbits,	Gn	Whitefly	Foliar spraying	BBCH 12-89	a) 6 b) 6	7	a) 4 b) 24	a) 240 b) 1440	500-1000		Plant height up to 50 cm: 0.2 mL prod./m <sup>2</sup> in 25 to 50 mL/m <sup>2</sup> water Plant height 50 up to 125 cm: 0.3 mL prod. /m <sup>2</sup> in 37.5 to 75 mL/m <sup>2</sup> water Plant height more than 125 cm: 0.4 mL prod./m <sup>2</sup> in 50 to 100 mL/m <sup>2</sup> Conc. 0.4% Spritzbrühe	
008	DE	Zucchini	Gn	Spider-mite	Foliar spraying	BBCH 12-89	a) 5 b) 5	7	a) 2 b) 10	a) 120 b) 600	500-1000			
009	DE	Zucchini	Gn	Whitefly	Foliar spraying	BBCH 12-89	a) 6 b) 6	7	a) 2 b) 12	a) 120 b) 720	500-1000			

010	DE	Tomato, Sweet pepper	G	Spider mite	Foliar spraying	BBCH 12-89	a) 5 b) 5	7	a) 4 b) 20	a) 240 b) 1200	250-1000		Plant height up to 50 cm: 2 L prod./ha in 25 0to 500 L/ha water Plant height 50 up to 125 cm: 3 L prod. /ha in 375 to 750 L/ha water Plant height more than 125 cm: 4 L prod./ha in 500 to 1000 L/ha Conc. 0.4% Spritzbrühe	
011	DE	Tomato, Sweet pepper	G	Whitefly	Foliar spraying	BBCH 12-89	a) 6 b) 6	7	a) 4 b) 24	a) 240 b) 1440	250-1000		Plant height up to 50 cm: 2 L prod./ha in 25 0to 500 L/ha water Plant height 50 up to 125 cm: 3 L prod. /ha in 375 to 750 L/ha water Plant height more than 125 cm: 4 L prod./ha in 500 to 1000 L/ha Conc. 0.4% Spritzbrühe	
012	DE	Cucurbits,	G	Whitefly	Foliar spraying	BBCH 12-89	a) 6 b) 6	7	a) 4 b) 24	a) 240 b) 1440	250-1000		Plant height up to 50 cm: 2 L prod./ha in 25 0to 500 L/ha water Plant height 50 up to 125 cm: 3 L prod. /ha in 375 to 750 L/ha water Plant height more than 125 cm: 4 L prod./ha in 500 to 1000 L/ha	

													Conc. 0.4% Spritzbrühe	
013	DE	Zucchini	G	Spider mite	Foliar spraying	BBCH 12-89	a) 5 b) 5	7	a) 2 b) 10	a) 120 b) 600	500-1000			
014	DE	Zucchini	G	Whitefly	Foliar spraying	BBCH 12-89	a) 6 b) 6	7	a) 2 b) 12	a) 120 b) 720	500-1000			
015	DE	Ornamental plant	G	Sucking insects	Foliar spraying	BBCH 12-89	a) 5 b) 5	7	a) 2 b) 10	a) 120 b) 600	100-500		Conc. 0.4% Spritzbrühe	
016	DE	Ornamental plant	Gn	Sucking insects	Foliar spraying	BBCH 12-89	a) 5 b) 5	7	a) 2 b) 10	a) 120 b) 600	100-500		Conc. 0.4% Spritzbrühe	
<b>Minor uses according to Article 51 (Germany)</b>														
--														

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

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

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
N	No safe use

## 8.1.2 Overall conclusion

### 8.1.2.1 Predicted environmental concentrations in soil ( $PEC_{soil}$ )

$PEC_{soil}$  was calculated for the active substance Orange oil considering a soil depth of 1.0 cm. Due to the fast degradation of the active substance Orange oil in soil the accumulation potential of Orange oil was not considered.

The  $PEC_{soil}$  values for the active substance were used in the eco-toxicological risk assessment for the intended uses of the plant protection product OROCIDÉ PLUS in Germany.

### 8.1.2.2 Predicted environmental concentrations in groundwater ( $PEC_{gw}$ )

#### Direct leaching into groundwater

Please refer to the core assessment.

Further to DAR evaluation and EFSA conclusion in 2013, a confirmatory data expertise was developed by ORO AGRÍ International Ltd on environmental fate for the botanical active substance, orange oil.

Physico-chemistry properties of the active substance, orange oil, were also confirmed with further tests to determine the partition coefficient ( $\text{LogKow} = 5.3$ ), to show the low water solubility of the substance (13.8 mg/L at 25°C) and to validate the volatility potential of this natural complex substance (9.88 Pascals at a flow rate of 20 mL/min. at 20°C)

As a conclusion, the natural complex substance, orange oil is not likely to reach nor accumulate in groundwater, therefore it is reasonable to conclude that determination of end points on groundwater contamination are not appropriate for orange oil.

*Calculation of predicted environmental concentrations in groundwater ( $PEC_{gw}$ ) is not appropriate for the complex active substance, orange oil.*

*Ground water contamination is not likely to happen, considering the high volatilisation, the low water solubility and the readily biodegradability of the botanical active substance, orange oil.*

#### Consequences for authorization:

None.

#### Groundwater contamination by bank filtration due to surface water exposure via runoff and drainage

Is not relevant.

#### Consequences for authorization:

None

### 8.1.2.3 Predicted environmental concentrations in surface water ( $PEC_{sw}$ )

Risk mitigation measures for the intended uses of plant protection products in Germany due to exposure of surface water consider two routes of entry (i) spray drift and volatilization with subsequent deposition and (ii) runoff, drainage separately.

Surface water exposure including effects of risk mitigation via spray drift and volatilization with subsequent deposition was estimated with the model EVA 3 using drift data by Rautmann and Ganzelmeier.

Surface water exposure including effects of risk mitigation via surface runoff and drainage was estimated using the model EXPOSIT 3.

The results of the specific national exposure assessment for the active substance were used in the ecotoxicological risk assessment.

#### **8.1.2.4 Fate and behaviour in air**

The vapour pressure at 20 °C of the active substance Orange oil is  $> 10^{-4}$  Pa. Hence the active substance Orange oil is regarded as volatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Orange oil due to volatilization with subsequent deposition was not considered.

### **8.2 Metabolites considered in the assessment**

Please refer to the core assessment.

### **8.3 Rate of degradation in soil (KCP 9.1.1)**

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

#### **8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)**

Please refer to the core assessment.

#### **8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)**

Not relevant for assessment.

### **8.4 Field studies (KCP 9.1.1.2)**

#### **8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)**

Please refer to the core assessment.

#### **8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)**

Please refer to the core assessment.

### **8.5 Mobility in soil (KCP 9.1.2)**

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.



### **8.5.1 Adsorption and desorption in soil (KCP 9.1.2.1)**

Please refer to the core assessment.

### **8.5.2 Column leaching (KCP 9.1.2.1)**

Please refer to the core assessment.

### **8.5.3 Lysimeter studies (KCP 9.1.2.2)**

Please refer to the core assessment.

### **8.5.4 Field leaching studies (KCP 9.1.2.3)**

Please refer to the core assessment.

## **8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)**

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

### **8.6.1 Water/sediment study (KCP 9.2.2)**

Please refer to the core assessment

**Table 8.6-1: Accumulation of active substance Orange oil and relevant metabolites in the sediment**

<b>Active substance</b>	Orange oil
<b>Accumulation potential in sediment</b>	no (see core assessment, No data on DT <sub>50</sub> in soil, water and sediment)

## 8.7 Predicted Environmental Concentrations in soil (PEC<sub>soil</sub>) (KCP 9.1.3)

Results of PEC<sub>soil</sub> calculation for OROCID E PLUS and its intended for uses in vineyard (worst case) according to EU assessment considering 5 cm soil depth are given in the core assessment, part B, section 8, chapter 8.7. In the German exposure assessment, the considered soil layer depth is based on experimental data.<sup>1</sup> Generally, a soil layer depth of 2.5 cm is applied in the calculation for active substances with a K<sub>Foc</sub> <500, whereas a soil layer depth of 1 cm is applied for active substances with a K<sub>Foc</sub> >500. A soil bulk density of 1.5 g/cm<sup>3</sup> is assumed as in the core assessment.

### 8.7.1 Justification of new endpoints

Not applicable as no new endpoints used.

### 8.7.2 Active substance and relevant metabolite(s)

The PEC<sub>soil</sub> calculations were performed with ESCAPE 2.0 based on the input parameters as presented in the tables below.

**Table 8.7-1: Input parameters for active substance and relevant metabolite(s) for PEC<sub>soil</sub> calculation**

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT <sub>50</sub> (days) EU endpoint	DT <sub>50</sub> (days) updated endpoint
Orange oil	Not required	-	No data on DT <sub>50</sub> in soil	No data on DT <sub>50</sub> in soil (see LOEP Confirmatory Data (March 2017))

Due to dissipate quickly via volatilisation of Orange oil in soil the accumulation potential of Orange oil does not need to be considered.

#### 8.7.2.1 PEC<sub>soil</sub>

Please refer to the core assessment.

Calculation of actual concentration is not applicable for the complex active substance, orange oil.

The calculated PEC<sub>soil</sub> used for German risk assessment for Orange oil as well as for the formulation OROCID E PLUS are summarised in Table 8.7-2. The presented calculation is only a theoretical assumption as no soil DT50 is available due to the rapid volatilization. As a worst case a soil DT50 of 1 day was assumed.

**Table 8.7-2: Results of PEC<sub>soil</sub> calculation for the intended use in vineyard used for German risk assessment**

<b>Plant protection product:</b>	OROCIDE PLUS
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<sup>1</sup> Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittelwirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999

<b>Use:</b>		00-001 vine				
<b>Number of applications/interval:</b>		9 x /7d				
<b>Application rate (g/ha):</b>		OROCIDE PLUS: 6.4 l/ha Orange oil: 384 g/ha				
<b>Crop interception (%):</b>		60% and 75%				
<b>Active substance/ Formulation</b> Assumption: DT50 1d	<b>Soil relevant ap- plication rate (g/ha)</b>	<b>Soil depth<sub>act</sub> (cm)</b>	<b>PEC<sub>act</sub> (mg/kg)</b>	<b>Tillage depth (cm)</b>	<b>PEC<sub>bkgd</sub> (mg/kg)</b>	<b>PEC<sub>accu</sub> = PEC<sub>act</sub> + PEC<sub>bkgd</sub> (mg/kg)</b>
OROCIDE PLUS Assumption: DT50 1d	Cum. single	2.5 2.5	6.9 6.8	-	-	-
Orange oil	5x 153.6 + 4x115.2	1.0	1.04	-	-	
Orange oil	1 x 153.6		1.02			

## 8.8 Predicted Environmental Concentrations in groundwater (PEC<sub>gw</sub>) (KCP 9.2.4)

Please refer to the core assessment.

Results of the PEC<sub>gw</sub> calculation of Orange oil for the intended uses of OROCID PLUS in vineyard according to EU assessment using FOCUS PELMO/PEARL are given in the core assessment, part B, section 8, chapter 8.8.

### 8.8.1 Justification of new endpoints

Please refer to the core assessment.  
Not applicable as no new endpoints used.

#### Consequences for authorisation:

None

### 8.8.2 Groundwater contamination by bank filtration due to surface water exposure via runoff and drainage

Not relevant

#### Consequences for authorization:

None

## 8.9 Predicted Environmental Concentrations in surface water (PEC<sub>sw</sub>) (KCP 9.2.5)

Risk mitigation measures for the intended uses of plant protection products in Germany due to exposure of surface water consider the two routes of entry (i) spray drift and volatilization with subsequent deposition and (ii) runoff, drainage separately.

Surface water exposure including effects of risk mitigation via spray drift and volatilization with subsequent deposition is estimated with the model EVA. Surface water exposure including effects of risk mitigation via surface runoff and drainage is estimated using the model EXPOSIT.

### 8.9.1 Justification of new endpoints

Please refer to the core assessment.

Not applicable as no new endpoints used.

### 8.9.2 PEC<sub>sw</sub> after exposure by spray drift and volatilization with subsequent deposition

The calculation of PEC<sub>sw</sub> after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 3. For a single application, the exposure assessment via spray drift is based on the application rate in conjunction with the 90<sup>th</sup> percentile of the drift values. For multiple applications, lower percentiles of the drift values for each application are applied, resulting in an overall 90<sup>th</sup> percentile of drift probabilities. Only one volatilization event following the last use of pesticide is generally considered.

**Table 8.9-1: Input parameters for OROCIDÉ PLUS related to the application used for PEC<sub>sw</sub> calculations with EVA 3**

<b>Use No.:</b>	00-001 vineyard	
<b>Number of applications/ interval:</b>	9 x/ 7d	
<b>Application rate (g a.s./ha)</b>	Orange oil: 384	

#### 8.9.2.1 Orange oil and its metabolites

Please refer to the core assessment.

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance Orange oil is > 10<sup>-4</sup> Pa. Hence the active substance Orange oil is regarded as volatile (volatilization from soil and plant surfaces). Therefore exposure of surface water by the active substance Orange oil due to volatilization with subsequent deposition does need to be considered.

The input parameters used for modelling of surface water exposure via spray drift and volatilization with subsequent deposition with EVA 3 are summarised below.

**Table 8.9-2: Input parameters for Orange oil used for the PEC<sub>sw</sub> calculations with EVA 3**

Parameter	Orange oil	Reference
Vapour pressure at 20 °C (Pa)	120	LoEP (2017)
Solubility in water at 25 °C (mg/L)	13.8	LoEP (2017)
DissT <sub>50</sub> water (d)	No quantitative data.	LoEP (2017)
DegT <sub>50</sub> water/sediment study, total system (d)	No quantitative data.	LoEP (2017)

For the active substance Orange oil the thus calculated peak PEC<sub>sw</sub> for multiple applications is lower than for one application. Thus, PEC<sub>sw</sub> for one single application are used as highest PEC<sub>sw</sub> here/ However, the dissipation of the active substance Orange oil from the water phase between the application events as described by a DissT<sub>50</sub> value of ... (SFO, worst case for dissipation from the water phase) is significantly shorter than the application interval of ... days, application events are regarded as independently from each other and exposure assessment is consequently based on a single application.

For PEC<sub>sw/sed</sub> due to spray drift and volatilization with subsequent deposition for Orange oil please refer to national Addendum Germany, Part B, Section 9, chapter 9.5.

### 8.9.3 PEC<sub>sw</sub> after exposure by surface runoff and drainage

Not relevant

### 8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Please refer to chapter 8.9.2.

### 8.11 Classification and labelling

#### 8.11.1 GHS Classification and labelling

Please refer to the core assessment Part B Section 9.

#### 8.11.2 National labelling and conditions of use

**Table 8.11-1 Mandatory conditions of use according to § 36 (1) PflSchG**

use group/use No	Conditions of use
00-01 -00-016	none



**DRAFT REGISTRATION REPORT**

**Part B**

**Section 9**

**Ecotoxicology**

Detailed summary of the risk assessment

Product code: ZV3 008883-00/00

Product name(s): OROCIDE PLUS

Chemical active substance:

Orange oil, 60 g/L

Central Zone

Zonal Rapporteur Member State: NL

National Addendum

Germany

(authorisation)

Applicant: Oro Agri International Ltd.

Submission date: 03/06/2016

MS Finalisation date: 04/2020

## Version history

When	What
April 2020	National assessment UBA



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## **9 Ecotoxicology (KCP 10)**

The risk assessment of the plant protection product OROCIDÉ PLUS in its intended uses in grape vine (field use) and tomatos (greenhouse) is documented in detail in the core assessment of the plant protection product OROCIDÉ PLUS dated from October 2019 performed by NL.

This national addendum has been produced to support a national decision on the authorisation of the product OROCIDÉ PLUS in Germany for the uses listed below. It reflects the impact of specific German environmental or agricultural circumstances on the exposure and risk assessment for OROCIDÉ PLUS including risk mitigation measures.

## 9.1 Critical GAP and overall conclusions

**Table 9.1-1: Table of critical GAPs**

1	2	3	4	5	6				7			13	14	15-21						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	Application rate		Water L/ha min/max			PHI (days)	Remarks: e.g. g safener/ synergist per ha	Conclusion				
kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Birds	Mammals	Aquatic organisms					Bees	Non-target arthro-		Soil organisms	Non-target plants							
<b>Intended uses in Germany</b>																				
001	DE	Grape	F	Powdery mildew	Foliar spraying	BBCH 53-81	a) 9 b) 9	7	a) 6.4 b) 57.6	a) 384 b) 3456	600-1600		Conc. 0.4% spray solution	A	A	R	J	A	A	A
002	DE	Grape	F	Botrytis	Foliar spraying	BBCH 81-89	a) 3 b) 9	3	a) 6 b) 18	a) 340 b) 3060	1000		Conc. 0.6% spray solution	A	A	R	J	A	A	A
003	DE	Grape	Fn	Powdery mildew	Foliar spraying	BBCH 53-81	a) 9 b) 9	7	a) 6.4 b) 57.6	a) 384 b) 3456	600-1600		Conc. 0.4% spray solution	A	A	R	J	A	A	A
004	DE	Grape	Fn	Botrytis	Foliar spraying	BBCH 81-89	a) 3 b) 9	3	a) 6 b) 18	a) 340 b) 3060	1000		Conc. 0.6% spray solution	A	A	R	J	A	A	A
005	DE	Tomato, Sweet pepper	Gn	Spider mite	Foliar spraying	BBCH 12-89	a) 5 b) 5	7	a) 4 b) 20	a) 240 b) 1200	250-1000		Plant height up to 50 cm: 0.2 mL prod./m <sup>2</sup> in 25 to 50 mL/m <sup>2</sup> water	A	A	A	J	A	A	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
													Plant height 50 up to 125 cm: 0.3 mL prod./m <sup>2</sup> in 37.5 to 75 mL/m <sup>2</sup> water Plant height more than 125 cm: 0.4 mL prod./m <sup>2</sup> in 50 to 100 mL/m <sup>2</sup> Conc. 0.4% spray solution							
006	DE	Tomato, Sweet pepper	Gn	Whitefly	Foliar spraying	BBCH 12-89	a) 6 b) 6	7	a) 4 b) 24	a) 240 b) 1440	250-1000		Plant height up to 50 cm: 0.2 mL prod./m <sup>2</sup> in 25 to 50 mL/m <sup>2</sup> water Plant height 50 up to 125 cm: 0.3 mL prod./ha in 37.5 to 75 mL/m <sup>2</sup> water Plant height more than 125 cm: 0.4 mL prod./m <sup>2</sup>	A	A	A	J	A	A	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
													in 50 to 100 mL/m <sup>2</sup> Conc. 0.4% spray solution							
007	DE	Cucurbits,	Gn	Whitefly	Foliar spraying	BBCH 12-89	a) 6 b) 6	7	a) 4 b) 24	a) 240 b) 1440	500-1000		Plant height up to 50 cm: 0.2 mL prod./m <sup>2</sup> in 25 to 50 mL/m <sup>2</sup> water Plant height 50 up to 125 cm: 0.3 mL prod. /m <sup>2</sup> in 37.5 to 75 mL/m <sup>2</sup> water Plant height more than 125 cm: 0.4 mL prod./m <sup>2</sup> in 50 to 100 mL/m <sup>2</sup> Conc. 0.4% spray solution	A	A	A	J	A	A	A
008	DE	Zucchini	Gn	Spider mite	Foliar spraying	BBCH 12-89	a) 5 b) 5	7	a) 2 b) 10	a) 120 b) 600	500-1000			-	-	-	-	-	-	-
009	DE	Zucchini	Gn	Whitefly	Foliar spraying	BBCH 12-89	a) 6 b) 6	7	a) 2 b) 12	a) 120 b) 720	500-1000			-	-	-	-	-	-	-
010	DE	Tomato, Sweet pepper	G	Spider mite	Foliar spraying	BBCH 12-89	a) 5 b) 5	7	a) 4 b) 20	a) 240 b) 1200	250-1000		Plant height up to 50 cm:	A	A	A	J	A	A	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
													2 L prod./ha in 25 0to 500 L/ha water Plant height 50 up to 125 cm: 3 L prod./ha in 375 to 750 L/ha water Plant height more than 125 cm: 4 L prod./ha in 500 to 1000 L/ha Conc. 0.4% spray solution							
011	DE	Tomato, Sweet pepper	G	Whitefly	Foliar spraying	BBCH 12-89	a) 6 b) 6	7	a) 4 b) 24	a) 240 b) 1440	250-1000		Plant height up to 50 cm: 2 L prod./ha in 25 0to 500 L/ha water Plant height 50 up to 125 cm: 3 L prod./ha in 375 to 750 L/ha water Plant height more than 125 cm: 4 L prod./ha	A	A	A	J	A	A	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
													in 500 to 1000 L/ha Conc. 0.4% spray solution							
012	DE	Cucurbits,	G	Whitefly	Foliar spraying	BBCH 12-89	a) 6 b) 6	7	a) 4 b) 24	a) 240 b) 1440	250-1000		Plant height up to 50 cm: 2 L prod./ha in 25 0to 500 L/ha water Plant height 50 up to 125 cm: 3 L prod./ha in 375 to 750 L/ha water Plant height more than 125 cm: 4 L prod./ha in 500 to 1000 L/ha Conc. 0.4% spray solution	A	A	A	J	A	A	A
013	DE	Zucchini	G	Spider mite	Foliar spraying	BBCH 12-89	a) 5 b) 5	7	a) 2 b) 10	a) 120 b) 600	500-1000			-	-	-	-	-	-	-
014	DE	Zucchini	G	Whitefly	Foliar spraying	BBCH 12-89	a) 6 b) 6	7	a) 2 b) 12	a) 120 b) 720	500-1000			-	-	-	-	-	-	-
015	DE	Ornamental plant	G	Sucking insects	Foliar spraying	BBCH 12-89	a) 5 b) 5	7	a) 2 b) 10	a) 120 b) 600	100-500		Conc. 0.4% spray solution	A	A	A	J	A	A	A
A016	DE	Ornamental plant	Gn	Sucking insects	Foliar spraying	BBCH 12-89	a) 5 b) 5	7	a) 2 b) 10	a) 120 b) 600	100-500		Conc. 0.4% spray	A	A	A	J	A	A	A



1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
													solution							

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

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

### Explanation for column 15 – 21 “Conclusion”

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
J	Refer to JKI assessment
N	No safe use

#### Remarks table:

- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li>(1) Numeration necessary to allow references</li> <li>(2) Use official codes/nomenclatures of EU</li> <li>(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)</li> <li>(4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application</li> <li>(5) Scientific names <u>and</u> EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named</li> <li>(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench<br/>Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated</li> </ul> | <ul style="list-style-type: none"> <li>(7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</li> <li>(8) The maximum number of application possible under practical conditions of use must be provided</li> <li>(9) Minimum interval (in days) between applications of the same product.</li> <li>(10) For specific uses other specifications might be possible, e.g.: g/m<sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products</li> <li>(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).</li> <li>(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.</li> <li>(13) PHI - minimum pre-harvest interval</li> <li>(14) Remarks may include: Extent of use/economic importance/restrictions</li> </ul> |
|--|---|

## 9.1.1 Overall conclusions

### 9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

TER values for birds and mammals were calculated by zRMS in the core assessment, taking into account the relevant toxicity data for rapeseed oil and calculated exposure levels for dietary exposure, for exposure via drinking water and for exposure via secondary poisoning, according to the intended uses of the product OROCIDÉ PLUS in grape vine (use 001 - 004). The calculated TER values presented in this national addendum do achieve the acceptability criterion  $TER \geq 10$  for acute effects on birds and mammals, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.1. For the intended uses 005 – 007, 010 – 012 and 015 - 016 no quantitative risk assessment is required as no relevant exposure of birds or mammals is expected for greenhouse uses. The results of the assessment indicate an acceptable risk for birds and mammals due to the intended use of OROCIDÉ PLUS in grape (field use), tomatoes, sweet pepper, cucurbits and ornamental plants (greenhouse uses) according to the label.

#### Consequences for authorisation

None

### 9.1.1.2 Effects on aquatic organisms (KCP 10.2)

TER values for aquatic organisms were calculated, taking into account the relevant toxicity data for orange oil (d-limonene as lead compound) and calculated exposure levels, according to the intended uses of the product OROCIDÉ PLUS in grapes, tomatoes, sweet pepper, cucurbits and ornamental plants. The calculated TER values do achieve the acceptability criterion  $TER \geq 100$  for acute effects on aquatic organisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.2, provided that risk mitigation measures are applied. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of OROCIDÉ PLUS in grapes, tomatoes, sweet pepper, cucurbits and ornamental plants according to the label.

Due to the properties of orange oil, i.e. considering the high volatilisation, the low water solubility and the readily biodegradability of the active substance orange oil, no relevant exposure via run-off and drainage is expected. As no relevant exposure is expected, the risk via run-off and drainage is considered as acceptable.

#### Consequences for authorisation

For the authorisation of the plant protection product OROCIDÉ PLUS, labelling and conditions of use are mandatory as follows:

#### Labelling requirements according to § 36 (3) PflSchG

NW262	d-limonene as lead compound of orange oil: <i>P. subcapitata</i> NOEC < 1 mg/L (assumed as ErC50 is 0.44 mg/L, hence NOEC must be < 1 mg/L)
NW264	d-limonene as lead compound of orange oil: <i>P. promelas</i> LC <sub>50</sub> = 0.702 mg/L <i>D. magna</i> EC <sub>50</sub> = 0.421 mg/L

### **Mandatory conditions of use according to § 36 (1) PflSchG for the protection of aquatic organisms**

NW 468	
Use group A (professional use)	
NW605-1/606	Drift-reduction technique– corresponding buffer zone: 90 % – 5 m; 75 % – 10 m; 50 % – 10 m; conv. – 10 m;
Use group A1 (professional use)	
NW605-1/606	Drift-reduction technique– corresponding buffer zone: 90 % – * m; 75 % – 5 m; 50 % – 10 m; conv. – 10 m;
Use group A2 and A3 (non-professional uses)	
NW608-1	Buffer zone only: 10 m

#### **9.1.1.3 Effects on bees (KCP 10.3.1)**

No data were provided for bumble bees or solitary bees and also no active substance data are available for honey bees. In the core assessment the risk for honey bees was assessed based on formulation data and formulation application rate. As highlighted by the zRMS, the active substance orange oil has a physical mode of action, i.e. the insects are killed because an oil film is formed on their body, which prevents them from breathing. Thus, the main risk would be posed by overspray which should not happen in off-field areas. However, drift during application cannot be completely excluded. Additionally the active substance is highly volatile, hence a contamination of off-crop areas via volatilization and deposition is possible but the exposure can be expected to be rather limited even if applied several times. For honey bees a semi-field study is available which included also one direct overspray of test organisms and resulted in no effect on mortality. The overspray application was performed with a spray solution concentration of 0.8% v/v i.e. 3.2 L of product/ha or 3260.8 g of product/ha in 400 litres of water, i.e. the worst case of 0.6% according to the intended uses for Germany is covered. Although this study was performed with honey bees, it gives at least some indication for pollinators in general. Based on the available information for orange oil, overall it is concluded that the risk for wild pollinators can be considered as acceptable.

The risk assessment for honey bees is conducted by JKI.

#### **Consequences for authorisation**

None.

#### **9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)**

TER values for non-target arthropods in off-field habitats were calculated, taking into account the relevant toxicity data for orange oil and calculated exposure concentrations in off-field habitats, according to the intended uses of the product OROCIDÉ PLUS in vine (field use) and tomatoes, sweet pepper, cucurbits and ornamental plants (greenhouse uses). The calculated TER values do achieve the acceptability criterion  $TER \geq 5$  (extended laboratory database) for effects on non-target arthropods, according to agreed EU Guidance in Document SANCO/10329/2002 rev 2 (as modified by specific German guidance) that overrides the prescriptions of Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.4. The results of the assessment indicate an acceptable risk for non-target arthropods in off-field habitats due to the intended use of OROCIDÉ PLUS according to the label.

#### **Consequences for authorisation**

None

#### **9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)**

The TER value for earthworms was calculated, taking into account the relevant toxicity data for OROCIDÉ PLUS and calculated exposure concentrations in soil, according to the intended uses of the product in grapes. The calculated TER value does not achieve the acceptability criterion  $TER \geq 10$  for acute effects on earthworms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5. The results of the assessment indicate an acceptable risk for earthworms due to the intended use of OROCIDÉ PLUS in grape according to the label. All other intended uses are covered by this assessment.

As also stated in the core assessment, no relevant exposure of soil organisms has to be expected due to the fate characteristics of the active substance orange oil. Thus, the acute and chronic risk for soil organisms is generally considered to be acceptable.

No data were provided for other soil organisms than earthworms. As stated above for earthworms, no relevant exposure of soil organisms has to be expected due to the fate characteristics of the active substance orange oil. Thus, the acute and chronic risk for soil organisms is generally considered to be acceptable.

Also no data were provided for soil microorganisms. However, based on qualitative information, D-limonene, the lead compound of orange oil, could be used by soil microorganisms. Hence the active substance rather has a positive than an adverse effect on microorganisms.

#### **Consequences for authorisation**

None

#### **9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)**

No quantitative risk assessment was performed by the zRMS. Based on the absence of effects in the efficacy studies, it can be concluded that the risk for non-target terrestrial plants is acceptable.

#### **Consequences for authorisation**

None

#### **9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)**

No data, not required.

#### **9.1.2 Grouping of intended uses for risk assessment**

Intended uses are grouped according to soil-relevant application rate, drift rate, estimated surface water exposure using FOCUS<sub>sw</sub>, maximum daily dose for birds and mammals, and in-field exposure for bees and other non-target arthropods. The soil-relevant application rate is based on the effective cumulative application rate including interception. For drift rate, the intended uses are grouped according to the application rate and the relevant drift scenario. For birds and mammals the application rate, minimum interval, number of applications and the relevant crop scenario are considered. Grouping for bees and other non-target arthropods is based on maximum single or cumulated field application rates.

**Table 9.1-2: Critical use pattern of OROCIDÉ PLUS**

Group	Intended uses	Application rate (g/ha)	Drift scenario
A	001 (professional)	9 x 384 g a.s./ha, interval 7 d	Vine
A1	002 (professional)	9 x 340 g a.s./ha, interval 3 d	Vine
A2	003 (non-professional)	9 x 384 g a.s./ha, interval 7 d	Vine
A3	004 (non-professional)	9 x 340 g a.s./ha, interval 3 d	Vine
B	010 (professional) 011, 012 (professional) 015 (professional)	5 x 240 g a.s./ha, interval 7 d 6 x 240 g a.s./ha, interval 7 d 5 x 120 g a.s./ha, interval 7 d	Greenhouse (no drift)
B1	005 (non-professional) 006, 007 (non-professional) 016 (non-professional)	5 x 240 g a.s./ha, interval 7 d 6 x 240 g a.s./ha, interval 7 d 5 x 120 g a.s./ha, interval 7 d	Greenhouse (no drift)

### 9.1.3 Consideration of metabolites

Please refer to the Core Assessment. No relevant metabolites.

## 9.2 Effects on birds (KCP 10.1.1)

Please refer to the Core Assessment.

### 9.2.1 Risk assessment for spray applications

Please refer to the Core Assessment.

The risk assessment for birds for the intended uses of the product OROCIDÉ PLUS indicates an acceptable acute and long-term risk for birds based on the screening and first tier risk assessment step for the active substance oilseed rape.

### 9.2.2 Indirect effects via trophic interactions

Not required as the only field use is a use in vine (recently not considered for the assessment of indirect effects) and all other uses are greenhouse uses.

### 9.2.3 Overall conclusions

TER values for birds were calculated by zRMS in the core assessment, taking into account the relevant toxicity data for rapeseed oil and calculated exposure levels for dietary exposure, for exposure via drinking water and for exposure via secondary poisoning, according to the intended uses of the product OROCIDÉ PLUS in grape vine (use 001 - 004). The calculated TER values presented in this national addendum do achieve the acceptability criterion  $TER \geq 10$  for acute effects on birds, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.1. For the intended uses 005 – 007, 010 – 012 and 015 - 016 no quantitative risk assessment is required as no relevant exposure of birds is expected for greenhouse uses. The results of the assessment indicate an acceptable risk for birds due to the intended use of OROCIDÉ PLUS in grape (field use), tomatos, sweet papper, curcubits and ornamental plants (greenhouse uses) according to the label.

## **Consequences for authorisation**

None

### **9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)**

Please refer to the Core Assessment.

#### **9.3.1 Risk assessment for spray applications**

The risk assessment for terrestrial vertebrates other than birds for the intended uses of the product OROCIDÉ PLUS indicates an acceptable acute and long-term risk for terrestrial vertebrates other than birds based on the screening and first tier risk assessment step for the active substance orange oil.

#### **9.3.2 Overall conclusions**

TER values for mammals were calculated by zRMS in the core assessment, taking into account the relevant toxicity data for rapeseed oil and calculated exposure levels for dietary exposure, for exposure via drinking water and for exposure via secondary poisoning, according to the intended uses of the product OROCIDÉ PLUS in grape vine (use 001 - 004). The calculated TER values presented in this national addendum do achieve the acceptability criterion  $TER \geq 10$  for acute effects on mammals, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.1. For the intended uses 005 – 007, 010 – 012 and 015 - 016 no quantitative risk assessment is required as no relevant exposure of mammals is expected for greenhouse uses. The results of the assessment indicate an acceptable risk for mammals due to the intended use of OROCIDÉ PLUS in grape (field use), tomatoes, sweet pepper, cucurbits and ornamental plants (greenhouse uses) according to the label.

## **Consequences for authorisation**

None

### **9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)**

Please refer to the Core Assessment. No data.

### **9.5 Effects on aquatic organisms (KCP 10.2)**

#### **9.5.1 Toxicity data**

Please refer to the Core Assessment.

##### **9.5.1.1 Justification for new endpoints**

Not required.

## 9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

For authorisation in Germany, three entry routes are considered separately in the exposure assessment for surface water: (i) spray drift together with volatilisation and subsequent deposition (where relevant), (ii) run-off, and (iii) drainage. Consequently, specific risk mitigation measures are defined and can be imposed separately for each entry route. Thus, the risk assessment from the core assessment is replaced by a specific national assessment for Germany, which is described below.

### Exposure of surface water bodies via spray drift and volatilisation with subsequent deposition

#### Exposure assessment

Concentrations of orange oil in surface water due to spray drift and volatilisation with subsequent deposition are calculated using the model EVA3, which refers to spray drift data by Rautmann and Ganzelmeier and an empirical model for volatilisation/deposition, based on vapour-pressure classes. Orange oil has a vapour pressure of 120 Pa and is therefore classified as volatile. Hence, deposition following volatilisation must be considered in the exposure assessment. The model input parameters for orange oil are provided in the Environmental Fate section.

#### Selection of relevant toxicity endpoint

Please refer to the core assessment.

**Table 9.5-1: Assessment of the risk for aquatic organisms due to the use of OROCIDÉ PLUS in grape (group A) – exposure to entries of orange oil via spray drift and volatilisation/deposition, considering risk mitigation measures**

<b>Active substance/product:</b>		Orange oil							
<b>Intended use:</b>		Group A							
<b>Application parameters:</b>		9 x 384 g a.s./ha, interval 7 d							
<b>DisT<sub>50</sub> water phase (SFO):</b>		< 1 d (estimated DT <sub>50</sub> from water = 3.4 hours)							
<b>Scenario, drift percentile:</b>		Vine, 90 <sup>th</sup> percentile (due to short DT <sub>50</sub> only single application considered)							
<b>PEC type:</b>		actual							
Buffer zone (m)	Spray drift		Deposition following volatilisation		PEC <sub>sw</sub> ; conventional and drift-reducing technique				
	(%)	(µg/L)	(%)	(µg/L)	0 % red.	50 % red.	75 % red.	90 % red.	
					(µg/L)				
3	8.02	10.266	2.789	3.549	13.815	8.682	6.116	4.576	
5	3.62	4.634	2.501	3.183	7.817	5.500	4.341	3.646	
10	1.23	1.574	1.905	2.424	3.999	3.212	2.818	2.582	
<b>Endpoint (µg/L):</b>		EC <sub>50</sub> <i>D. magna</i> 421 µg a.s./L							
<b>TER acceptability criterion:</b>		100							
<b>Buffer zone (m)</b>					<b>TER</b>				
3					<b>30.5</b>	<b>48.5</b>	<b>68.8</b>	<b>92.0</b>	
5					<b>53.9</b>	<b>76.5</b>	<b>97.0</b>	<b>115.5</b>	

10	105.3	131.1	149.4	163.1
<b>Risk mitigation measures:</b>	Professional use 001: NW 605-1/606: 90% 5 m, 75% 10 m, 50% 10 m; conv. 10 m Non-professional use 003: NW 608-1: 10 m			

PEC: predicted environmental concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger

**Table 9.5-2: Assessment of the risk for aquatic organisms due to the use of OROCIDÉ PLUS in grape (group A1) – exposure to entries of orange oil via spray drift and volatilisation/deposition, considering risk mitigation measures**

<b>Active substance/product:</b>		Orange oil						
<b>Intended use:</b>		Group A1						
<b>Application parameters:</b>		9 x 340 g a.s./ha, interval 7 d						
<b>DisT<sub>50</sub> water phase (SFO):</b>		< 1 d (estimated DT <sub>50</sub> from water = 3.4 hours)						
<b>Scenario, drift percentile:</b>		Vine, 90 <sup>th</sup> percentile (due to short DT <sub>50</sub> only single application considered)						
<b>PEC type:</b>		actual						
<b>Buffer zone (m)</b>	<b>Spray drift</b>		<b>Deposition following volatilisation</b>		<b>PEC<sub>sw</sub>; conventional and drift-reducing technique</b>			
	<b>(%)</b>	<b>(µg/L)</b>	<b>(%)</b>	<b>(µg/L)</b>	<b>0 % red.</b>	<b>50 % red.</b>	<b>75 % red.</b>	<b>90 % red.</b>
					<b>(µg/L)</b>			
3	8.02	9.089	2.789	3.143	12.232	7.687	5.415	4.052
5	3.62	4.103	2.501	2.818	6.921	4.870	3.844	3.229
10	1.23	1.394	1.905	2.147	3.541	2.844	2.495	2.286
<b>Endpoint (µg/L):</b>		EC <sub>50</sub> <i>D. magna</i> 421 µg a.s./L						
<b>TER acceptability criterion:</b>		100						
<b>Buffer zone (m)</b>					<b>TER</b>			
3					<b>34.4</b>	<b>54.8</b>	<b>77.7</b>	103.9
5					<b>60.8</b>	<b>86.5</b>	109.5	130.4
10					118.9	148.1	168.7	184.2
<b>Risk mitigation measures:</b>		Professional use 002: NW 605-1/606: 90% * m, 75% 5 m, 50% 10 m; conv. 10 m Non-professional use 004: NW 608-1: 10 m						

PEC: predicted environmental concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger



**Table 9.5-3: Assessment of the risk for aquatic organisms due to the use of OROCIDÉ PLUS in grape (group B) – exposure to entries of orange oil via spray drift and volatilisation/deposition, considering risk mitigation measures**

<b>Active substance/product:</b>		Orange oil				
<b>Intended use:</b>		Group B (greenhouse, covering B1)				
<b>Application parameters:</b>		6 x 240 g a.s./ha, interval 7 d				
<b>DisT<sub>50</sub> water phase (SFO):</b>		< 1 d (estimated DT <sub>50</sub> from water = 3.4 hours)				
<b>Scenario, drift percentile:</b>		No drift, only volatilization relevant for greenhouse				
<b>PEC type:</b>		actual				
Buffer zone (m)	Spray drift		Deposition following volatilisation		PEC <sub>sw</sub> volatilisation	
	(%)	(µg/L)	(%)	(µg/L)	Drift not relevant	
1	-	-	0.564	0.451	0.451	-
<b>Endpoint (µg/L):</b>		EC <sub>50</sub> <i>D. magna</i> 421 µg a.s./L				
<b>TER acceptability criterion:</b>		100				
Buffer zone (m)					TER	
1					932.6	-
<b>Risk mitigation measures:</b>			Not required			

PEC: predicted environmental concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger

### Exposure of surface water bodies via run-off or drainage

Due to the properties of orange oil, i.e considering the high volatilisation, the low water solubility and the readily biodegradability of the active substance orange oil, no relevant exposure via run-off and drainage is expected.

As no relevant exposure is expected, no quantitative risk assessment was performed.

### 9.5.3 Overall conclusions

TER values for aquatic organisms were calculated, taking into account the relevant toxicity data for orange oil (d-limonene as lead compound) and calculated exposure levels, according to the intended uses of the product OROCIDÉ PLUS in grapes, tomatos, sweet pepper, curcubits and ornamental plants . The calculated TER values do achieve the acceptability criterion  $TER \geq 100$  for acute effects on aquatic organisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.2, provided that risk mitigation measures are applied. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of OROCIDÉ PLUS in grapes, tomatos, sweet pepper, curcubits and ornamental plants according to the label.

Due to the properties of orange oil, i.e considering the high volatilisation, the low water solubility and the readily biodegradability of the active substance orange oil, no relevant exposure via run-off and drainage is expected. As no relevant exposure is expected, the risk via run-off and drainage is considered as acceptable.

### Consequences for authorisation

For the authorisation of the plant protection product OROCIDÉ PLUS, labelling and conditions of use are mandatory as follows:

**Table 9.5-4 Labelling requirements according to § 36 (3) PflSchG**

NW262	d-limonene as lead compound of orange oil: <i>P. subcapitata</i> NOEC < 1 mg/L (assumed as ErC50 is 0.44 mg/L, hence NOEC must be < 1 mg/L)
NW264	d-limonene as lead compound of orange oil: <i>P. promelas</i> LC <sub>50</sub> = 0.702 mg/L <i>D. magna</i> EC <sub>50</sub> = 0.421 mg/L

**Table 9.5-5 Mandatory conditions of use according to § 36 (1) PflSchG for the protection of aquatic organisms**

NW 468	
Use group A (professional use)	
NW605-1/606	Drift-reduction technique– corresponding buffer zone: 90 % – 5 m; 75 % – 10 m; 50 % – 10 m; conv. – 10 m;
Use group A1 (professional use)	
NW605-1/606	Drift-reduction technique– corresponding buffer zone: 90 % – * m; 75 % – 5 m; 50 % – 10 m; conv. – 10 m;
Use group A2 and A3 (non-professional uses)	
NW608-1	Buffer zone only: 10 m

## 9.6 Effects on bees (KCP 10.3.1)

### 9.6.1 Toxicity data

Please refer to the Core Assessment.

#### 9.6.1.1 Justification for new endpoints

#### 9.6.2 Risk assessment

Based on the concentration in the spray solution, the intended uses 002 and 004 with 340 g a.s./ha in 1000 L water (i.e. 0.6% v/v) present the worst case uses for the risk assessment of bees and wild pollinators. All other intended uses are covered by use 002 and 004.

##### 9.6.2.1 Hazard quotients for bees

Refer to JKI assessment.

##### 9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Refer to JKI assessment.

### **9.6.3 Effects on bumble bees**

No data were provided for bumble bees and also no active substance data are available for honey bees. In the core assessment the risk for honey bees was assessed based on formulation data and formulation application rate. As highlighted by the zRMS, the active substance orange oil has a physical mode of action, i.e. the insects are killed because an oil film is formed on their body, which prevents them from breathing. Thus, the main risk would be posed by overspray which should not happen in off-field areas. However, drift during application cannot be completely excluded. Additionally the active substance is highly volatile, hence a contamination of off-crop areas via volatilization and deposition is possible but the exposure can be expected to be rather limited even if applied several times. For honey bees a semi-field study is available which included also one direct overspray of test organisms and resulted in no effect on mortality. The overspray application was performed with a spray solution concentration of 0.8% v/v i.e. 3.2 L of product/ha or 3260.8 g of product/ha in 400 litres of water, i.e. the worst case of 0.6% according to the intended uses for Germany is covered. Although this study was performed with honey bees, it gives at least some indication for pollinators. Based on the available information for organo oil, overall it is concluded that the risk for wild pollinators can be considered as acceptable.

### **9.6.4 Effects on solitary bees**

See explanations for bumble bees above.

### **9.6.5 Overall conclusions**

The risk assessment for honey bees is conducted by JKI.

Based on the available information for organo oil, overall it is concluded that the risk for wild pollinators can be considered as acceptable. For details refer to chapter 9.6.3 Effect on bumble bees.

### **Consequences for authorisation**

None.

Decisions on honey-bee specific risk mitigation measures are made by the JKI.

## **9.7 Effects on arthropods other than bees (KCP 10.3.2)**

### **9.7.1 Toxicity data**

Please refer to the Core Assessment.

### **9.7.2 Risk assessment**

A risk assessment according to the recommendations of the “Guidance Document on Terrestrial Ecotoxicology” (SANCO/10329/2002) and in consideration of the recommendations of the guidance document ESCORT 2 is documented in the core assessment. For authorisation in Germany, a modified off-field risk assessment is relevant that takes into account the possible additional exposure route via volatilisation with subsequent deposition and addresses the availability of specific national risk mitigation measures.<sup>1</sup>

<sup>1</sup> Schulte et al., UWSF (5) 261-266 (1999), Bewertungskriterien des Umweltbundesamtes: Auswirkungen von

### *Exposure assessment*

Exposure levels of OROCIDÉ PLUS in terrestrial off-field habitats due to spray drift and volatilisation with subsequent deposition are calculated using the model EVA3 (see chapter on effects on aquatic organisms for further explanations).

To extrapolate from exposure in a 2-dimensional toxicity test system to exposure in 3-dimensional field vegetation structures, a 2D/3D correction factor analogous to the ESCORT 2 ‘vegetation distribution factor’ (vdf) is applied in the risk assessment for national authorisations in Germany. This factor is derived from experimental data on spray drift deposits on meadows and hedgerows<sup>2</sup> and recalculated quotients of theoretically expected vs. measured residues. While several quotients were found to be lower than the ESCORT 2 vdf of 10, a 2D/3D correction factor of 5 was considered to appropriately define the required realistic worst case for a risk assessment.

Within the core assessment the zRMS included the following statement:

“The studies submitted were considered fully reliable and fully relevant for assessing effects on non-target arthropods that are not directly hit by the spray liquid but come into contact with the dried residue, e.g. because they were hiding under crop leaves or entering the field from the off-field area. It is noted that orange oil works as a contact insecticide and is expected to have a stronger effect on *Typhlodromus pyri*, *Chrysoperla carnea* and *Aphidius rhopalosiphi* than seen in this study in case the organisms were directly hit. In a sense this study represents an aged residue exposure scenario instead of an extended lab study.”

We generally agree that regarding the physical mode of action of orange oil, the extended laboratory studies may do not address the most critical exposure way of exposure, i.e. a direct overspray. But the same accounts for the standard laboratory glass plate tests. Regarding off-crop areas, a full direct overspray is not expected but an exposure via drift and volatilization. Non-target arthropods can get on contact with residues after deposition or can directly be hit. The contact with residues is covered by the glass plate tests and can be refined by extended laboratory data as usual. Hence, the extended laboratory endpoint for the most sensitive species *Typhlodromus pyri* was considered for the national assessment. As stated by the zRMS, the direct contact with the product or active substance orange oil via drift and/or volatilization is especially important for the physical mode of action. However, recently there is no standard test design or approach to specifically address such a physical mode of action. But this is a general problem, which cannot be addressed in the frame of a product authorization.

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Pflanzenschutzmitteln auf terrestrische Arthropoden.

<sup>2</sup> Koch H, Weißer P and Landfried M (2003): Effect of drift potential on drift exposure in terrestrial habitats. Nachrichtenblatt Deut. Pflanzenschutzdz., 55, 181-188.

**Table 9.7-1: Assessment of the risk for non-target arthropods in off-field habitats due to the use of OROCIDÉ PLUS in grapes (group A), considering risk mitigation measures**

<b>Active substance/product:</b>		Orange oil						
<b>Intended use:</b>		Group A (covering group A1, A2, A3)						
<b>Application parameters:</b>		9 x 384 g a.s./ha, interval 7 d						
<b>MAF:</b>		3.6						
<b>Scenario, drift percentile:</b>		Vine, 67 <sup>th</sup> percentile						
<b>2D/3D correction factor:</b>		5						
Buffer zone (m)	Spray drift		Deposition following volatilisation		PER <sub>off-field</sub> ; conventional and drift-reducing technique			
	(%)	(g/ha)	(%)	(g/ha)	0 % red.	50 % red.	75 % red.	90 % red.
3	6.26	17.251	2.789	2.130	19.380	10.755	6.442	3.855
<b>Endpoint (g/ha):</b>		LR <sub>50</sub> > 443.41 g a.s./ha ( <i>Typhlodromus pyri</i> , extended lab 2-D)						
<b>TER acceptability criterion:</b>		5 (extended lab)						
Buffer zone (m)					TER			
3					22.9	41.2	68.8	115.0
<b>Risk mitigation measures:</b>		Not required						

PER: predicted environmental rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger

**Table 9.7-2: Assessment of the risk for non-target arthropods in off-field habitats due to the use of OROCIDÉ PLUS in (group B, B1), considering risk mitigation measures**

<b>Active substance/product:</b>		Orange oil			
<b>Intended use:</b>		Group B (covering B1)			
<b>Application parameters:</b>		6 x 240 g a.s./ha, interval 7 d (worst case of group B)			
<b>MAF:</b>		3.2			
<b>Scenario, drift percentile:</b>		Greenhouse (no drift)			
<b>2D/3D correction factor:</b>		5			
Buffer zone (m)	Spray drift		Deposition following volatilisation		PER <sub>off-field</sub>
	(%)	(g/ha)	(%)	(g/ha)	(g/ha)
1	-	-	0.564	0.271	0.271
<b>Endpoint (g/ha):</b>		LR <sub>50</sub> > 443.41 g a.s./ha ( <i>Typhlodromus pyri</i> , extended lab 2-D)			
<b>TER acceptability criterion:</b>		5			
Buffer zone (m)					TER
1					> 1637
<b>Risk mitigation measures:</b>			Not required		

PER: predicted environmental rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger

### 9.7.3 Overall conclusions

TER values for non-target arthropods in off-field habitats were calculated, taking into account the relevant toxicity data for orange oil and calculated exposure concentrations in off-field habitats, according to the intended uses of the product OROCIDÉ PLUS in vine (field use) and tomatoes, sweet pepper, cucurbits and ornamental plants (greenhouse uses). The calculated TER values do achieve the acceptability criterion  $TER \geq 5$  (extended laboratory database) for effects on non-target arthropods, according to agreed EU Guidance in Document SANCO/10329/2002 rev 2 (as modified by specific German guidance) that overrides the prescriptions of Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.4. The results of the assessment indicate an acceptable risk for non-target arthropods in off-field habitats due to the intended use of OROCIDÉ PLUS according to the label.

#### Consequences for authorisation

None

### 9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

#### 9.8.1 Toxicity data

Please refer to the Core Assessment.

## 9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

### *Exposure assessment*

In the German exposure assessment, the considered soil layer depth is based on experimental data.<sup>3</sup> Generally, a soil layer depth of 2.5 cm is applied in the calculation for active substances with a  $K_{f,oc} < 500$ , whereas a soil layer depth of 1 cm is applied for active substances with a  $K_{f,oc} > 500$ . A soil bulk density of 1.5 g/cm<sup>3</sup> is assumed as in the core assessment.

### 9.8.2.1 First-tier risk assessment

The relevant  $PEC_{soil}$  for risk assessments covering the proposed use pattern are taken from National Addendum Germany, Section 8 (Environmental Fate), Chapter 8.7.2,. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for orange oil.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A (grape field use) also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (all greenhouse uses with less applications and lower rates).

#### Argumentation presented in the core assessment:

OROCIDÉ PLUS is recommended for an application on grapes when the canopy is already well developed at BBCH 53-81, therefore foliar interception will be significant. Then considering the high volatility of the botanical active substance, orange oil, OROCIDÉ PLUS is not likely to be persistent once diluted and sprayed on the crop. Information in Section 8 (CA) give qualitative information on the non-persistence of orange oil in soil due to its ready biodegradability.

According to the fate section (B.8, CA), the predicted environmental concentrations in soil ( $PEC_{soil}$ ) were not calculated, because core parameters could not be quantified due to the extensive and comprehensive bio-degradation by soil biota.

As consequence first-tier assessment of the acute and chronic risk for earthworms due to the use of OROCIDÉ PLUS in grapes (fungicide / vineyard) becomes not relevant.

We agree, that overall it can be assumed that there is no relevant exposure of soil organisms. However, a  $PEC_{soil}$  was estimated based on a worst case assumption of a  $DT_{50}$  of 1 d in soil (refer to Section 8 NA, chapter 8.7). Based on this estimated  $PEC_{soil}$  and the available endpoint for earthworms acute, a risk assessment was performed (see table 9.8-1 below).

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<sup>3</sup> Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittelwirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999

**Table 9.8-1: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of OROCIDÉ PLUS in grapes (group A)**

<b>Intended use</b>	Group A (worst case)		
<b>Acute effects on earthworms</b>			
<b>Product/active substance</b>	<b>LC<sub>50</sub> (mg/kg dw)</b>	<b>PEC<sub>soil</sub> (mg/kg dw)</b>	<b>TER<sub>a</sub> (criterion TER ≥ 10)</b>
OROCIDÉ PLUS	999.7	6.9	145
<b>Chronic effects on earthworms</b>			
No data (refer to core assessment)			
<b>Chronic effects on other soil macro- and mesofauna</b>			
No data (refer to core assessment)			

TER values shown in bold fall below the relevant trigger.

### 9.8.2.2 Higher-tier risk assessment

Not relevant.

### 9.8.3 Overall conclusions

#### Earthworms

The TER value for earthworms was calculated, taking into account the relevant toxicity data for OROCIDÉ PLUS and calculated exposure concentrations in soil, according to the intended uses of the product in grapes. The calculated TER value does achieve the acceptability criterion  $TER \geq 10$  for acute effects on earthworms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5. The results of the assessment indicate an acceptable risk for earthworms due to the intended use of OROCIDÉ PLUS in grape according to the label. All other intended uses are covered by this assessment.

As also stated in the core assessment, no relevant exposure of soil organisms has to expected due to the fate characteristics of the active substance orange oil. Thus, the acute and chronic risk for soil organisms is generally considered to be acceptable.

#### Other organisms of the soil macro- and mesofauna

No data were provided for other soil organisms than earthworms. As stated above for earthworms, no relevant exposure of soil organisms has to expected due to the fate characteristics of the active substance orange oil. Thus, the acute and chronic risk for soil organisms is generally considered to be acceptable.

#### Consequences for authorisation

None



## **9.9 Effects on soil microbial activity (KCP 10.5)**

### **9.9.1 Toxicity data**

Please refer to the Core Assessment.

### **9.9.2 Risk assessment**

Please refer to the Core Assessment.

### **9.9.3 Overall conclusions**

No data were provided for soil microorganisms. However, based on qualitative information, D-limonene, the lead compound of orange oil, could be used by soil microorganisms. Hence the active substance rather has a positive than an adverse effect on microorganisms.

### **Consequences for authorisation**

None

## **9.10 Effects on non-target terrestrial plants (KCP 10.6)**

### **9.10.1 Toxicity data**

Please refer to the Core Assessment.

### **9.10.2 Risk assessment**

According to the core assessment, efficacy studies on plants demonstrated no adverse effect. The risk to non-target terrestrial plants is considered acceptable.

### **9.10.3 Overall conclusions**

No quantitative risk assessment was performed by the zRMS. Based on the absence of effects in the efficacy studies, it can be concluded that the risk for non-target terrestrial plants is acceptable.

### **Consequences for authorisation**

None

## **9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)**

No data

## 9.12 Monitoring data (KCP 10.8)

No data.

## 9.13 Classification and Labelling

### 9.13.1 National labelling and conditions of use

**Table 9.13-1 Labelling requirements according to § 36 (3) PflSchG**

NW262	d-limonene as lead compound of orange oil: <i>P. subcapitata</i> NOEC < 1 mg/L (assumed as ErC50 is 0.44 mg/L, hence NOEC must be < 1 mg/L)
NW264	d-limonene as lead compound of orange oil: <i>P. promelas</i> LC <sub>50</sub> = 0.702 mg/L <i>D. magna</i> EC <sub>50</sub> = 0.421 mg/L

**Table 9.13-2 Mandatory conditions of use according to § 36 (1) PflSchG**

NW 468	
Use group A (professional use)	
NW605-1/606	Drift-reduction technique– corresponding buffer zone: 90 % – 5 m; 75 % – 10 m; 50 % – 10 m; conv. – 10 m;
Use group A1 (professional use)	
NW605-1/606	Drift-reduction technique– corresponding buffer zone: 90 % – * m; 75 % – 5 m; 50 % – 10 m; conv. – 10 m;
Use group A2 and A3 (non-professional uses)	
NW608-1	Buffer zone only: 10 m

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

Please refer to the Core Assessment.

## **Appendix 2 Detailed evaluation of the new studies**

Please refer to the Core Assessment.