

**DRAFT**  
**REGISTRATION REPORT**  
**Part A**

**Risk Management**

**Product code:** A18881A (Ampexio)  
**Active Substance:** Mandipropamid 250 g/kg  
Zoxamide 240 g/kg

**COUNTRY: Germany**  
**Central Zone**  
**Zonal Rapporteur Member State: Austria**

**NATIONAL ASSESSMENT**

**Applicant:** Syngenta Agro GmbH  
**Date:** 20 June 2017



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## **PART A – Risk Management**

This document describes the acceptable use conditions required for the registration of A18881A (Ampexio) containing Mandipropamid and Zoxamide in Germany. This evaluation is required subsequent to the inclusion of Mandipropamid and Zoxamide on Annex 1.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C and where appropriate the addendum for Germany. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to A18881A where that data has not been considered in the EU review. Otherwise assessments for the safe use of A18881A have been made using endpoints agreed in the EU review of Mandipropamid and Zoxamide.

This document describes the specific conditions of use and labelling required for Germany for the re-registration/registration of A18881A.

Appendix 1 (for technical reasons see Appendix 4) of this document provides a copy of the final product authorisation Germany.

Appendix 2: Appendix 2: The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 65 of Regulation (EC) No 1107/2009 and Commission Regulation (EU) No 547/2011.

Appendix 3: Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

Appendix 4: of this document provides a copy of the final product authorisation Germany.

## **1 Details of the application**

### **1.1 Application background**

This application was submitted by Syngenta Agro GmbH on 15.10.2014.

The application was for approval of A18881A water dispersible granule (WG) containing 250 g/kg Mandipropamid and 240 g/kg Zoxamide for use as a fungicide in wine grapes.

### **1.2 Annex I inclusion**

#### **Mandipropamid**

Mandipropamid was included on Annex I of Directive 91/414/EEC on 1. August 2013 under Inclusion Regulation (EU) No 188/2013.

The Annex I Commission Implementing Regulation (EU) No 188/2013 for Mandipropamid provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on Mandipropamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 February 2013 shall be taken into account.

Conditions of use shall include risk mitigation measures, where appropriate.

The applicant shall submit confirmatory information as regards the potential for preferential enantiomeric transformation or racemisation of mandipropamid at the soil surface as a result of soil photolysis. The applicant shall submit to the Commission, the Member States and the Authority that information by 31 July 2015.

These specific concerns are addressed within the current submission or will be addressed within the timelines set.

### **Zoxamide**

Zoxamide was included on Annex I of Directive 91/414/EEC on 1 April 2004 - now under Inclusion Directive 540 (EU) No 540/2011.

The Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 provides no specific provisions for zoxamide which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

## **1.3 Regulatory approach**

To obtain approval the product A18881A must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

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

## **1.4 Data protection claims**

Where protection for data is being claimed for information supporting registration of A18881A (Ampexio), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7, core assessment.

## **1.5 Letters of Access**

As regards Zoxamide Annex II data the applicant submitted a LoA.

## 2 Details of the authorisation

### 2.1 Product identity

Product Name	A18881A (Ampexio)
Authorization Number (for re-registration)	008314-00/00
Function	Fungicide
Applicant	Syngenta Crop Protection AG
Composition	250 g/kg mandipropamid 240 g/kg zoxamide
Formulation type	Water dispersable granule [Code: WG]
Packaging	0.25 kg to 10 kg HDPE jerry can

### 2.2 Classification and labelling

#### 2.2.1 Classification and labelling under Directive 99/45/EC

Not proposed.

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

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

<i>Hazard classes and categories:</i>	
Skin sens. 1	
<i>Hazard pictograms:</i>	
GHS07	exclamation mark
GHS09	environment
<i>Signal word:</i>	
Warning	
<i>Hazard statements:</i>	
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
<i>Precautionary statements:</i>	
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.
P302+P352	IF ON SKIN: Wash with plenty of water/...
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash before reuse.
P501	Dispose of contents/container to ...
<i>Special rule for labelling of PPP:</i>	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
<i>Further labelling statements under Regulation (EC) No 1272/2008:</i>	
EUH 208 - Contains zoxamide.. May produce an allergic reaction.	



### 2.2.3 Standard phrases under Regulation (EC) No 547/2011

None

### 2.3 Other phrases notified under Regulation (EC) No 547/2011

#### 2.3.1 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.
SB110	The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed.
SB166	Do not eat, drink or smoke when using this product.
SF245-01	Treated areas/crops may not be entered until the spray coating has dried.
SS110	Wear standard protective gloves (plant protection) when handling the undiluted product.
SS120	Wear standard protective gloves (plant protection) when handling/applying the product ready for application.
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.
SS530	Wear face protection when handling the undiluted product.
Integrated pest management (IPM)/sustainable use	
NN2001	The product is classified as slightly harmful for populations of relevant beneficial insects.
WMFH5	Mode of action (FRAC-group): H5 (for mandipropamid)
WMFB3	Mode of action (FRAC-group): B3 (for zoxamide)
Ecosystem protection	
NW 262	The product is toxic for algae.
NW 264	The product is toxic for fish and aquatic invertebrates.
NW 265	The product is toxic for higher aquatic plants.
NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and 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.

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)
NN1002	The product is classified as non-harmful for populations of relevant beneficial predatory mites and spiders.

### 2.3.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions (mandatory labelling):  
See 2.4 (Product uses)

Integrated pest management (IPM)/sustainable use	
NN134	The product is classified as harmless for populations of the species Typhlodromus pyri (predatory mite).
WG734	Use of the product for spontaneous fermentation can lead to a delay in fermentation.
WW750	The maximum number of applications is limited due to active substance-specific reasons. Sufficient control is therefore not expected in all cases. If necessary, use products containing other active substances afterwards or alternately.
WW762	Due to resistance management, do not apply the product (including other products with the same active substance, with an active substance from the same active substance group or with a cross-resistant active substance) more often than is stated in the instructions for use. If in doubt, consult extension services.
WW7091	Repeated applications of the product, or products of the same active substance group, or those with cross-resistance, may result or have resulted in a reduction of efficacy. To prevent resistance, the product should, if possible be applied alternately with products from other active substance groups with no cross-resistance. If in doubt, consult extension services.
Ecosystem protection	
NW 605-1	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%      * 75 %      10 m 50%      10 m
NW 606	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 15 m
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## 2.4 Product uses

**Reg.-No.** 008314-00/00

**GAP rev.1, date:** 2016-06-30

PPP (product name/code): AMPEXIO  
Active substance 1: Zoxamide  
Active substance 2: Mandipropamid  
Applicant: Syngenta Agro GmbH  
Zone(s): central/interzonal <sup>(d)</sup>  
Verified by MS: Yes

Formulation type: WG <sup>(a, b)</sup>  
Conc. of as 1: 240.00 g/kg <sup>(c)</sup>  
Conc. of as 2: 250.00 g/kg <sup>(c)</sup>  
Professional use: Yes  
Non professional use: No  
Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha  a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		

001	DE	grape vine (VITVI) utilisation as table and wine grape	F	downy mildew of grapevine (Plasmopara viticola) (PLASVI)	spraying or fine spraying (low volume spraying)	In case of danger of infection and/or after warning service appeal 13 to 85	a) 3 b) 3	8 to 14 days	a) basic application rate: 0.16 kg/ha  a) BBCH 61: 0.32 kg/ha  a) BBCH 71: 0.48 kg/ha  a) BBCH 75: 0.48 kg/ha  b) 1.44 kg/ha	a) a.s. 1: 0.0384 kg/ha a.s. 2: 0.04 kg/ha  a) a.s. 1: 0.0768 kg/ha a.s. 2: 0.08 kg/ha  a) a.s. 1: 0.1152 kg/ha a.s. 2: 0.12 kg/ha  a) a.s. 1: 0.1152 kg/ha a.s. 2: 0.12 kg/ha  b) a.s. 1: 0.3456 kg/ha a.s. 2: 0.36 kg/ha	basic application rate: -/400  BBCH 61: -/800  BBCH 71: -/1200  BBCH 75: -/1600	21	WG734, WW750, WW762, WW7091  NW605-1/606 (90%/*, 75%/10m, 50%/10m / 15m)
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002	DE	grape vine (VITVI) utilisation as table and wine grape	F	downy mildew of grapevine (Plasmopara viticola) (PLASVI)	spraying or fine spraying (low volume spraying) only with rotor-driven aircrafts (no fixed-wing aircrafts)	In case of danger of infection and/or after warning service appeal 13 to 85	a) 3 b) 3	8 to 14 days	a) basic application rate: 0.16 kg/ha  a) BBCH 61: 0.32 kg/ha  a) BBCH 71: 0.48 kg/ha  a) BBCH 75: 0.48 kg/ha  b) 1.44 kg/ha	a) a.s. 1: 0.0384 kg/ha a.s. 2: 0.04 kg/ha  a) a.s. 1: 0.0768 kg/ha a.s. 2: 0.08 kg/ha  a) a.s. 1: 0.1152 kg/ha a.s. 2: 0.12 kg/ha  a) a.s. 1: 0.1152 kg/ha a.s. 2: 0.12 kg/ha  b) a.s. 1: 0.3456 kg/ha a.s. 2: 0.36 kg/ha	basic application rate: 150 – 300  BBCH 61: 150 – 300  BBCH 71: 150 – 300  BBCH 75: 150 – 300	-	No authorisation possible due to bystander protection  WG734, WW750, WW762, WW7091  NW605-1/606 (90%/*, 75%/10m, 50%/10m / 15m)
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**Remarks table heading:**

- (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (b) Catalogue of pesticide formulation types and international coding system Crop Life 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
- 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).

- 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 38263-3152-4), including where relevant, information on season at time of application
- 12 If water volume range depends on application equipment (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
- 13 PHI - minimum pre-harvest interval

### **3 Risk management**

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

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

###### **Overall Summary:**

The product A18881A (Ampexio) is a water dispersible granule formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of brown coloured solid, with a loamy, chalky odour. It is not explosive and has no oxidising properties. It has a self-ignition temperature of 191°C. In aqueous solution, it has a pH value of 4.5. The stability data indicate a shelf life of at least two years at ambient temperature. The technical characteristics of A18881A (Ampexio) are acceptable for a water dispersible granule formulation.

###### **Implications for labelling:**

None.

###### **Compliance with FAO specifications:**

The product A18881A (Ampexio) complies with FAO specifications.

###### **Compliance with FAO guidelines:**

The product A18881A (Ampexio) complies with FAO guidelines, as far as could be assessed.

###### **Compatibility of mixtures:**

No tank mixes recommended.

###### **Nature and characteristics of the packaging:**

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

###### **Nature and characteristics of the protective clothing and equipment:**

Information regarding the required protective clothing and equipment for the safe handling of A18881A (Ampexio) has been provided and is considered to be acceptable.

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

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

In the product A18881A (Ampexio) the active substances Mandipropamid and Zoxamide are analysed using a HPLC system with UV detection. The methods are validated and suitable according to SANCO/3030/99 rev. 4.

There is no CIPAC method available for the simultaneous determination of Mandipropamid and Zoxamide in WG formulations.



The relevant impurity SYN545038 of mandipropamid is determined by HPLC and MS scan. The method is validated and suitable for the determination of SYN545038 in A18881A (Ampexio) according to SANCO/3030/99 rev. 4 with an LOQ of 0.00025 % w/w (2.5 mg/kg).

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

The analytical methods are active substance data and were provided in the EU review of Mandipropamid and Zoxamide. They were considered adequate for food of plant origin, soil, water and air. Analytical methods for body fluids and tissues are not required since the active substances are not classified as toxic or highly toxic.

### **3.1.3 Mammalian Toxicology**

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected for use 001 (field application on grape vine). Use 002 (application with rotor-driven aircrafts on grape vine) is not authorised due to bystander protection. As a basic principal in Germany an authorisation for plant protection products with sensitising properties is not possible for aircraft application.

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 AT.

#### **3.1.3.1 Acute Toxicity**

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

#### **3.1.3.2 Operator Exposure**

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

#### **3.1.3.3 Bystander Exposure**

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

#### **3.1.3.4 Worker Exposure**

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

### **Implications for labelling resulting from operator, worker, bystander assessments:**

See 2.2

### 3.1.4 Residues and Consumer Exposure

The intended use in grape vine 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 AT.

#### 3.1.4.1 Residues

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

#### 3.1.4.2 Consumer exposure

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

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

A full exposure assessment for the plant protection product Ampexio is documented in detail in the core assessment of the plant protection product Ampexio performed by Austria.

The following chapters summarise specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of Ampexio in Germany according to its intended use in vines (Uses No. 00-001, -002).

**Table: Relevant uses for risk assessment**

Crop	Substance	Application rate [g a.s. / ha]	Application method	No. of applications	Minimum application interval [days]	Application timing	Crop interception [%] <sup>A)</sup>	Total seasonal soil load <sup>B)</sup> [g a.s./ha]
Vines	Mandipropamid	125	Foliar spray	3	8	> BBCH 13	50	187.5
	Zoxamide	120						180

<sup>A)</sup> FOCUS groundwater report (2009, 2011)

<sup>B)</sup> Conservative soil loading based on crop canopy at initial application and not taking account of increased canopy during later applications.

#### *Active substances*

Mandipropamid According to field studies the DT<sub>50</sub> in soil is 72.3 days. In soil the metabolite CGA 380778 was detected and considered for the further assessment. The metabolite degrades faster with a DT<sub>50</sub> of 38.8 days.

Adsorption is high for mandipropamid with a K<sub>foc</sub> of 847. The metabolite CGA380778 is also well adsorbed with a K<sub>foc</sub> of 448.

In water/sediment studies mandipropamid showed a DissT<sub>50</sub> of 3.6 days and was also to be found in sediment. In the whole system a DT<sub>50</sub> of 12.2 days could be derived. In the water phase the metabolite SYN504851 and SYN500003 were found. In sediment also the two former mentioned metabolites plus

SYN521196 and SYN539678 occurred.

Mandipropamide

### ***Zoxamide***

The resulting highest DT<sub>50</sub> values from laboratory studies (10 d) was used in the core assessment for PEC<sub>soil</sub> calculations. A mean of 2.8 d, derived under standard laboratory conditions, was considered for the estimation of PEC<sub>gw</sub> values.

As described in the core assessment major degradates of Zoxamide are RH-127450 (de-chlorinated substance, 2.94-15.1% AR), RH-24549 (benzoic acid derivative, 5.5-33.8% AR) and RH-163353 (acid, 7.9-15% AR). Maximum levels of these metabolites were found on days 3-14 in an aerobic soil degradation study. Mineralisation to CO<sub>2</sub> was significant (max. = 58% AR). Besides, significant levels of non-extractable residues were formed (25.6-39% AR by days 28-120), associated primarily with humic and fulvic acids and humins.

Adsorption in soil for the active substance is strong with Koc values between 815- 1431. For the metabolites it can be stated that RH-127450 is also well adsorbed with similar values whereby the metabolite RH-24549 shows only Koc values between 90.5 and 307.4 and the metabolite RH-163353 is weaker adsorbed to soil surfaces with a Koc around 50.

In the water/sediment study the DT<sub>50</sub> for the whole systems was 3.6 – 8 days. The active substance could be found in the sediment up to 23 % after 7-14 days. In water and sediment the metabolites RH-127450 and RH-163353 could also be found in relevant amounts.

### ***Metabolites***

#### ***Mandipropamide***

No new study on the fate and behaviour of Mandipropamide or Ampexio has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

The risk assessment for groundwater by direct leaching for the application of the plant protection product and its intended use includes the soil metabolites of Mandipropamide.

#### ***Zoxamide***

No new study on the fate and behaviour of Zoxamide or Ampexio has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

The risk assessment for groundwater by direct leaching for the application of the plant protection product and its intended use includes the soil metabolites of Zoxamide.

### **3.1.5.1 Predicted Environmental Concentration in Soil (PEC<sub>soil</sub>) (Part B, Section 5, Points 9.4 and 9.5)**

For the intended use of the plant protection product Ampexio in vines according to uses No 001, -002 PEC<sub>soil</sub> was calculated for the active substance Mandipropamide considering a soil depth of 2.5 cm. Due to the fast degradation of the active substance Mandipropamide in soil the accumulation potential of Mandipropamide was not considered.

PEC<sub>soil</sub> was calculated for the active substance Zoxamide considering a soil depth of 1 cm. Due to the fast degradation of the active substance Zoxamide in soil the accumulation potential of Zoxamide was not considered.

**Table: Relevant PEC<sub>soil</sub> values for risk assessment**

active substance/ formulation	soil relevant application rate (g/ha) (crop interception 50 %)	soil depth <sub>act</sub> (cm)	PEC <sub>act</sub> (mg/kg)
Ampexio	250	1	4.6399
Mandipropamid	62,5	1	1.1600
Zoxamide	60	1	0.7617

The results for PEC<sub>soil</sub> for the active substances and the metabolites were used for the eco-toxicological risk assessment.

### **3.1.5.2 Predicted Environmental Concentration in Ground Water (PEC<sub>GW</sub>) (Part B, Section 5, Point 9.6)**

#### *1. Direct leaching into groundwater*

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3, a groundwater contamination of the active substance Mandipropamide in concentrations  $\geq 0.1 \mu\text{g/L}$  is not expected for the intended use in vines.

For the metabolites CGA380778 of Mandipropamid concentrations of  $\geq 0.1 \mu\text{g/L}$  in groundwater can be excluded.

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3, a groundwater contamination of the active substance Zoxamide in concentrations  $\geq 0.1 \mu\text{g/L}$  is not expected for the intended use in vines.

For the metabolites RH-127450, RH-24549, and RH-163353 of Zoxamide groundwater concentrations  $\geq 0.1 \mu\text{g/L}$  can be excluded according to the results of the groundwater simulation.

#### *2. Ground water contamination by bank filtration due to surface water exposure via run-off and drainage*

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations  $\geq 0.1 \mu\text{g/L}$  by the active substance Mandipropamide due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations  $\geq 0.1 \mu\text{g/L}$  by the active substance Zoxamide due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

### 3.1.5.3 Predicted Environmental Concentration in Surface Water (PEC<sub>sw</sub>) (Part B, Section 5, Points 9.7 and 9.8)

For the intended use of the plant protection product Ampexio in vines according to uses No 001,002 PEC<sub>sw</sub> was calculated for the active substances Mandipropamide and Zoxamide considering the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately.

The calculation of concentrations in surface water was based on spray drift data by Rautmann and Ganzelmeier.

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 Mandipropamid is  $< 10^{-5}$  Pa. Hence the active substance Mandipropamid is regarded as non-volatile. Therefore exposure of surface water by the active substance Mandipropamid due to volatilization with subsequent deposition does not need to be considered.

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 Zoxamide is  $< 10^{-5}$  Pa. Hence the active substance Zoxamide is regarded as non-volatile. Therefore exposure of surface water by the active substance Zoxamide due to volatilization with subsequent deposition does not need to be considered.

The concentrations of the active substances Mandipropamide and Zoxamide in adjacent ditch due to surface run-off and drainage were calculated using the model EXPOSIT.

**Table: Summary of PEC<sub>sw</sub> values for the intended use in vines used for German risk assessment**

active substance/ formulation	PEC <sub>sw</sub> Spray-Drift (incl. volatilisation) [µg/L] – with 3 m default buffer - scenario agriculture	PEC <sub>sw</sub> run-off [µg/L] – without buffer	PEC <sub>sw</sub> drainage [µg/L] – scenario autumn/winter/early spring	PEC <sub>sw</sub> drainage [µg/L] – scenario spring/summer
<b>Mandipropamide</b>	5.394	1.14	0.03	0.08
<b>Zoxamide</b>	3.263	0.15	0.001	0.01
<b>Preparation Ampexio</b>	11.65	-	-	-

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

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

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 Mandipropamid is  $< 10^{-5}$  Pa. Hence the active substance Mandipropamid is regarded as non-volatile. Therefore exposure of surface water by the active substance Mandipropamid due to volatilization with subsequent deposition does not need to be considered.

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 Zoxamide is  $< 10^{-5}$  Pa. Hence the active substance Zoxamide is regarded as non-volatile. Therefore exposure of surface water by the active substance Zoxamide due to volatilization with subsequent deposition does not need to be considered.

#### **Implications for labelling resulting from environmental fate assessment:**

Based on the data on the active substances Mandipropamide and Zoxamide the plant protection product Ampexio is considered to be not readily degradable in the sense of the CLP regulation.

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

A full risk assessment according to Uniform Principles for the plant protection product Ampexio in its intended uses vines, tomatoes and grapes is documented in detail in the core assessment of the plant protection product Ampexio performed by Austria. The intended use of Ampexio in Germany is generally covered by the uses evaluated in the course of the core assessment by Austria.

The authorization in Austria is linked with the following risk mitigation measure regarding effects on non-target organisms (see Part A, National Assessment – Austria,).

The following chapters summarise specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of Ampexio in Germany according to its intended use in vines (uses No. 00-001 and 002).

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

The risk assessment for effects on birds and other terrestrial vertebrates was carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

**Table: EU endpoints - toxicity of Mandipropamide to birds**

Study	EU agreed endpoints (EFSA Scientific Report, EFSA Journal 2012;10(11):2935)
Acute toxicity	LD <sub>50</sub> > 2000 mg /kg bw
Reproductive toxicity (long-term)	NOEL = 83.6 mg a.s./kg bw per day (NOEL = 1 000 mg a.s./kg feed)

**Table: EU endpoints - toxicity of Zoxamide to birds**

Study	EU agreed endpoints (SANCO/10297/2003, dated 4 <sup>th</sup> February 2004)
Acute toxicity	LD <sub>50</sub> (bobwhite quail) > 2000 mg a.s./kg b.w.
Short-term toxicity	LC <sub>50</sub> (bobwhite quail) > 5250 mg a.s./kg diet equivalent to LD <sub>50</sub> > 1500 mg a.s./kg b.w./day
Reproductive toxicity (long-term)	NOEC (mallard duck) = 1000 mg a.s./kg diet equivalent to NOEL = 100 mg a.s./kg b.w./day

**Table: EU endpoints - toxicity of Mandipropamide to mammals**

Study	EU agreed endpoints (EFSA Scientific Report, EFSA Journal 2012;10(11):2935)
Acute toxicity	LD <sub>50</sub> > 5 000 mg a.s./kg bw per day
Reproductive toxicity (long-term)	NOAEL = 20 mg a.s./kg bw per day

**Table: EU endpoints - toxicity of Zoxamide to mammals**

Study	EU agreed endpoints (SANCO/10297/2003 – dated 4 <sup>th</sup> February 2004)
Acute toxicity	LD <sub>50</sub> > 5000 mg a.s./kg b.w.
Reproductive toxicity (long-term)	NOEL = 50 mg a.s./kg b.w./day

Based on the presumptions of the screening step and Tier 1, the calculated TER values for the acute and long-term risk resulting from an exposure of birds and mammals to the active substances Mandipropamide and Zoxamide according to the intended use of the formulation Ampexio in vines achieve the acceptability criteria  $TER \geq 10$  and  $TER \geq 5$ , respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for birds and mammals.

The refined long-term TER for the vole is still slightly below the trigger value of 5 for mandipropamid. The calculated TER of 4.8 is based on the conservative assumption that the animals spend their entire time in contaminated fields and feed exclusively on contaminated food. Furthermore the highest dt50 value from the decline studies with mandipropamid has been used for risk assessment. As these are conservative assumptions and the calculation bare a considerably margin of safety, could the use in vineyards be considered as acceptable based on a weight of evidence approach.

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

Results of aquatic risk assessment for the intended use of Ampexio in vines based on FOCUS Surface Water PEC values are presented in the Core Assessment Austria, Part B, Section 6, chapter 6.4.

The relevant endpoint for the risk assessment derives from an early life stage study on fish with the active substance Zoxamide resulting in NOEC of 3.48 µg/L. Study on the preparation and the occurring metabolites do not demonstrate increased levels of toxicity.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spray-drift and volatilization with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

#### *1. Exposure by spray-drift and deposition following volatilization*

Based on the relevant toxicity of Mandipropamide, the calculated TER-values for the risk to aquatic organisms resulting from an exposure of surface water by spray-drift and volatilization from Ampexio according to the uses No 00-001,002 achieve the acceptability criteria of  $TER \geq 10$ , according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2 without risk mitigation measures.

Based on the relevant toxicity of Zoxamide, the calculated TER-values for the risk to aquatic organism resulting from an exposure of surface water by spray-drift from Ampexio according to the uses No 00-001, 002 achieve the acceptability criteria of  $TER \geq 10$ , according to commission implementing



regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2 only if appropriate risk mitigation measures are applied (15 m buffer zone or drift reducing technique).

## 2. Exposure by surface run-off and drainage

The concentrations of Mandipropamide and Zoxamide in adjacent ditch due to surface run-off and drainage was calculated using the model EXPOSIT 3.01.

The calculated TER-values for the risk to aquatic organisms resulting from an exposure of surface water by Mandipropamide and Zoxamide due to run-off and drainage according to the uses No 00-001,002 achieve the acceptability criteria of  $TER \geq 100$  or 10 respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2..

### Consequences for authorization:

For the authorization of the plant protection product Ampexio the following labelling and conditions of use are mandatory:

### Required Labelling

NW 262 Zoxamide: *Scenedesmus subspicatus*. NOEC = 0.007 mg/L

NW 264 Zoxamide: *Oncorhynchus mykiss*. NOEC = 0.00348 mg/L

Zoxamide: *Daphnia magna*. NOEC = 0.039 mg/L

NW 265 Zoxamide: *Lemna gibba*. NOEC = 0.009 mg/L

### Conditions for use

Ampexio NW 468  
uses No. 00-001,002 NW 605-1/606 Drift-reduction technique– corresponding buffer zone:  
90 % – \*; 75 % – 10 m; 50 % – 10 m; conv. – 15 m;

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

- Insert summary of the data/risk assessment for bees and other arthropods

#### Bees

Effects on bees for A18881A were not evaluated as part of the EU review of mandipropamid and zoxamide. However further data on A18881A is not relevant as active substance data on toxicity to bees is used and additional formulation data are not considered essential. Therefore all relevant data were assessed in the EU review. Risk assessments for A18881A with the proposed use pattern were provided and are considered adequate.

#### EU Conclusions - Toxicity to bees of mandipropamid

test substance	oral LD <sub>50</sub>	contact LD <sub>50</sub>	reference
mandipropamid	> 200 µg a.s./bee	> 200 µg a.s./bee	EU agreed endpoint (EFSA Journal 2012;10(11):2935)

zoxamide	> 36.75 µg a.s./bee	> 100 µg a.s./bee	EU agreed endpoint (EU Commission SANCO/10297/2003 (2004))
A18881A	> 570 µg a.s./bee	> 500 µg a.s./bee	Kling A, (2013) (A18881A_10006)

The risks of A18881A to honey-bees was assessed from hazard quotients between toxicity endpoints, estimated from acute oral and contact studies with active ingredient and formulated product, and the maximum single application rate of 1.44 kg formulation/ha (*500 g formulation/ha*).

test substance	application rate	oral LD <sub>50</sub>	contact LD <sub>50</sub>	Hazard quotients	
				oral	contact
A18881A	500 g product/ha	> 570 µg A18881A/bee	> 500 µg A18881A/bee	< 0.88	< 1.0
Mandipropamid	125 g a.s./ha	> 200 µg a.s./bee	> 200 µg a.s./bee	< 0.63	< 0.63
Zoxamide	120 g a.s./ha	> 36.75 a.s./bee	> 100 µg a.s./bee	< 3.3	< 1.2

All the hazard quotients are considerably less than 50, indicating that the active ingredients poses a low risk to bees. Therefore a low risk to bees is expected from the application of A18881A according to the recommended use pattern.

### Other non-target arthropods

TER values for non-target arthropods in off-field habitats were calculated, taking into account the relevant toxicity data for AMPEXIO (ER501800 g Prod/ha) and calculated exposure concentrations in off-field habitats, according to the intended uses of the product AMPEXIO in grapevines. The calculated TER values do achieve the acceptability criterion  $TER \geq 10$  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 AMPEXIO in grapevines according to the label.

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

**Table: Endpoints of Mandipropamide, Zoxamide and Ampexio for the risk assessment of earthworms**

Substance	Time scale	LC <sub>50</sub>	NOEL/ NOEC
Mandipropamide)	acute	> 500 mg a.s./kg	-
Zoxamide	acute	> 267,5 mg a.s./kg	-
Zoxamide metabolite RH-127450	acute	> 1000 mg a.s./kg	-
Ampexio	Subchronic reproductive		25 mg/kg dw-
Mandipropamide	Subchronic reproductive	-	≥ 16 (corr.) mg a.s./kg soil
Zoxamide	Subchronic reproductive	-	0.5 mg a.s./kg artificial soil 7.0 mg a.s./kg natural soil

#

Table: Chronic effects on other soil macro- and mesofauna

Product/active substance	NOEC (mg/kg dw)
Mandipropamid	> 10 ( <i>Folsomia candida</i> )
AMPEXIO	50 ( <i>Folsomia candida</i> )
AMPEXIO	500 ( <i>Hypoaspis aculeifer</i> )

Based on the predicted concentrations of Mandipropamide and Zoxamide in soils, the TER-values describing the long-term risk for earthworms following exposure to Mandipropamide and Zoxamide according to the GAP of the formulation Ampexio achieve the acceptability criterion  $TER \geq 5$  according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of Ampexio in vines according to the label.

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

According to Commission regulation (EU) No 544/2011 studies with other soil macro-organisms are not required. Moreover, the field DT<sub>90</sub>-values of Mandipropamide, Zoxamide and their metabolites are below 365 days. Mandipropamide and their metabolites have field DT<sub>90</sub>-values of a few days. Zoxamide and their metabolites have half-lives below 10 days.

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

Based on the predicted concentrations of Mandipropamide and Zoxamide in soils, the risk to soil microbial processes following exposure to Mandipropamide and Zoxamide according to the GAP of the formulation Ampexio is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

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

#### *Terrestrial plants*

As described in the core assessment to assess the effects of ampexio' on terrestrial plants, a seedling emergence test on different species of non target-plants was carried out. This study showed an ER<sub>50</sub> > 600 g as/ha.

Based on the predicted concentrations of Mandipropamide and Zoxamide in off-field areas, the risk to non-target terrestrial plants following exposure to Mandipropamide and Zoxamide according to the GAP of the formulation Ampexio is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

### Implications for labelling resulting from ecotoxicological assessment:

For the authorization of the plant protection product Ampexio the following labelling and conditions of use are mandatory:

#### Classification and labelling

Relevant toxicity	Active substance: Zoxamide (content 24 %) LC <sub>50</sub> = 0.16 mg/L ( <i>Oncorhynchus mykiss</i> ) E <sub>b</sub> C <sub>50</sub> = 0.011 mg/L <i>Scenedesmus subspicatus</i> NOEC = 0.044 mg/L ( <i>Oncorhynchus mykiss</i> ) M-factor = 10 Formulation LC <sub>50</sub> = 0.0795 mg/L ( <i>Pseudokirchneriella subcapitata</i> )
Classification and labelling according to Regulation 1272/2008	
Hazard symbol	GHS09
Signal word	Warning
Hazard statement	H400 H410

#### Standard Phrases for special risks and safety precautions under Regulation (EU) 547/2011 Annex II and III / conditions of use

#### *All uses:*

NW 468

Fluids left over from application and their remains, products and their remains, empty containers and packaging, and 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.

NW 605-1                      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 provided for 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%	*
	75 %	10 m
	50%	10 m

NW 606                      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 : 15 m

#### Other labels

NW 262	The product is toxic for algae.
NW 264	The product is toxic for fish and aquatic invertebrates.
NW 265	The product is toxic for aquatic plants.

### **3.1.6 Efficacy (Part B, Section 7, Point 8)**

A18881A is a water dispersible granule (WG) formulation containing 250 g/kg mandipropamid and 240 g/kg zoxamide for use as foliar spray for the control of *Plasmopara viticola* in grapes. The proposed maximum rate of A18881A application on grapes is 0.5 kilograms per hectare (kg/ha) with a maximum of three applications per season. Per application 125.0 + 120.0 g mandipropamid + zoxamide per hectare will be delivered.

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

Overall, 9 trials were considered supportive to verify the minimum effective dose in the Maritime EPPO zone. Disease control (severity) on leaves and bunches reveal a positive dose response to increasing amounts of the test product. Control levels at the target rate attained 90 % on leaves and 87 % on bunches, respectively. Disease pressure in the respective plant parts attained means of 37 % and 63 %.

#### **Efficacy tests**

The efficacy in the Maritime EPPO zone is verified by a total of 13 trials. Disease control (severity) of the test product both on leaves and bunches show average results of 86% and 85%, resting on infestation

levels of 34% and 62% respectively. Based on the given data, the efficacy of the test product may be considered justified in the Maritime EPPO zone.

#### **Impact on the quality of plants and plant products**

A18881A is not expected to impair the organoleptic characteristics of table grapes. However, application of A18881A imposes the risk of markings on black berries.

#### **Effects on the processing procedure**

A18881A is not expected to impair inner quality parameters and organoleptic characteristics of processed grapes. However, results did not depict a clear pattern of effects on the fermentation kinetics. A delay of spontaneous fermentation/malolactic fermentation cannot be excluded.

#### **Effects on the yield of treated plants and plant products**

A18881A is not expected to cause any negative effect on yield quantity of grapes since the product aims at the avoidance of yield losses by *Plasmopara viticola* control.

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

Phytotoxicity symptoms were not observed when A18881A was applied in compliance with the proposed GAP. Thus, A18881A is generally deemed to be safe. However, application of A18881A was shown to impose the risk of markings on black berries.

#### **Adverse effects on beneficial organisms (other than bees)**

The toxicity of A18881A on beneficial organisms have been investigated by carrying out tests under extended laboratory conditions on *Aphidius rhopalosiphi*, *Typhlodromus pyri*, *Aleochara bilineata* and *Chrysoperla carnea*. On the basis of the presented results no effects  $\geq 25\%$  are expected for populations of *Typhlodromus pyri* and *Aleochara bilineata*, when A18881A is applied according to the recommended use pattern. The results for *Aphidius rhopalosiphi* and *Chrysoperla carnea* showed effects of 25-50%, suggesting the product is slightly harmful for populations of relevant beneficial insects when A18881A is applied according to the recommended use pattern. *Aphidius rhopalosiphi* is not a relevant beneficial organism in the intended crops.

The product can be classified as slightly harmful for populations of relevant beneficial insects and as non-harmful for predatory mites and spiders.

Label phrases NN1002 and NN2001 are assigned to the product.

#### **Adverse effects on parts of plants used for propagating purposes**

Adverse effects on parts of plants used for propagation purposes are considered unlikely to occur after application of A18881A.

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

A18881A is applied on a perennial crop. Therefore, an impact on succeeding crops is deemed unlikely.

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

An impact on other plants including adjacent crops is deemed unlikely.

#### **Possible development of resistance or cross-resistance**

The active substances are placed in two different MOA/FRAC groups and are non-cross resistant.

The target organism *Plasmopara viticola* is listed as high risk pathogen with known resistance to the active substance *mandipropamid*. Although the risk to develop resistance is considered low to medium for both active substances, the combined risk may be estimated at least as medium/moderate. Resistance development is deemed likely under unrestricted use. Therefore, resistance management strategies are recommended.

In order to avoid resistance development the following resistance management strategies are necessary:

- The use of fungicide mixture combining two active ingredients non-cross resistant (realized in this product).
- Restriction of the number of applications (3 x) as described in the GAP (Apply a maximum of 50% of the total number of intended applications for disease control not exceeding a total of 4 CAA fungicide sprays during one crop cycle. In areas of high resistance the total number should not exceed a maximum of 3 applications during one crop cycle.)
- Alternation with fungicides having other modes of action in spray programs.
- Emphasis on preventive applications.
- 

Regarding the intended use against *Plasmopara viticola* in grapevine, the suggested measures are considered appropriate.

All the data regarding the efficacy of the product have been submitted. These data demonstrate that A18881A fulfils all criteria for the authorization of preparations described in Directive 97/57/EC (Uniform Principles, Annex VI to Directive 91/414/EEC). No phytotoxicity, effects on neighbouring or following crops were observed.

### 3.2 Conclusions

With respect to identity, physical, chemical and technical properties, further information and packaging as well as analytical methods (formulation and residues) an authorisation can be granted.

With respect to toxicology, residues and consumer protection an authorisation can be granted for use 001 (field application on grape vine). Use 002 (application with rotor-driven aircrafts on grape vine) is not authorised due to bystander protection. As a basic principal in Germany an authorisation for plant protection products with sensitising properties is not possible for aircraft application.

With respect to efficacy and sustainable use an authorisation can be granted for both uses.

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.

**An authorisation can be granted for use 001 (field application on grape vine). Use 002 is not authorised (rotor-driven aircrafts on grape vine) due to bystander protection.**

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

None

## **Appendix 1 – Copy of the product authorisation**

- See Appendix 4



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

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 65 of Regulation (EC) No 1107/2009 and Commission Regulation (EU) No 547/2011.

### **Appendix 3 – Letter of Access**

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

## **Appendix 4 – Copy of the product authorisation**



Bundesamt für  
Verbraucherschutz und  
Lebensmittelsicherheit

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IHR ZEICHEN  
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.008314-00/00.114665  
(bitte bei Antwort angeben)

DATUM 20. Juni 2017

**ZV3 008314-00/00**

**AMPEXIO**

**Zulassungsverfahren für Pflanzenschutzmittel**

Bescheid

Das oben genannte Pflanzenschutzmittel

mit den Wirkstoffen:           250 g/kg     Mandipropamid  
  240 g/kg     Zoxamide

Zulassungsnummer:           008314-00

Versuchsbezeichnungen:     SYD-21950-F-0-WG

Antrag vom:                    15. Oktober 2014

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 31. Januar 2019.

## Festgesetzte Anwendungsgebiete bzw. Anwendungen

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

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008314-00/00-001	Falscher Mehltau (Plasmopara viticola)	Weinrebe	Nutzung als Tafel- und Keltertraube

## 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:

(NW468)

Anwendungsflüssigkeiten und deren Reste, Mittel und dessen Reste, entleerte Behältnisse oder Packungen 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:

Die im o.g. Pflanzenschutzmittel enthaltenen Wirkstoffe Zoxamide und Mandipropamide weisen aufgrund ihrer 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 übersteigt, 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.

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:

Verpackungsart	Verpackungsmaterial	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Kanister	HDPE	1		0,25	10,00	kg

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

## **Auflagen**

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

Kennzeichnungsaufgaben:

(NN2001)

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

(NW262)

Das Mittel ist giftig für Algen.

(NW264)

Das Mittel ist giftig für Fische und Fischnährtiere.

(NW265)

Das Mittel ist giftig für höhere Wasserpflanzen.

(SB001)

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

(SB110)

Die Richtlinie für die Anforderungen an die persönliche Schutzausrüstung im Pflanzenschutz "Persönliche Schutzausrüstung beim Umgang mit Pflanzenschutzmitteln" des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit ist zu beachten.

(SB166)

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

(SF245-01)

Behandelte Flächen/Kulturen erst nach dem Abtrocknen des Spritzbelages wieder betreten.

(SS110)

Universal-Schutzhandschuhe (Pflanzenschutz) tragen beim Umgang mit dem unverdünnten Mittel.

(SS206)

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

(SS2101)

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

(SS530)

Gesichtsschutz tragen beim Umgang mit dem unverdünnten Mittel.

(WMFB3)

Wirkungsmechanismus (FRAC-Gruppe): B3

(WMFH5)

Wirkungsmechanismus (FRAC-Gruppe): H5

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):

(H317)

Kann allergische Hautreaktionen verursachen.

(H400)

Sehr giftig für Wasserorganismen.

(H410)

Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

(EUH 208-0191)

Enthält Zoxamide. 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.

(P302+P352)

BEI BERÜHRUNG MIT DER HAUT: Mit viel Wasser/... waschen.

(P333+P313)

Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

(P362+P364)

Kontaminierte Kleidung ausziehen und vor erneutem Tragen waschen.

(P501)

Inhalt/Behälter ... zuführen.



## Abgelehnte Anwendungsgebiete bzw. Anwendungen

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

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008314-00/00-002	Falscher Mehltau (Plasmopara viticola)	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).

(NN1002)

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

### Weitere Hinweise und Bemerkungen

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 bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift 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: 008314-00/00-001

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Falscher Mehltau (*Plasmopara viticola*)

Pflanzen/-erzeugnisse/Objekte: Weinrebe

Verwendungszweck: Nutzung als Tafel- und Keltertraube

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Weinbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	13 bis 85
Anwendungszeitpunkt:	Bei Infektionsgefahr bzw. ab Warndiensthinweis
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	3
- für die Kultur bzw. je Jahr:	3
- Abstand:	8 bis 14 Tage
Anwendungstechnik:	spritzen oder sprühen
Aufwand:	
- Basisaufwand:	0,16 kg/ha in maximal 400 l Wasser/ha
- ES 61:	0,32 kg/ha in maximal 800 l Wasser/ha
- ES 71:	0,48 kg/ha in maximal 1200 l Wasser/ha
- ES 75:	0,48 kg/ha in maximal 1600 l Wasser/ha

#### 2.2 Sonstige Kennzeichnungsauflagen

(NN134)

Das Mittel wird als nichtschädigend für Populationen der Art *Typhlodromus pyri* (Raubmilbe) eingestuft.

(WG734)

Die Anwendung des Mittels kann bei Spontangärung zu Gärverzögerungen führen.

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt. Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

(WW762)

Aus Gründen des Resistenzmanagements das Mittel (einschließlich anderer Mittel mit gleichem Wirkstoff, mit einem Wirkstoff aus der gleichen Wirkstoffgruppe oder mit kreuzresistentem Wirkstoff) insgesamt nicht häufiger anwenden als in der Gebrauchsanleitung angegeben. Im Zweifel einen Beratungsdienst hinzuziehen.

### 2.3 Wartezeiten

21 Tage

Freiland: Weinrebe (Tafel- und Keltertrauben)

## 3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "\*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.

reduzierte Abstände: 50% 10 m, 75% 10 m, 90% \*

#### Begründung:

Das Pflanzenschutzmittel AMPEXIO bzw. der darin enthaltene Wirkstoff Zoxamid weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für *Oncorhynchus mykiss* von 3,48 µg/L. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Zoxamid in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 6, Kapitel 6.4).

(NW606)

Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

15 m

Begründung:

Siehe Anwendungbestimmung NW605-1

## Anlage 2 nicht zugelassene Anwendung: 008314-00/00-002

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Falscher Mehltau (*Plasmopara viticola*)

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

Stadium der Kultur: 13 bis 85

Anwendungszeitpunkt: Bei Infektionsgefahr bzw. ab Warndiensthinweis

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Abstand: 8 bis 14 Tage

Anwendungstechnik: spritzen oder sprühen

- Erläuterungen: nur mit rotorgetriebenen Luftfahrzeugen (keine Starrflügler)

Aufwand:

- Basisaufwand: 0,16 kg/ha in 150 bis 300 l Wasser/ha

- ES 61: 0,32 kg/ha in 150 bis 300 l Wasser/ha

- ES 71: 0,48 kg/ha in 150 bis 300 l Wasser/ha

- ES 75: 0,48 kg/ha in 150 bis 300 l Wasser/ha

### 3 Begründung

Rückstandsverhalten und Toxikologie:

Zu KCP 7.2.2 (Exposition umstehender Personen):

Bei der Ausbringung des Mittels AMPEXIO mit Luftfahrzeugen an Weinreben kann ein gesundheitliches Risiko für unbeteiligte Dritte infolge der sensibilisierenden Eigenschaften des Mittels nicht ausgeschlossen werden.

Begründung:

Die Anwendung 00/00-002 in Weinrebe mit rotorgetriebenen Luftfahrzeugen ist nur in Deutschland beantragt worden und war nicht Teil des zonalen Zulassungsverfahrens, d. h. diese Anwendung ist vom zRMS AT nicht bewertet und auch nicht zugelassen worden. Weist ein Pflanzenschutzmittel sensibilisierende Eigenschaften auf, stellt dies in Deutschland grundsätzlich ein Ausschlusskriterium für die Ausbringung mit Luftfahrzeugen dar. Ich verweise auf die Bekanntgabe der Anforderungen für die Genehmigung von Anwendungen mit

Luftfahrzeugen durch das BVL im Rahmen der Antragstellerkonferenzen vom 20. Mai 2014 und 16. Juni 2015, publiziert auf der Internetseite des BVL am 04. Juni 2014 bzw. am 07. Juli 2015.

**DRAFT REGISTRATION REPORT**

**Part B**

**Section 5**

**Environmental Fate**

Detailed summary of the risk assessment

Product code: ZV3 008314-00/00

Product name(s): Ampexio

Chemical active substances:

Mandipropamid 250 g/kg

Zoxamide 240 g/kg

Central Zone

Zonal Rapporteur Member State: Austria

**NATIONAL ADDENDUM – GERMANY**

Applicant: Syngenta

Submission date: 15 October 2014 (start 4 November 2014)

MS Finalisation date: 20 June 2017



## Version history

<b>When</b>	<b>What</b>
20 June 2017	First Draft RR by UBA

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

The exposure assessment of the plant protection product Ampexio in its intended uses in vines is documented in detail in the core assessment of the plant protection product Ampexio dated from February 2016 performed by Austria.

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for authorization of the plant protection product Ampexio for the intended for uses in Germany considering specific environmental or agricultural circumstances.

Regarding  $PEC_{gw}$  relevant risk mitigation measures, if necessary, are documented in this document.

$PEC_{soil}$ ,  $PEC_{sw}$  are used for risk assessment to derive specific risk mitigation measures if necessary (see National Addendum Germany, Part B, section 6).

## 5.1 Critical GAP and overall conclusions

### 5.1.1 Table of critical GAPs

**Table 5.1-1:** 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 situ- ation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (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			Groundwater
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>														
001, 002	DE, AT, CZ, HU, RO, SI, SK	Grapevine (VITVI)	F	Plasmopara viti- cola (PLASVI)	Foliar spray	BBCH 13 - 85 March- August	a) 3 (8 days) b) 3 (8 days)		a) 0.5 b) 1.5	as 1: a) 125 b) 375 as 2: a) 120 b) 360	150-1000	21		
<b>Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)</b>														
--														
<b>Minor uses according to Article 51 (zonal uses)</b>														
--														
<b>Minor uses according to Article 51 (interzonal uses)</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

## 5.1.2 Overall conclusion

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

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

The PEC<sub>soil</sub> values for the active substances were used in the eco-toxicological risk assessment for the intended uses of the plant protection product Ampexio in Germany.

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

The PEC<sub>soil</sub> values for the active substances were used in the eco-toxicological risk assessment for the intended uses of the plant protection product Ampexio in Germany.

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

#### Direct leaching into groundwater

Results of modelling with FOCUS PELMO study show that the active substance Mandipropamid is not expected to penetrate into groundwater at concentrations of  $\geq 0.1\mu\text{g/L}$  in the intended uses of Ampexio in Germany according to use No.001 and 002

For the metabolite CGA380778 of Mandipropamid concentrations of  $\geq 0.1\mu\text{g/L}$  in groundwater can be excluded. For the assessment of the relevance of metabolite CGA380778 of Mandipropamid please refer to the results of EU approval of Mandipropamid. The metabolites CGA380778 are classified as not relevant for groundwater.

Results of modelling with FOCUS PELMO show that the active substance Zoxamide is not expected to penetrate into groundwater at concentrations of  $\geq 0.1\mu\text{g/L}$  in the intended uses of Ampexio in Germany according to use No.00-001 and -002

For the metabolites of Zoxamide RH-127450, RH-163353 and RH-24549 concentrations of  $\geq 0.1\mu\text{g/L}$  in groundwater can be excluded. For the assessment of the relevance of metabolite RH-127450, RH-163353 and RH-24549 of Zoxamide please refer to the results of EU approval of Zoxamide. The metabolites RH-127450, RH-163353 and RH-24549 are classified as not relevant for groundwater.

#### Consequences for authorization:

None

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

According modelling with EXPOSIT 3, groundwater contamination at concentrations  $\geq 0.1\mu\text{g/L}$  by the active substances Mandipropamid and Zoxamide due to surface runoff and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

#### Consequences for authorization:

none

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

For the intended uses of the plant protection product Ampexio in Germany PEC<sub>sw</sub> was calculated for the active substances Mandipropamid and Zoxamide considering the two routes of entry (i) spray drift and volatilization with subsequent deposition and (ii) runoff, drainage separately. Surface water exposure via spray drift and volatilization with subsequent deposition is estimated with the model EVA 3 using drift data by Rautmann and Ganzelmeier.

Surface water exposure via surface runoff and drainage is estimated using the model EXPOSIT 3.0.

The results of the PEC surface water simulations for the active substances and its metabolites were used in the eco-toxicological risk assessment.

### **5.1.2.4 Fate and behaviour in air**

The vapour pressure at 20 °C of the active substance Mandipropamid is  $< 10^{-5}$  Pa. Hence the active substance Mandipropamid is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Mandipropamid due to volatilization with subsequent deposition was not considered.

The vapour pressure at 20 °C of the active substance Zoxamide is  $< 10^{-5}$  Pa. Hence the active substance Zoxamide is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Zoxamide due to volatilization with subsequent deposition was not considered.



## **5.2 Metabolites considered in the assessment**

Please refer to the core assessment dated from February 2016 performed by Austria.

### **Metabolites of Mandipropamid**

The risk assessment for the metabolites of Mandipropamid has already been performed for EU approval (see EFSA Journal 2012 10(11); 2935) as well as in the core assessment by Austria from February 2016. For the soil metabolites CGA380778 of Mandipropamid, occurring in soil at relevant concentrations, national groundwater risk assessment is carried out (see chapter 5.8).

### **Metabolites of Zoxamide**

The risk assessment for the metabolites of Zoxamide has already been performed for EU approval (see SANCO/10297/2003, dated 4th February 2004) as well as in the core assessment by Austria from February 2016.

For the soil metabolites RH-127450, RH-163353 and RH-24549 of Zoxamide, occurring in soil at relevant concentrations, national groundwater risk assessment is carried out (see chapter 5.8).

### 5.3 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 substances.

#### 5.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

##### 5.3.1.1 Mandipropamid

The DT<sub>50</sub> values of Mandipropamid listed in the core assessment by Austria from February 2016, Part B, section 5, table 9.1.1-1 were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC<sub>gw</sub>) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

The statistical results for Mandipropamid according to the program INPUT DECISION 3.3 are listed in the following table.

**Table 5.3-1: Statistical values according to INPUT DECISION 3.3 for Mandipropamid for PEC<sub>gw</sub> modelling**

Does the active substance dissociate?	no	
Correlation DT <sub>50</sub> and pH	Kendall-τ: 0.000 p-value: 1.000	not significant
Coefficient of variation	49%	Sufficiently low
DT <sub>50</sub> for PEC <sub>gw</sub> (d)	43.9	Geometric mean (n=5)

The DT<sub>50</sub> values of the metabolite CGA380778 of Mandipropamid listed in the core assessment Part B, section 5, table 9.1.1-2 were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC<sub>gw</sub>) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

The statistical results for the metabolite CGA380778 according to the program INPUT DECISION 3.3 are listed in the following table.

**Table 5.3-2: Statistical values according to INPUT DECISION 3.3 for the metabolite CGA380778 for PEC<sub>gw</sub> modelling**

Does the active substance dissociate?	no	
Correlation DT <sub>50</sub> and pH	Kendall-τ: 0.200 p-value:0.806	not significant
Coefficient of variation	70%	Sufficiently low
DT <sub>50</sub> for PEC <sub>gw</sub> (d)	15.1	Geometric mean (n=5)

### 5.3.1.2 Zoxamide

The DT<sub>50</sub> values of Zoxamide listed in the core assessment by Austria from February 2016, Part B, section 5, table 9.1.1-4 were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC<sub>gw</sub>) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

The statistical results for Zoxamide according to the program INPUT DECISION 3.3 are listed in the following table.

**Table 5.3-3: Statistical values according to INPUT DECISION 3.3 for Zoxamide for PEC<sub>gw</sub> modelling**

Does the active substance dissociate?	no	
Correlation DT <sub>50</sub> and pH	Kendall-τ: -0.552 p-value: 0.181	not significant
Coefficient of variation	90	Too high
DT <sub>50</sub> for PEC <sub>gw</sub> (d)	3,5 10.6	geometric mean 90 <sup>th</sup> perzentil

The DT<sub>50</sub> values of the metabolites RH-127450, RH-24549 and RH-163353 of Zoxamide listed in the core assessment by Austria from February 2016 were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC<sub>gw</sub>) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

The statistical results for the metabolite RH-127450 according to the program INPUT DECISION 3.3 are listed in the following table.

**Table 5.3-4: Statistical values according to INPUT DECISION 3.3 for the metabolite RH-127450 for PEC<sub>gw</sub> modelling**

Does the active substance dissociate?	no	
Correlation DT <sub>50</sub> and pH	Kendall-τ: -0.183 p-value: 1.000	not significant
Coefficient of variation	46	Sufficiently low
DT <sub>50</sub> for PEC <sub>gw</sub> (d)	7.7 11.7	geometric mean 90 <sup>th</sup> perzentil

The statistical results for the metabolite , RH-24549 according to the program INPUT DECISION 3.3 are listed in the following table.

**Table 5.3-5: Statistical values according to INPUT DECISION 3.3 for the metabolite RH-24549 for PEC<sub>gw</sub> modelling**

Does the active substance dissociate?	no	
Correlation DT <sub>50</sub> and pH	Kendall-τ: - p-value: -	-

Coefficient of variation	40	Sufficiently low
DT <sub>50</sub> for PEC <sub>gw</sub> (d)	7,4 10.3	Geometric mean 90 <sup>th</sup> perzentil

The statistical results for the metabolite RH-163353 according to the program INPUT DECISION 3.3 are listed in the following table.

**Table 5.3-6: Statistical values according to INPUT DECISION 3.3 for the metabolite RH-163353 for PEC<sub>gw</sub> modelling**

Does the active substance dissociate?	yes	
Correlation DT <sub>50</sub> and pH	Kendall-τ: - p-value: -	-
Coefficient of variation	64	too high
DT <sub>50</sub> for PEC <sub>gw</sub> (d)	8 13.9	geometric mean 90 <sup>th</sup> perzentil

### 5.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Not relevant for assessment.

## 5.4 Field studies (KCP 9.1.1.2)

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

#### 5.4.1.1 Mandipropamid and its metabolites

Please refer to the core assessment by Austria from February 2016, part B section 5, point IIIA 9.2

#### 5.4.1.2 Zoxamide and its metabolites

Please refer to the core assessment by Austria from February 2016, part B section 5, point IIIA 9.2

### 5.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Please refer to the core assessment by Austria from February 2016, part B section 5, point IIIA 9.2.3

## 5.5 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 substances.

### 5.5.1 Adsorption and desorption in soil (KCP 9.1.2.1)

#### 5.5.1.1 Mandipropamid and its metabolites

In the core assessment performed by Austria from February 2016, part B section 5, point III 9.3  $K_{Foc}$  values from the EU assessment were considered.

The  $K_{Foc}$  values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater ( $PEC_{gw}$ ) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

**Table 5.5-1: Statistical values according to INPUT DECISION 3.2 for Mandipropamid for  $PEC_{gw}$  modelling**

Does the active substance dissociate?	no	
Correlation $K_F$ and oc	Kendall- $\tau$ :0.714 p-value:0.018	not positive (p-value < significance level)
Coefficient of variation $K_{Foc}$	35%	sufficiently low ( $\leq 60$ )
Correlation $K_F$ and pH	Kendall- $\tau$ : 0.524 p-value: 0.133	not relevant (p-value > significance level)
Correlation $K_F$ and other soil parameters (clay, CEC)	CEC: Kendall- $\tau$ : 0.619 p-value: 0.036	not relevant
$K_{Foc}/K_F$ for $PEC_{gw}$	848	arithmetic mean all soils, n= 7
1/n $PEC_{gw}$	0.846	arithmetic mean all soils, n= 7

**Table 5.5-2: Statistical values according to INPUT DECISION 3.2 for metabolite CGA380778 of Mandipropamid for  $PEC_{gw}$  modelling**

Does the active substance dissociate ?	no	
correlation $K_f$ and oc	Kendall- $\tau$ : 1.000 p-value: 0.500	not significant (p-Wert > significance level)
coefficient of variation $K_{foc}$	19 %	sufficiently low ( $\leq 60\%$ )
Correlation $K_f$ and pH	Kendall- $\tau$ : -0.333 p-value: 1.000	not significant (p-Wert > significance level)
Correlation $K_f$ and other soil parameters (clay, CEC)	-	not significant

$K_{foc}$ for $PEC_{GW}$	448	arithmetic mean all soils, n= 3
1/n $PEC_{GW}$	0.85	arithmetic mean all soils, n= 3

### 5.5.1.2 Zoxamide and its metabolites

In the core assessment performed by Austria from February 2016, part B section 5, point III 9.3  $K_{Foc}$  values from the EU assessment were considered.

The  $K_{Foc}$  values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater ( $PEC_{gw}$ ) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

**Table 5.5-3: Statistical values according to INPUT DECISION 3.2 for Zoxamide for  $PEC_{gw}$  modelling**

Does the active substance dissociate?	no	
Correlation $K_f$ and oc	Kendall- $\tau$ : p-value:0.0.5	not significant (p-value > significance level)
Coefficient of variation $K_{Foc}$	23 %	sufficiently low ( $\leq 60$ )
$K_{Foc}/K_f$ for $PEC_{gw}$	1207	arithmetic mean all soils with an oc content >0.3%
1/n $PEC_{gw}$	0.970	arithmetic mean all soils with an oc content >0.3%

**Table 5.5-4: Statistical values according to INPUT DECISION 3.2 for metabolite RH-127450 of Zoxamide for  $PEC_{gw}$  modelling**

Does the active substance dissociate ?	no	
correlation $K_f$ and oc	Kendall- $\tau$ : p-value: 0.500	not relevant (p-Wert > significance level)
coefficient of variation $K_{foc}$	63 %	too high (> 60%)
coefficient of variation $K_f$ ,	26	Sufficiently low (< 100%)
$K_f$ for $PEC_{GW}$	13.89	arithmetic mean all soils,

**Table 5.5-5: Statistical values according to INPUT DECISION 3.2 for metabolite RH-24549 of Zoxamide for  $PEC_{gw}$  modelling**

Does the active substance dissociate ?	no	
correlation $K_f$ and oc	Kendall- $\tau$ : p-value: 0.5	Not relevant (p-Wert > significance level)
correlation $K_f$ and pH	p-value=1	not relevant (p>0.05) LoEP: PH DEPENDENCE FOR METABOLITE RH-24549 (LOWER SORPTION AT HIGHER PH).

coefficient of variation $K_{foc}$	61 %	too high (> 60%)
coefficient of variation $K_f$ ,	37%	Sufficiently low (< 100%)
$K_f$ for PECGW, horizon 1-3	3.13	Ar. mean, all soils

**Table 5.5-6: Statistical values according to INPUT DECISION 3.2 for metabolite RH-163353 of Zoxamide for  $PEC_{gw}$  modelling**

Does the active substance dissociate ?	yes	
correlation $K_f$ and oc	Kendall- $\tau$ : p-value: 0.500	not relevant (p-Wert > significance level)
coefficient of variation $K_{foc}$	24 %	sufficiently low ( $\leq 60\%$ )
$K_{foc}$ for $PEC_{GW}$	68	arithmetic mean all soils,
1/n $PEC_{GW}$	0.839	arithmetic mean all soils,

### 5.5.2 Column leaching (KCP 9.1.2.1)

Please refer to the core assessment by Austria from February 2016.

### 5.5.3 Lysimeter studies (KCP 9.1.2.2)

Please refer to the core assessment by Austria from February 2016.

### 5.5.4 Field leaching studies (KCP 9.1.2.3)

Please refer to the core assessment by Austria from February 2016.

## 5.6 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 substances.

### 5.6.1 Water/sediment study (KCP 9.2.2)

#### 5.6.1.1 Mandipropamid

Please refer to the core assessment by Austria from February 2016.

**Table 5.6-1: Accumulation of active substance Mandipropamid and relevant metabolites in the sediment**

active substance	Mandipropamid
Accumulation potential in sediment	no ( $DT_{90, \text{whole system}} < 1$ year, see core assessment)
Accumulation factor (SFO) $f_{\text{accu}} = e^{-kt}/(1 - e^{-kt})$	--

#### 5.6.1.2 Zoxamide

Please refer to the core assessment by Austria from February 2016.

**Table 5.6-2: Accumulation of active substance Zoxamide and relevant metabolites in the sediment**

active substance	Zoxamide
Accumulation potential in sediment	no ( $DT_{90, \text{whole system}} < 1$ year, see core assessment)
Accumulation factor (SFO) $f_{\text{accu}} = e^{-kt}/(1 - e^{-kt})$	--



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

### 5.7.1 Justification of new endpoints

Not applicable, german scenario

### 5.7.2 Active substances and relevant metabolite(s)

Results of PEC<sub>soil</sub> calculation for Ampexio according to EU assessment considering 5 cm soil depth are given in the core assessment by Austria from February 2016, part B, section 5, chapter IIIA 9.4.

For German exposure assessment the applied soil depth is based on experimental data (Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittel-wirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999). Generally for active substances with a  $K_{Foc} < 500$  a soil depth of 2.5 cm is applied whereas for active substances with a  $K_{Foc} > 500$  a soil depth of 1 cm is applied. As soil bulk density  $1.5 \text{ g cm}^{-3}$  is assumed.

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

**Table 5.7-1: Input parameters related to application for PEC<sub>soil</sub> calculations**

<b>Use No/use group</b>	00-001, -002
<b>Crop</b>	grapevines
<b>Application rate (g as/ha)</b>	125 g Mandiproamid/ha 120 g Zoxamid /ha
<b>Number of applications/interval</b>	3 x/ 8 days
<b>Crop interception (%)</b>	50%
<b>Depth of soil layer (relevant for plateau concentration) (cm)</b>	1 (no tillage)

**Table 5.7-2: Input parameter for active substances and relevant metabolite(s) for PEC<sub>soil</sub> calculation**

<b>Compound</b>	<b>Molecular weight (g/mol)</b>	<b>Max. occurrence (%)</b>	<b>DT<sub>50</sub> (days) EU endpoint</b>	<b>DT<sub>50</sub> (days) updated endpoint</b>
Mandiproamid	4119	-	72,3d , (pseudo-SFO, Field study, see Table 9.2-1 core assessment by Austria from February 2016)	not applicable
Zoxamide	336.65	-	10 d	

Due to the fast degradation of Mandiproamid in soil ( $DT_{90} < 365$  d, laboratory/field data) the accumulation potential of Mandiproamid does not need to be considered.

Due to the fast degradation of Zoxamide in soil ( $DT_{90} < 365$  d, laboratory/field data) the accumulation

potential of Zoxamide does not need to be considered.

The calculated  $PEC_{soil}$  used for German risk assessment for Mandipropamid and Zoxamide as well as for the formulation Ampexio are summarized in Table 5.7-3.

Additional  $PEC_{soil,act}$  was calculated for the formulation Ampexio for a soil depth of 2.5 cm. No short-term and long-term  $PEC_{soil}$  were calculated since  $PEC_{soil,act}$  is considered sufficient for German risk assessment.

**Table 5.7-3: Results of  $PEC_{soil}$  calculation for the intended use in grapevine used for German risk assessment**

<b>Plant protection product:</b>		Ampexio				
<b>Use:</b>		00-001, -002				
<b>Number of applications/intervall</b>		3 x /8 d				
<b>Application rate:</b>		500 g/ha Ampexio 125 g/ha Mandipropamid 120 g/ha Zoxamide				
<b>Crop interception:</b>		50% (worst case)				
<b>Active substance/ formulation</b>	<b>Soil relevant ap- plication rate (g/ha)</b>	<b>Soil depth<sub>act</sub> (cm)</b>	<b><math>PEC_{act}</math> (mg/kg)</b>	<b>Tillage depth (cm)</b>	<b><math>PEC_{bkgd}</math> (mg/kg)</b>	<b><math>PEC_{accu} =</math> <math>PEC_{act} +</math> <math>PEC_{bkgd}</math> (mg/kg)</b>
Ampexio	250	1	4.6399	-	-	4.6399
Mandipropamid	62,5	1	1.1600	-	-	1.1600
Zoxamide	60	1	0.7617	-	-	0.7617

## **5.8 Predicted Environmental Concentrations in groundwater (PECgw) (KCP 9.2.4)**

Results of the PECgw calculation of Mandipropamid and Zoxamide for the intended uses of Ampexio in grapevines using FOCUS PELMO are given in the core assessment by Austria from February 2016, part B, section 5, chapter 5.7.1

For authorization in Germany, risk assessment for groundwater considers two pathways, (i) direct leaching of the active substance into the groundwater after soil passage and (ii) surface runoff and drainage of the active substance into an adjacent ditch with subsequent bank filtration into the groundwater.

Direct leaching after soil passage is assessed following the recommendations of the publication of Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PECgw) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011) for tier 1 and tier 2 risk assessment. According to Hold et al, 2011, endpoints for groundwater modelling are derived with the program INPUT DECISION 3.1 and subsequent simulations are performed with FOCUS PELMO for the groundwater scenarios “Hamburg” or with the scenarios “Hamburg” and “Kremsmünster”.

In tier 3 risk assessment, results of experimental studies (lysimeter studies and/or field leaching studies) can also be considered in German groundwater risk assessment.

Surface runoff and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.01.

### **5.8.1 Jusitification of new endpoints**

Mandipropamid:

Not applicable as no new endpoints used.

Zoxamide

Not applicable as no new endpoints used.

### **5.8.2 Active substances and relevant metabolite(s) (KCP 9.2.4.1) Direct Leaching into groundwater**

Results of modelling with FOCUS PELMO 4.4.3 in the core assessment by Austria from February 2016, part B, section 5, chapter IIIA 9.6 show that the active substance Mandipropamid is not expected to penetrate into groundwater at concentrations of  $\geq 0.1\mu\text{g/L}$  in the intended uses of Ampexio in vines. That result can be transferred to the intended uses of Ampexio in Germany in grapevines according to use No. 00-001 and -002.

Results of modelling with FOCUS PELMO 5.5.3 in the core assessment by Austria from February 2016, part B, section 5, chapter IIIA 9.6 show that the active substance Zoxamide is not expected to penetrate into groundwater at concentrations of  $\geq 0.1\mu\text{g/L}$  in the intended uses of Ampexio in grapevine. That result can be transferred to the intended uses of Ampexio in Germany in grapevine according to use No. 00-001 and -002

#### **Consequences for authorization:**

None

### 5.8.3 Summary on estimation of PEC<sub>gw</sub> after direct leaching

Results of modelling with FOCUS PELMO show that the active substance Mandipropamid is not expected to penetrate into groundwater at concentrations of  $\geq 0.1\mu\text{g/L}$  in the intended uses of Ampexio in grapevine according to use No. 00-001 and -002

For the metabolites CGA380778 of MAndipropamid concentrations of  $\geq 0.1\mu\text{g/L}$  in groundwater can be excluded.

Results of modelling with Focus PELMO show that the active substance Zoxamide is not expected to penetrate into groundwater at concentrations of  $\geq 0.1\mu\text{g/L}$  in the intended uses of Ampexio in grapevine according to use No.00-001 and -002.

For the metabolites RH-127450, RH-163353 and RH-24549 concentrations of  $\geq 0.1\mu\text{g/L}$  in groundwater can be excluded.

#### Consequences for authorization:

None

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

Surface runoff and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.01.

**Table 5.8-1: Input parameters related to application of Ampexio for PEC<sub>gw</sub> calculations**

Use No.	00-001, -002
Crop	grapevine
Application rate (g as/ha)	Mandipropamid: 125 Zoxamide: 120
Number of applications/interval (d)	3 x , 8 days
Crop interception (%)	50%

#### 5.8.4.1 Mandipropamid and its metabolites

**Table 5.8-2: Input parameters for Mandipropamid used for PEC<sub>gw</sub> calculations with EX-POSIT 3.01**

Parameter	Mandipropamid	Reference
K <sub>Foc, Runoff</sub>	848	arithm. mean (see core assessment)
K <sub>Foc, mobility class</sub>	848	arithm. mean
DT <sub>50</sub> soil (d)	43,2	arithm. mean (laboratory studies, n=5)
Solubility in water (mg/L)	4.2	LoEP EFSA, 2012
Mobility class	1	default
Reduction by bank filtration	100%	default

### *Metabolites of Mandipropamid*

Not required. No soil metabolites are formed > 10 % in soil.

### **PEC<sub>gw</sub> of Mandipropamid and its metabolites due to bank filtration**

As the reduction by bank filtration is assumed to be 100 % for Mandipropamid and for CGA 380778, no calculation is necessary.

### **Consequences for authorization:**

none

### **5.8.4.2 Zoxamide and its metabolites**

**Table 5.8-3: Input parameters for Zoxamide used for PEC<sub>gw</sub> calculations with EXPOSIT 3.01**

Parameter	Zoxamide	Reference
K <sub>Foc, Runoff</sub>	1224	arithm. mean (see core assessment)
K <sub>Foc, mobility class</sub>	1224	arithm. mean
DT <sub>50</sub> soil (d)	2.8	arithm. mean (see core assessment)
Solubility in water (mg/L)	0.68	see core assessment
Mobility class	1	
Reduction by bank filtration	100%	

### *Metabolites of Zoxamide*

The potential ground water contamination due to bank filtration via surface water exposure by run-off and drainage needs to be assessed using EXPOSIT 3.01.

**Table 5.8-4: Input parameter for soil metabolites of Zoxamide for EXPOSIT 3.01**

Parameter	Metabolite RH-127450	Metabolite RH-163353	Metabolite RH-24549
Molecular weight (g/mol)	302.2	332.2	205
Correction factor molecular weight	302.2/ 336.65	332.2/ 336.65	205/ 336.65
Maximum occurrence in soil (%)	15.1	15	33.8
K <sub>Foc, Runoff</sub>	669	68	183
K <sub>Foc, mobility class</sub>	404	68	90
DT <sub>50</sub> soil (d)	11.7 (90.Perc.)	13.9 (90.Perc.)	10.3 (90.Perc.)
Solubility in water (mg/L)	-	-	-
Mobility class	2	4	3
Reduction by bank filtration	75%	100%	90%

### **PEC<sub>gw</sub> of Zoxamide and its metabolites due to bank filtration**

As the reduction by bank filtration is assumed to be 100 % for Zoxamide, no calculation is necessary.

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations  $\geq 0.1 \mu\text{g/L}$  by the active substance Zoxamide due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

As the reduction by bank filtration is assumed to be 100 % for the metabolite RH-163353 of Zoxamide, no calculation is necessary.

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations  $\geq 0.1 \mu\text{g/L}$  by the metabolite RH-163353 of Zoxamide due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

**Table 5.8-5: PEC<sub>gw</sub> for soil metabolite RH 127450 of Zoxamide after surface runoff and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)**

Metabolite		RH-127450			
Use No.	Application rate	PEC <sub>gw</sub> due to			
		Runoff		Drainage	
		Vegetated buffer strip (m)	Bank filtrate ( $\mu\text{g/L}$ )	Time of application	Bank filtrate ( $\mu\text{g/L}$ )
001	3x 8 g/ha	0	0.002	spring/summer	0.001
		5	0.002		
		10	0.001	autumn/winter/ early spring	0.003
		20	0.001		
<b>Required labelling</b>		none			

**Table 5.8-6: PEC<sub>gw</sub> for soil metabolite RH-24549 of Zoxamide after surface runoff and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)**

Metabolite		RH-24549			
Use No.	Application rate	PEC <sub>gw</sub> due to			
		Runoff		Drainage	
		Vegetated buffer strip (m)	Bank filtrate ( $\mu\text{g/L}$ )	Time of application	Bank filtrate ( $\mu\text{g/L}$ )
001	3x 12 g/ha	0	0.001	spring/summer	0.000
		5	0.001		
		10	0.001	autumn/winter/ early spring	0.001
		20	0.001		
<b>Required labelling</b>		none			

Groundwater contamination at concentrations  $\geq 0.1 \mu\text{g/L}$  by the soil metabolites RH-127450 and RH-24549 of Zoxamide due to surface runoff and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

**Consequences for authorization:**

None

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

Results of PEC<sub>sw</sub> calculation of Mandipropamid and Zoxamide for the intended uses of Ampexio in grapevine using FOCUS Surface Water are given in the core assessment by Austria from February 2016, part B, section 5, chapter IIIA 9.7.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spray drift and volatilisation with subsequent deposition and (ii) runoff, drainage separately in order to allow risk mitigation measures separately for each entry route.

Surface water exposure via spray drift and volatilization with subsequent deposition is estimated with the model EVA. Surface water exposure via surface runoff and drainage is estimated using the model EX-POSIT.

### 5.9.1 Justification of new endpoints

Not applicable as no new endpoints used.

### 5.9.2 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 5.9-1: Input parameters for Ampexio related to the application used for PEC<sub>sw</sub> calculations with EVA 3**

<b>Use No.:</b>	00-001, -002
<b>Number of applications/ interval:</b>	3 x / 8 days
<b>Application rate (g a.s./ha)</b>	Mandipropamid: 125 Zoxamide: 120

#### 5.9.2.1 Mandipropamid and its metabolites

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 Mandipropamid is < 10<sup>-5</sup> Pa. Hence the active substance Mandipropamid is regarded as non-volatile. Therefore exposure of surface water by the active substance Mandipropamid due to volatilization with subsequent deposition does not 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 summarized below.

**Table 5.9-2: Input parameters for Mandipropamid used for the PEC<sub>sw</sub> calculations with EVA 3**

Parameter	Mandipropamid	Reference
Vapour pressure at 20 °C (Pa)	not required since no v/d	LoEP (2012)
Solubility in water at 20 °C (mg/L)	not required since no v/d	
DissT <sub>50</sub> water (d)	1000 (only for multiple application)	SFO (worst case) see LoEP (EFSA Journal 2012, 10(11):2935)
DegT <sub>50</sub> water/sediment study, total system (d)	12.2 (only for multiple application)	SFO (goem. mean) see LoEP (EFSA Journal 2012, 10(11):2935)

For PEC<sub>sw/sed</sub> due to spray drift for Mandipropamid please refer to national Addendum Germany, Part B, Section 6, chapter 6.5.

### 5.9.2.2 Zoxamide and its metabolites

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 Zoxamide is < 10<sup>-5</sup> Pa. Hence the active substance Zoxamide is regarded as non-volatile. Therefore exposure of surface water by the active substance Zoxamide due to volatilization with subsequent deposition does not need to be considered.

**Table 5.9-3: Input parameters for Zoxamide used for the PEC<sub>sw</sub> calculations with EVA 3**

Parameter	Zoxamide	Reference
Vapour pressure at 20°C (Pa)	not required since no v/d	LoEP(2003) SANCO/10297/2003, dated 4 <sup>th</sup> February 2004;
Solubility in water at 20 °C (mg/L)	not required since no v/d	
DissT <sub>50</sub> water (d)	3 (only for multiple application)	SFO,SANCO/10297/2003, dated 4 <sup>th</sup> February 2004;
DegT <sub>50</sub> water/sediment study, total system (d)	not relevant	-

For PEC<sub>sw/sed</sub> due to spray drift for Zoxamide please refer to national Addendum Germany, Part B, Section 9, chapter 9.5.

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

The concentration of the active substance Mandipropamid and Zoxamide in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.

**Table 5.9-4: Input parameters for Ampexio related to the application used for PEC<sub>sw</sub> calculations with Exposit 3**

<b>Use No.:</b>	00-001, -002
<b>Number of applications/ interval:</b>	3 x /8 days
<b>Application rate (g a.s./ha)</b>	Mandipropamid: 125 Zoxamide: 120
<b>Crop interception:</b>	50%

The substance specific input parameters used for modelling surface water exposure via runoff and drainage



in an adjacent ditch with EXPOSIT 3.01 are summarized in chapter 5.8.4 of this document.

For  $PEC_{sw/sed}$  due to surface runoff and drainage please refer to national Addendum Germany, Part B, Section 6, chapter 6.5.

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

Please refer to chapter 5.9.2.

## **5.11 Classification and labelling**

### **5.11.1 GHS Classification and labelling**

Please refer to the core assessment Part B Section 6.

### **5.11.2 National labelling**

No specific labelling required.

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

Use No.	Safety precautions related to the environment
00-001, -002	

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

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

**DRAFT REGISTRATION REPORT**

**Part B**

**Section 6**

**Ecotoxicology**

Detailed summary of the risk assessment

Product code: 008314-00/00

Product name: AMPEXIO

Chemical active substances:

Mandipropamid, 250 g/kg

Zoxamide, 240 g/kg

Central Zone

Zonal Rapporteur Member State: Austria

NATIONAL ADDENDUM Germany

Applicant: Syngenta

Submission date: 15 October 2017 (start 4 November 2017)

MS Finalisation date: 20 June 2017

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## Version history

<b>When</b>	<b>What</b>
20 June 2017	Finalisation RR by UBA (DE)

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- \* 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
C	To be confirmed by cMS
N	No safe use

#### Remarks table:

- (1) Numeration necessary to allow references
- (2) Use official codes/nomenclatures of EU
- (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)
- (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



## **6.1.1 Overall conclusions**

### **6.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2),**

Please refer to core assessment by zRMS AT.

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

TER values for aquatic organisms were calculated, taking into account the relevant toxicity data for zoxamide and calculated exposure levels, according to the intended uses of the product AMPEXIO in grapevines. The calculated TER values do achieve the acceptability criterion  $TER \geq 10$  for chronic 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 (spray drift) are applied. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of AMPEXIO in grapevines according to the label.

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

Please refer to core assessment by zRMS AT.

### **6.1.1.4 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 AMPEXIO and calculated exposure concentrations in off-field habitats, according to the intended uses of the product AMPEXIO in grapevines. The calculated TER values do achieve the acceptability criterion  $TER \geq 10$  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 AMPEXIO in grapevines according to the label.

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

TER values for earthworms were calculated, taking into account the relevant toxicity data for mandipropamid/zoxamide/AMPEXIO and calculated exposure concentrations in soil, according to the intended uses of the product AMPEXIO in grapevines. The calculated TER values do achieve the acceptability criterion  $TER \geq 10$  for acute effects and the acceptability criterion  $TER \geq 5$  for chronic 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 AMPEXIO in grapevines according to the label.

Concerning the effects on soil microbial activity please refer to core assessment.

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

TER values for non-target terrestrial plants were calculated, taking into account the relevant toxicity data for AMPEXIO and calculated exposure concentrations in off-field habitats, according to the intended uses of the product AMPEXIO in grapevines. The calculated TER values do achieve the acceptability criterion  $TER \geq 10$  for effects on non-target plants, according to agreed EU Guidance in Document SANCO/10329/2002 rev 2 (as modified by specific German guidance) that insofar amends Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of AMPEXIO in grapevines according to the label.

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

Please refer to core assessment.

### **6.1.2 Consideration of metabolites**

Please refer to core assessment.

## **6.2 Effects on birds (KCP 10.1.1)**

### **6.2.1 Toxicity data**

Please refer to core assessment.

#### **6.2.1.1**

### **6.2.1.2 Justification for new endpoints**

Please refer to core assessment.

### **6.2.2 Risk assessment for spray applications**

Please refer to core assessment.

#### **6.2.2.1 Drinking water exposure**

Please refer to core assessment.

### **6.2.2.2 Effects of secondary poisoning**

Please refer to core assessment.

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

### **6.3.1 Toxicity data**

Please refer to core assessment.

#### **6.3.1.1 Justification for new endpoints**

Please refer to core assessment.

### **6.3.2 Risk assessment for spray applications**

Please refer to core assessment.

#### **6.3.2.1 First-tier assessment (screening/generic focal species)**

Please refer to core assessment.

#### **6.3.2.2 Higher-tier risk assessment**

Please refer to core assessment.

The specific ecological properties of voles in combination with a relatively low uncertainty regarding the extrapolation of toxicity values from test species to species in the wild allow for a reduction of the numerical TER acceptability criteria. Thus, a TER value  $\geq 2$  for long-term reproductive effects is considered to indicate an acceptable risk for voles.<sup>1</sup>

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#### **6.3.2.3 Drinking water exposure**

Please refer to core assessment.

#### **6.3.2.4 Effects of secondary poisoning**

Please refer to core assessment.

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<sup>1</sup> Announcement BVL 10/02/14 in the Federal Gazette (Bundesanzeiger) Nr. 94. p. 2228 ff., 29.06.2010

## 6.4 Effects on aquatic organisms (KCP 10.2)

### 6.4.1 Toxicity data

Please refer to core assessment.

#### 6.4.1.1 Justification for new endpoints

Please refer to core assessment.

### 6.4.2 Risk assessment

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 mandipropamid/zoxamide/AMPEXIO 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. Mandipropamid and zoxamide have a vapour pressure of  $< 10^{-5}$  Pa and are therefore classified as non-volatile. Hence, deposition following volatilisation can be disregarded in the exposure assessment. The model input parameters are provided in the Environmental Fate section.

##### *Selection of relevant toxicity endpoint*

Several ecotoxicological endpoints are available to assess the risk of the active substances mandipropamid, zoxamide and the product AMPEXIO. The selection of the relevant assessment scenario is based on a comparison of the ratios between the regulatory acceptable concentrations (RAC; effect value for toxicity divided by relevant assessment factor) for each substance and their respective numerical shares in the product.

**Table 6.4-1: Selection of decision-relevant assessment scenario based on ratios of RAC values for substances and their respective numerical shares in the product**

Substance	Sensitive species	Effect value (µg/L)	AF	RAC (µg/L)	Fraction of compd. in product	RAC/ fraction-compd.
Mandipropamid	<i>Daphnia magna</i>	76	10	7.6	25 %	2.5
Zoxamide	<i>Oncorhynchus mykiss</i>	3.48	10	0.348	24 %	2.4
AMPEXIO	<i>Pseudokirchneriella subcapitata</i>	79.5	10	7.95		

RAC: regulatory acceptable concentration; AF: Assessment factor

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The lowest ratio of RAC vs. numerical share in the product was found for zoxamide with regard to the effects on *Oncorhynchus mykiss*, which is therefore identified as the decision-relevant scenario for the risk assessment.

**Table 6.4-2: Assessment of the risk for aquatic organisms due to the use of AMPEXIO in vines (00-001/00-002) – exposure to entries of zoxamide via spray drift, considering risk mitigation measures**

<b>Active substance/product:</b>		zoxamide						
<b>Intended use:</b>		00-001, 00-002						
<b>Application parameters:</b>		Grapevines, 3 x 0.5 kg/ha (8 d)						
<b>DisT<sub>50</sub> water phase (SFO):</b>		3						
<b>Scenario, drift percentile:</b>		Vines, 77 <sup>th</sup>						
<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	6.9	3.263	---	---	3.263	1.632	0.816	0.326
5	3.07	1.452	---	---	1.452	0.726	0.363	0.145
10	1.02	0.482	---	---	0.482	0.241	0.121	0.048
15	0.54	0.255	---	---	0.255	0.128	0.064	0.026
20	0.34	0.161	---	---	0.161	0.080	0.040	0.016
<b>Endpoint (µg/L):</b>		NOEC = 3.48 ( <i>O. mykiss</i> )						
<b>Relevant TER:</b>		10						
<b>Buffer zone (m)</b>					<b>TER</b>			
3					<b>1.1</b>	<b>2.1</b>	<b>4.3</b>	10.7
5					<b>2.4</b>	<b>4.8</b>	<b>9.6</b>	24
10					<b>7.2</b>	14.4	28.9	72.1
15					13.6	27.3	54.5	136.3
20					21.6	43.3	86.6	216.4
<b>Risk mitigation measures:</b>			NW605/606					

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

### Exposure assessment

The concentrations of the active substance zoxamide in an adjacent ditch due to surface run-off or drainage are calculated using the model EXPOSIT 3.01. The relevant input parameters for exposure modelling are provided in the Environmental Fate section.

### Selection of relevant toxicity endpoint

See above (assessment for exposure via spray drift and volatilisation with subsequent deposition).

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**Table 6.4-3: Assessment of the risk for aquatic organisms due to the use of AMPEXIO in vines (00-001, 00-002) – exposure to entries of zoxamide via run-off or drainage, considering risk mitigation measures**

<b>Active substance:</b>	Zoxamide	
<b>Intended use</b>	00-001, 00-002	
<b>Application parameters:</b>	Grapevines, 3 x 0.5 kg/ha (8 d)	
<b>Endpoint (µg/L):</b>	NOEC = 3.48	
<b>TER acceptability criterion:</b>	10	
<b>Run-off</b>		
<b>Buffer zone (m)</b>	<b>PEC (µg/L)</b>	<b>TER</b>
0	0.15	24
5	0.13	27
10	0.11	32
20	0.08	46
<b>Drainage</b>		
<b>Time of application</b>	<b>PEC (µg/L)</b>	<b>TER</b>
Spring/summer	0	780
Autumn/winter	0.01	254
<b>Risk mitigation measures:</b>	---	

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

### 6.4.3 Overall conclusions

TER values for aquatic organisms were calculated, taking into account the relevant toxicity data for zoxamide and calculated exposure levels, according to the intended uses of the product AMPEXIO in grapevines. The calculated TER values do achieve the acceptability criterion  $TER \geq 10$  for chronic 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 (spray drift) are applied. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of AMPEXIO in grapevines according to the label.

### Consequences for authorisation

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

**Table 6.4-4 Labelling requirements according to § 36 (3) PflSchG**

NW262	Zoxamide: NOEC = 0.007 mg/L ( <i>Scenedesmus subspicatus</i> ) AMPEXIO: NOEC = 0.032 mg/L ( <i>Pseudokirchneriella subcapitata</i> )
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NW264	Mandipropamid: NOEC = 0.5 mg/L ( <i>Pimephales promelas</i> ) NOEC = 0.076 mg/L ( <i>Daphnia magna</i> ) Zoxamide: NOEC = 0.00348 mg/L ( <i>Oncorhynchus mykiss</i> ) NOEC = 0.039 mg/L ( <i>Daphnia magna</i> ) AMPEXIO: LC <sub>50</sub> = 2.75 mg/L ( <i>Oncorhynchus mykiss</i> )
NW265	Zoxamide: NOEC = 0.009 mg/L ( <i>Lemna gibba</i> )

**Table 6.4-5 Mandatory conditions of use according to § 36 (1) PflSchG for the protection of aquatic organisms (all uses)**

NW468	
NW605/606	Drift-reduction technique– corresponding buffer zone: 90 % – *; 75 % – 10 m; 50 % – 10 m; conv. – 15 m;

## 6.5 Effects on bees (KCP 10.3.1)

Please refer to core assessment.

## 6.6 Effects on arthropods other than bees (KCP 10.3.2)

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>2</sup>

### *Exposure assessment*

Exposure levels of mandipropamid/zoxamide/AMPEXIO 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>3</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.

<sup>2</sup> Schulte et al., UWSF (5) 261-266 (1999), Bewertungskriterien des Umweltbundesamtes: Auswirkungen von Pflanzenschutzmitteln auf terrestrische Arthropoden.

<sup>3</sup> Koch H, Weißer P and Landfried M (2003): Effect of drift potential on drift exposure in terrestrial habitats. Nachrichtenblatt Deut. Pflanzenschutzd., 55, 181-188.

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**Table 6.6-1: Assessment of the risk for non-target arthropods in off-field habitats due to the use of AMPEXIO in grapevines (00-001, 00-002), considering risk mitigation measures**

<b>Product:</b>		AMPEXIO						
<b>Intended use:</b>		00-001, 00-002						
<b>Application parameters:</b>		Grapevines, 3 x 0.5 kg/ha (8 d)						
<b>MAF:</b>		2.7						
<b>Scenario, drift percentile:</b>		Vines, 77 <sup>th</sup>						
<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.
					(g/ha)			
3	6.9	18.524	---	---	18.524	9.262	4.631	1.852
5	3.07	8.242	---	---	8.242	4.121	2.06	0.824
<b>Endpoint (g/ha):</b>		1800 (sublethal effects; <i>Chrysoperla carnea</i> , <i>Aleochara bilineata</i> )						
<b>TER acceptability criterion:</b>		10						
Buffer zone (m)					TER			
3					97	194	389	972
5					218	437	874	2184
<b>Risk mitigation measures:</b>			None					

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

### 6.6.1 Overall conclusions

TER values for non-target arthropods in off-field habitats were calculated, taking into account the relevant toxicity data for AMPEXIO and calculated exposure concentrations in off-field habitats, according to the intended uses of the product AMPEXIO in grapevines. The calculated TER values do achieve the acceptability criterion  $TER \geq 10$  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 AMPEXIO in grapevines according to the label.

### Consequences for authorisation

None



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

### 6.7.1 Toxicity data

Please refer to core assessment.

### 6.7.2 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>4</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.

#### 6.7.2.1 First-tier risk assessment

Germany does not follow the conclusion of the zRMS AT that the NOEC has to be set to 12.5 mg AMPEXIO/kg soil d.w. The threshold value for statistical not relevant but biologically relevant effects is very difficult to determine. Therefore Germany follows the conclusion of the applicant and uses a NOEC of 25 mg AMPEXIO/kg soil d.w.

**Table 6.7-1: 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 AMPEXIO in grapevines (00-001, 00-002)**

Intended use			
<b>Acute effects on earthworms</b>			
Product/active substance	LC <sub>50</sub> (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	TER <sub>a</sub> (criterion TER ≥ 10)
Mandipropamid	> 500 (corr.)	1.16	431
Zoxamide	> 267.5	0.76	352
<b>Chronic effects on earthworms</b>			
Product/active substance	NOEC (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	TER <sub>lt</sub> (criterion TER ≥ 5)
Mandipropamid	≥ 16 (corr.)	1.16	14
Zoxamide	0.25 (artificial soil) (corr.) 7 (natural soil)	0.76	<b>0.33</b>  9

<sup>4</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

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AMPEXIO	25	4.64	5.4
<b>Chronic effects on other soil macro- and mesofauna</b>			
<b>Product/active substance</b>	<b>NOEC (mg/kg dw)</b>	<b>PEC<sub>soil</sub> (mg/kg dw)</b>	<b>TER<sub>tt</sub> (criterion TER ≥ 5)</b>
Mandipropamid	> 10 ( <i>Folsomia candida</i> )	1.16	8.6
AMPEXIO	50 ( <i>Folsomia candida</i> )	4.64	10.8
AMPEXIO	500 ( <i>Hypoaspis aculeifer</i> )	4.64	108

TER values shown in bold fall below the relevant trigger.

### 6.7.2.2 Higher-tier risk assessment

Not relevant.

### 6.7.3 Overall conclusions

TER values for earthworms were calculated, taking into account the relevant toxicity data for mandipropamid/zoxamide/AMPEXIO and calculated exposure concentrations in soil, according to the intended uses of the product AMPEXIO in grapevines. The calculated TER values do achieve the acceptability criterion  $TER \geq 10$  for acute effects and the acceptability criterion  $TER \geq 5$  for chronic 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 AMPEXIO in grapevines according to the label.

### Consequences for authorisation

None

### 6.8 Effects on soil microbial activity (KCP 10.5)

Please refer to core assessment.

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

A risk assessment according to the recommendations of the “Guidance Document on Terrestrial Ecotoxicology” (SANCO/10329/2002) 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>5</sup>

For the basic toxicity data set with values for 6 plant species, an acceptability criterion  $TER \geq 10$  is used in the risk assessment for national authorisations in Germany. This takes account for the lack of information on chronic effects from the standard tests as well as the great diversity of the plant realm, for

<sup>5</sup> Füll et al., UWSF (11) 145-149 (1999), Prüfanforderungen des Umweltbundesamtes zur Bewertung der Auswirkungen von Pflanzenschutzmitteln auf terrestrische Pflanzen.

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which the test species stand as representatives. Due to a tendency towards large fields and intensive farming, plant biocoenoses in the German agricultural landscape typically have to be considered as highly vulnerable; hence, a high level of safety is required in the risk assessment to ensure that the legally defined protection goal is met.

**Table 6.9-1: Assessment of the risk for non-target terrestrial plants due to the use of AMPEXIO in grapevines (00-001, 00-002), considering risk mitigation measures**

<b>Active substance/product:</b>		AMPEXIO						
<b>Intended use:</b>		00-001, 00-002						
<b>Application parameters:</b>		Grapevines, 3 x 0.5 kg/ha (8 d)						
<b>MAF:</b>		2.3						
<b>Scenario, drift percentile:</b>		Vines, 77 <sup>th</sup>						
<b>Interception (off-crop):</b>		50 %						
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.
					(g/ha)			
3	6.9	39.453	---	---	39.453	19.726	9.863	3.945
5	3.07	17.554	---	---	17.554	8.777	4.388	1.755
<b>Endpoint (g/ha):</b>		ER <sub>50</sub> > 600 (seedling emergence)						
<b>TER acceptability criterion:</b>		10						
Buffer zone (m)					TER			
3					15	30	61	152
5					34	68	137	342
<b>Risk mitigation measures:</b>			None					

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

### 6.9.1 Overall conclusions

TER values for non-target terrestrial plants were calculated, taking into account the relevant toxicity data for AMPEXIO and calculated exposure concentrations in off-field habitats, according to the intended uses of the product AMPEXIO in grapevines. The calculated TER values do achieve the acceptability criterion  $TER \geq 10$  for effects on non-target plants, according to agreed EU Guidance in Document SANCO/10329/2002 rev 2 (as modified by specific German guidance) that insofar amends Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of AMPEXIO in grapevines according to the label.

### Consequences for authorisation

None

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

Please refer to core assessment.

**6.11            Classification and Labelling**

Please refer to core assessment.