

REGISTRATION REPORT

Part A

Risk Management

Product code: Cymoxanil 33% + Zoxamide 33% WG

Product name: **Lieto 66 WG**

Chemical active substances:

Cymoxanil, 330 g/kg

Zoxamide, 330 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT: Poland
(product re-registration)

Applicant: Sipcam Oxon S.p.A.

Submission date: 30/12/2020

MS Finalisation date: 01/06/2021

Revision date: December 2021

DATA PROTECTION CLAIM

Under Article 59 of Regulation 1107/2009/EC, the applicant claims data protection for these studies. The data protection status and corresponding justification as valid for the respective country is confirmed in the respective PART A.

STATEMENT FOR OWNERSHIP

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- following expiry of any period of exclusive use, by offering – in certain jurisdictions – mandatory compensation, unless the period of protection of the proprietary data concerned has expired.

Version history

When	What
30 th December 2020	Submission of initial Version 0 by the applicant.
21 st April 2021	Version revised by the applicant, highlighting in grey colour studies already evaluated during product authorisation and highlighting in green colour confirmatory-like studies which are under evaluation by the Latvia RMS for Zoxamide and concerned Member States in an interzonal procedure.
1 June 2021	Version evaluated by zRMS PL
December 2021	Revised version, addressing the comments of MSs and comments and supplements of the applicant .

Table of Contents

1	Details of the application	6
1.1	Application background	7
1.2	Letters of Access	8
1.3	Justification for submission of tests and studies	8
1.4	Data protection claims	8
2	Details of the authorisation decision	8
2.1	Product identity	8
2.2	Conclusion	9
2.3	Substances of concern for national monitoring	9
2.4	Classification and labelling	9
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	9
2.4.2	Standard phrases under Regulation (EU) No 547/2011	10
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	10
2.5	Risk management	10
2.5.1	Restrictions linked to the PPP	10
2.5.2	Specific restrictions linked to the intended uses	11
2.6	Intended uses (Poland)	12
3	Background of authorisation decision and risk management	14
3.1	Physical and chemical properties (Part B, Section 2)	14
3.2	Efficacy (Part B, Section 3)	14
3.4	Methods of analysis (Part B, Section 5)	21
3.4.1	Analytical method for the formulation	21
3.4.2	Analytical methods for residues	22
3.5	Mammalian toxicology (Part B, Section 6)	24
3.5.1	Acute toxicity	24
3.5.2	Operator exposure	25
3.5.3	Worker exposure	25
3.5.4	Bystander and resident exposure	26
3.6	Residues and consumer exposure (Part B, Section 7)	26
3.6.1	Residues	28
3.6.2	Consumer exposure	28
3.7	Environmental fate and behaviour (Part B, Section 8)	29
3.7.1	Predicted environmental concentrations in soil (PEC _{soil})	31
3.7.2	Predicted environmental concentrations in groundwater (PEC _{gw})	32
3.7.3	Predicted environmental concentrations in surface water (PEC _{sw})	32
3.7.4	Predicted environmental concentrations in air (PEC _{air})	33
3.8	Ecotoxicology (Part B, Section 9)	33
3.8.1	Effects on terrestrial vertebrates	33
3.8.2	Effects on aquatic species	33
3.8.3	Effects on bees	40
3.8.4	Effects on arthropod species other than bees	40
3.8.5	Effects on soil organisms	41

3.8.6	Effects on non-target terrestrial plants	42
3.8.7	Effects on other terrestrial organisms (Flora and Fauna).....	42
3.9	Relevance of metabolites (Part B, Section 10)	42
Appendix 1	Copy of the product authorisation	44
Appendix 2	Copy of the product label	45
Appendix 3	Letter of Access	46
Appendix 4	Lists of data considered for national authorisation	47

PART A

RISK MANAGEMENT

1 Details of the application

This document describes the acceptable use conditions of the plant protection product Cymoxanil 33% + Zoxamide 33 % WG (trade name Lieto 66 WG), a WG formulation containing 330 g/kg zoxamide and 330 g/kg cymoxanil, for re-registration in EU countries. The evaluation is required subsequent to the authorisation request under article 43 of regulation 1107/2009.

Cymoxanil 33% + Zoxamide 33 % WG is a product on the EU market. It is a fungicide that has been jointly developed by the companies Gowan Crop Protection Ltd. (legal successor of the company Gowan Comercio Internacional e Servicos Limitada) and Sipcam Oxon S.p.A. (legal successor of the company OXON Italia S.p.A.). Cymoxanil 33% + Zoxamide 33 % WG is a fungicide, for which re-registration according to article 43 of regulation 1107/2009 is requested after the renewal of zoxamide according to Regulation (EU) 2018/692 of 7 May 2018.

The aim of this step of the art. 43 process is to update the existing dossier information with regard to and limited to new information on the active substance zoxamide as follows:

- to comply with data requirements or criteria which were not in force when the authorisation of the plant protection product was granted and
- to demonstrate that the formulated product meets the requirements set out in the Regulation on the renewal of approval of the active substance zoxamide and to comply with provisions of article 29 of Regulation (EU) No. 1107/2009 thereof.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report Part B Sections 0-10 and Part C. The information, data and assessments submitted in Registration Report Parts B include assessment of further data or information as required for national registration by the EU review of the active substances. They also include assessment of data and information related to Cymoxanil 33% + Zoxamide 33 % WG where that data has not been considered in the EU review. Otherwise, assessments for the safe use of Cymoxanil 33% + Zoxamide 33 % WG have been made based on endpoints agreed in the EU review of zoxamide and Cymoxanil.

For the active substance **zoxamide** the company Gowan Crop Protection Ltd. (former name Gowan Comércio Internacional e Serviços, Limitada) as sole notifier submitted in 2014 a dossier to Latvia as RMS and France as co-RMS to support the renewal of approval of the active substance zoxamide on EU level. The final Renewal Assessment Report (RAR) was issued in 2017 together with the EFSA Peer Review Conclusion (2017) and the EC Renewal Report in 2018. Commission Implementing Regulation (EU) 2018/846 extended the approval until 31 January 2019, but on 1st of July 2018 the active substance zoxamide got renewal of approval in the EU until 30th of June 2033 according to Commission Implementing Regulation (EU) No 844/2012. The applicant - the company Gowan Plant Protection Ltd. - is the sole owner of all zoxamide data.

In its Peer Review Conclusion, EFSA (2017) identified data gaps, including those areas in which a study may have been made available during the peer review process but was not considered for procedural reasons. A first set of zoxamide, its metabolite's and impurities' studies has been provided to Latvia as interzonal RMS and all concerned MSs in July 2020. After consultation with EFSA, Latvia (as RMS for zoxamide AIR) agreed to take on this work and to review the additional zoxamide data in an interzonal procedure within art. 43 renewal of zoxamide products' authorisations according to Regulation (EC) No

1107/2009. A second set of active substance data will be provided to Latvia as RMS for zoxamide and zRMS for this interzonal procedure, as well as all concerned MSs beginning of 2021.

As such, Gowan Crop Protection Ltd. refers to the EU concluded data: The RAR Zoxamide (2017), EFSA Peer Review Conclusion (2017) and the EC Renewal Report in 2018. These documents are considered to provide the relevant summary of information on the active substance zoxamide and its metabolites – besides the data and information provided subsequently to Latvia and the cMSs for post AIR evaluation. All relevant active substance data are also provided within this application for the renewal of the product Cymoxanil 33% + Zoxamide 33 % WG.

In accordance with article 43 of Regulation (EC) No. 1107/2009, studies on zoxamide, its metabolites and the plant protection product are submitted, while exemption from the submission of studies applies for the active substance **cymoxanil** and its metabolites. Cymoxanil is currently under renewal on EU level.

This document describes the specific conditions of use for the re-registration of the product Cymoxanil 33% + Zoxamide 33 % WG after AIR of zoxamide.

Applicant details

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xxx
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xxx
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1.1 Application background

Cymoxanil 33% + Zoxamide 33 % WG is a fungicide, for which re-registration according to article 43 of regulation 1107/2009 is requested here on behalf of Gowan Crop Protection Ltd., UK. The same dossier is submitted by Gowan Crop Protection Ltd. and Sipcam Oxon S.p.A. for the renewal of authorisation of products in countries where they have identical GAP uses.

The dossier follows the data requirements of

- Regulation (EC) No. 544/2011 for the active substance cymoxanil,
- Regulation (EC) No. 283/2013 for the active substance zoxamide and
- Regulation (EC) No. 284/2013 for the plant protection product Cymoxanil 33% + Zoxamide 33% WG.

This document describes the specific conditions of use for the re-registration of the product Cymoxanil 33% + Zoxamide 33 % WG after AIR of zoxamide.

In accordance with article 43 of Regulation (EC) No. 1107/2009, studies on zoxamide, its metabolites and the plant protection product are submitted, while exemption from the submission of studies applies for the active substance cymoxanil and its metabolites. Cymoxanil is currently under renewal on EU level.

This dossier contains the consolidated version of the previous assessment for the parts which do not require a re-evaluation, including all assessment and data on Cymoxanil. The consolidated text has been shaded in grey in the present dRR section

1.2 Letters of Access

A Letter of Access of the company Gowan Crop Protection Ltd. grants the right to Sipcam Oxon SpA to refer to their active substance data and the other way around.

1.3 Justification for submission of tests and studies

All studies and data provided with this application are requested by current guidelines for authorisation of a plant protection product in EU countries.

All new vertebrate studies on the active substance zoxamide were requested by EFSA (2017) in their Peer Review Conclusion under point 7 (data gaps) after review of the AIR data and consultation with the EU Member State's experts. The studies have been started after consultation with the zRMSs and the RMS Latvia.

1.4 Data protection claims

According to Article 59 of Regulation 1107/2009/EC, Gowan Crop Protection Ltd. claims data protection for all denoted studies in the List of References in Appendix 4 of this document as well as for all summary documents of the dossier (Part A, B and C). Gowan Crop Protection Ltd. holds all proprietary rights on these study reports and summary documents.

2 Details of the authorisation decision

2.1 Product identity

Product code	GWN-9823
Synonym	Cymoxanil 33% + Zoxamide 33% WG
Product name in MS /Authorisation number	Lieto 66 WG (Auth. No. R-163/2015)
Function	Fungicide
Applicant	Sipcam Oxon SpA
Active substance(s) (incl. content)	Cymoxanil 330 g/kg Zoxamide 330 g/kg
Formulation type	Water dispersible granules [WG]
Packaging	The formulated product (WG formulation) is intended for containment in cardboard boxes of 0.2, 0.5, 1, 2.5 and 5 kg, containing a heated sealed PA/ALU/PE bag (sealing of cardboard box with points of glue, not reclosable), and will be distributed in cartons (outer packaging) at 50 x 0.2 kg, 10 x 0.5 kg, 10 x 1 kg, 4 x 2.5 kg or 4 x 5 kg. The boxes are not returnable. They are intended for professional use
Coformulants of concern for national authorizations	None

Restrictions related to identity	None.
Mandatory tank mixtures	None
Recommended tank mixtures	None.

2.2 Conclusion

The evaluation of the application for product Cymoxanil 33% + Zoxamide 33% WG (Lieto 66 WG) resulted in the decision to grant the authorization.

All uses applied for were authorised

2.3 Substances of concern for national monitoring

None.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Acute toxicity, Cat. 4 Skin sensitization, Cat. 1 Reproductive toxicity, Cat. 2 Specific target organ toxicity (repeated exposure), Cat. 2 Aquatic Acute 1 Aquatic Chronic 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet.

Hazard pictograms:	GHS07, GHS08, GHS09
Signal word:	Warning!
Hazard statement(s):	H302 - Harmful if swallowed H317 - May cause an allergic skin reaction H361fd – Suspected of damaging fertility. Suspected of damaging the unborn child H373 – May cause damage to organs (blood, thymus) through prolonged or repeated exposure H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
Precautionary statement(s):	P101- If medical advice is needed, have product container or label at hand. P102 - Keep out of reach of children. P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood P261 - Avoid breathing mist/vapours/spray. P264 - Wash hands thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P272 - Contaminated work clothing should not be allowed out of the workplace P273 - Avoid release to the environment, if this is not the intended use.

	<p>P280 - Wear protective gloves/protective clothing/eye protection/face protection. P301+P312 - IF SWALLOWED: Call a POISON CENTER / doctor if you feel unwell P302+P352 IF ON SKIN: Wash with plenty of water and soap. P308+P313 - IF exposed or concerned: Get medical advice/attention P330 - Wash mouth P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention P362+P364 Take off contaminated clothing and wash it before reuse. P333+P317 If skin irritation or rash occurs: Get medical help. P391 - Collect spillage P405 - Store locked up P501 - Dispose of contents/container in accordance with local/regional/national/international regulations..</p>
Additional labelling phrases:	<p>To avoid risks to man and the environment, comply with the instructions for use. [EUH401] Contains zoxamide and cymoxanil</p>

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	

See Part C and Part B Sections 6 and 9 for justification of the classification and labelling proposal.

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
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2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
	<p>Potatoes field , tractor mounted spraying devices: Normal work wear M/L+A</p> <p>* Due to the product classification (H317), normal work wear is recommended during M/L+A and gloves are generally proposed for mixing loading and maintenance</p>
Worker protection:	
	Potatoes field: Normal work wear
Bystander protection:	

	None
Resident protection:	
	None
Integrated pest management (IPM)/sustainable use:	
	None.
Environmental protection	
	For the intended worst-case GAP uses of zoxamide on potato fields (with 3 x 0.45 kg prod./ha) the implementation of the following measures is necessary: <ul style="list-style-type: none"> For potatoes a 10 m vegetated buffer zone.
Other specific restrictions	
	None.

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

Integrated pest management (IPM)/sustainable use:	
	The product is classified as non-hazardous to honey bees. The product is classified as non-hazardous to bumble bees. The product is classified as non-hazardous to <i>Chrysoperla</i> . The product is classified as non-hazardous to <i>T. pyri</i> . The product is classified as non-hazardous to <i>Aphidius</i> . The product is classified as non-hazardous to <i>Orius</i> .

2.5.2 Specific restrictions linked to the intended uses

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

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	None.	-
Environmental protection:		Relevant for use no.
-	None.	-

2.6 Intended uses (Poland)

GAP rev. 0 date: 2020 December

PPP (product name/code): Cymoxanil 33% + Zoxamide 33 % WG / Lieto 66 WG

Formulation type: WG ^(a, b)

Active substance 1: Zoxamide

Conc. of as 1: 330 g/kg

Active substance 2: Cymoxanil

Conc. of as 2: 330 g/kg

Safener: --

Conc. of safener: -- (c)

Synergist: --

Conc. of synergist: -- (c)

Applicant: Sipcam Oxon S.p.A.

Professional use: ☒Zone(s): Central ^(d)Non professional use: ☐

Verified by MS: no

Field of use: fungicide

[illegible]

Remarks table heading:	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008 (c) g/kg or g/l	(d) Select relevant (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1 (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1 Numeration necessary to allow references 2 Use official codes/nomenclatures of EU Member States 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure) 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application 8 The maximum number of application possible under practical conditions of use must be provided. 9 Minimum interval (in days) between applications of the same product 10 For specific uses other specifications might be possible, e.g.: g/m ³ 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 equipment (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”. 13 PHI - minimum pre-harvest interval 14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a granular formulation with a characteristic odour. It has a tap density of 0.650 g/L (20 °C). A 1 % aqueous solution of the preparation has a pH of 6.84. It is not explosive, highly flammable, auto-flammable or oxidizing. The product is stable over 14 days at 54°C in the commercial packaging (cardboard box, containing a heated sealed aluminised bag; sealing of cardboard box with points of glue; not reclosable), the compatibility of the formulation in a 1 kg box has been proven. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in the commercial packaging (i.e. 1 kg cardboard box). Storage stability after 24 months at ambient temperature resulted in physical-chemical properties comparable to those of a fresh sample. Its technical characteristics are acceptable for a WG formulation; they are such that no particular problems are expected when it is stored in the intended commercial packaging and used as recommended.

3.2 Efficacy (Part B, Section 3)

The present application is for the renewal of the authorisation of the product Cymoxanil 33% + Zoxamide 33% WG after the renewal of the active ingredient Zoxamide (Reg. (EU) 2018/692).

The product has a long history of safe use and, considering that the GAP remains unchanged, only the assessment of resistance needs to be updated.

3.3 Efficacy data

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

EPPO guideline number	Title
EPPO guideline PP 1/213 (2)	Resistance Risk Analysis

Cymoxanil 33% + Zoxamide 33% WG, a Water dispersible Granules (WG) formulation, containing 330 g/Kg of cymoxanil and 330 g/Kg of zoxamide, is intended for use as a fungicide for control of Late blight (*Phytophthora infestans*) in potato and tomato, *Phytophthora* species in aubergine and Downy mildew (*Plasmopara viticola*) in grapevine.

For the supported uses, the maximum label rates of CYMOXANIL 33% + ZOXAMIDE 33% WG are 0.35 Kg, 0.4 Kg or 0.45 Kg product/ha, with a maximum of 2 or 3 applications per season dependent on crop and country, made within the crop growth stage range of 13-89 (BBCH) and with minimum intervals between applications of 7-10 days and applications made in water volumes of 200-1000 L/ha.

Mode of action

Cymoxanil

Cymoxanil is a cyanoacetamide-oxime fungicide with an unknown mode of action (MoA Group U; FRAC code 27). Whilst the primary mode of action and target site of cymoxanil is unknown, it has been proposed to inhibit nucleic acid synthesis, reduce membrane permeability and mycelial respiration and

disrupt cysteine, glycine and serine synthesis. This leads to inhibition of mycelial and germ tube growth and reduced sporulation. Cymoxanil is rapidly taken up by the leaves and has local systemic activity, giving preventative and curative control during the incubation period and prevents the appearance of disease symptoms on the crop.

Zoxamide

Zoxamide belongs to the benzamide group of chemistry (toluamides) that inhibit mitosis and cell division by targeting β -tubulin assembly in mitosis (MoA Group B3; FRAC code 22), thereby preventing proper functioning of the cytoskeleton through direct interactions with β -tubulin polymerisation. By binding to and penetrating the cuticle, zoxamide inhibits the formation of zoospores within the sporangia, preventing fungal penetration of the host plant cells to give preventive control. Additionally, there is some evidence that zoxamide can reduce the number of viable motile zoospores¹.

Mechanism of resistance

Cymoxanil

Despite widespread use to control the disease in potatoes over a number of years, there are no recorded cases of Late blight (*Phytophthora infestans*) resistance to cymoxanil to date. Sensitivity testing of isolates of *Phytophthora infestans* for different fungicides by Gui-ning ZHU *et al.*, 2008 and P. Leroux *et al.*, 1987, found none to be resistant to cymoxanil.

Shifts in the sensitivity of downy mildew (*Plasmopara viticola*) of grapevine to cymoxanil has been reported in Italy and France (Guillino *et al.*, 1997). As the mode of action of cymoxanil is as yet unknown, the mechanism of this resistance has not been established.

Zoxamide

Laboratory studies conducted by Young *et al.*, 2001 unsuccessfully attempted to generate mutants of *Phytophthora capsici* and *Phytophthora infestans* with resistance to zoxamide by mycelial adaptation on fungicide-amended medium. The authors concluded that failure to isolate mutants resistant to zoxamide results from the diploid nature of the Oomycetes and the possibility that target-site mutations would produce a recessive phenotype. This indicates that the risk of a highly resistant pathogen population developing rapidly in the field is much lower for zoxamide compared to different mode of action single site inhibitors. In a more recent study, a laboratory generated zoxamide resistant strain of *Phytophthora capsici* was found to be controlled by two recessive, non-target site genes, and resistance required at least one pair of alleles to be homozygous².

In the absence of any known cases of resistance to zoxamide, potential mechanisms of resistance have therefore not been identified.

Evidence of resistance

Cymoxanil

According to the FRAC list of first confirmed cases of plant pathogenic organisms resistant to disease control agents (revised May 2020), there is no evidence of resistance against *Phytophthora infestans* in potato and tomato or *Phytophthora* species in aubergine to cymoxanil despite widespread use of this active substance in products approved and widely used for the control of this disease in EU countries and other parts of the world for a number of years.

¹ Edmonds J, Young D (2004) Studies on the Mechanism of Tuber Blight Control by Zoxamide: Investigations into Effects on Sporangia and Zoospores of *Phytophthora*. PPO-Special Report no 10: 165

² Yang B, Chen L, Cai, M *et al.* (2014) Two Non-target Recessive Genes Confer Resistance to the Anti-Oomycete Microtubule Inhibitor Zoxamide in *Phytophthora capsici*. PLoS ONE 9(2):e89336
doi:10.1371/journal.pone.0089336

Evidence of resistance to cymoxanil in *Plasmopara viticola* in grapevine was first reported in vineyards in Italy in 1997³ and cases of reduced sensitivity to cymoxanil have been found to occur in other countries, including France and Portugal. However, with management of the resistance risk by use in mixtures and programs with active substances with other modes of action, products that include cymoxanil in co-formulation with other active substances continue to give good performance against *Plasmopara viticola* in the field even on populations shown to be less sensitive to cymoxanil in leaf disc assays and cymoxanil continues to effectively contribute to control of this disease despite shifts in sensitivity that may have occurred in some areas.

Zoxamide

list of first confirmed cases of plant pathogenic organisms resistant to disease control agents (revised May 2020), there is no evidence of resistance having developed in the field in any target diseases in potato, grapevine, tomato, Cucurbit crops (both edible and non-edible peel) or Allium crops to zoxamide MoA despite widespread use of this active substance in products approved and widely used for the control of these diseases in EU countries and other parts of the world for a number of years.

Cross resistance

Cymoxanil

To date, there is no evidence of isolates of PLASVI with reduced sensitivity to cymoxanil having multiple resistance to other modes of action. There are no recorded cases of resistance of *Phytophthora* species to the MoA of cymoxanil and isolates of these pathogens with resistance to other modes of action do not exhibit reduced sensitivity to cymoxanil.

Zoxamide

With no recorded cases of resistance of fungal pathogens to zoxamide in the field, there is no cross resistance between zoxamide and ethaboxam, the only other fungicide within the same mode of action group (MoA code B3, FRAC Group 22), or with any other fungicidal mode of action groups, where resistance exists.

Sensitivity data

Cymoxanil

Whilst no new data are summarised on sensitivity of target diseases to cymoxanil, products containing this active substance have been used over a number of years and continue to give consistent efficacy in the field. There is no evidence of a significant shift in sensitivity of PHYTIN to cymoxanil in the field and despite some evidence of reduced sensitivity to cymoxanil in populations of PLASVI in certain parts of southern Europe, products containing cymoxanil still provide effective control of this disease in grapevine.

Zoxamide

***Phytophthora infestans* (PHYTIN)**

The sensitivity of *Phytophthora infestans* isolates to zoxamide has been continuously monitored across Europe before and following the testing in trials and subsequent approval of products containing this active substance.

The sensitivity of PHYTIN to zoxamide has been tested on a total of 426 isolates, either laboratory strains or from commercial crops and field trials across countries in Europe in 1 study carried out between 1993 and 2014.

³ Sensitivity to cymoxanil in populations of *Plasmopara viticola* in northern Italy. M. L. Gullino *et al*, 1997

Initially, sensitivity tests conducted between 1997 and 2003 were carried out using an *in vivo* potato leaf disc method, with the *in vivo* leaf disc method then tested alongside a more reliable *in vitro* poisoned agar technique from 2000-2004, with the latter then being the sole method used to test isolates from 2004 onwards and also 1 isolate tested in 1997.

A total of 33 laboratory isolates, 20 isolates from commercial crops and 326 isolates from field trials carried out across 13 European countries (Belgium, France, Germany, Greece, Republic of Ireland, Italy, the Netherlands, Poland, Portugal, Romania, Spain and the British Isles, including the United Kingdom and Jersey) were tested for sensitivity to zoxamide.

Data on zoxamide sensitivity of PHYTIN isolates across all monitoring studies carried out between 1993 and 2014 are summarised in Table -1.

Table -1: Summary of zoxamide sensitivity data for PHYTIN isolates treated with zoxamide compared to those from untreated plots in field trials or laboratory isolates never previously exposed to zoxamide

PHYTIN isolate type	Total no. of isolates	<i>In vivo</i> test method		<i>In vitro</i> test method	
		No. of isolates	Mean MIC (mg zoxamide/L)	No. of isolates	Mean EC ₅₀ (µg zoxamide/L)
Non-zoxamide treated (baseline lab isolates)	33	33	3.4	0	-
Non-zoxamide treated	187	100	8.2	109	19.3
zoxamide treated	112	55	9.4	75	18.3
Not known	47	17	13.6	37	18.7

Across 33 isolates that had never previously been exposed to zoxamide and 172 isolates collected from field trials that were tested between 1997 and 2003 using the *in vivo* method, MIC values ranged from 0.5 to >40 mg zoxamide/L.

Across 221 isolates tested using the *in vitro* method, one in 1997 and all others between 2000 and 2014, EC₅₀ values ranged from 1 to 88 µg/L.

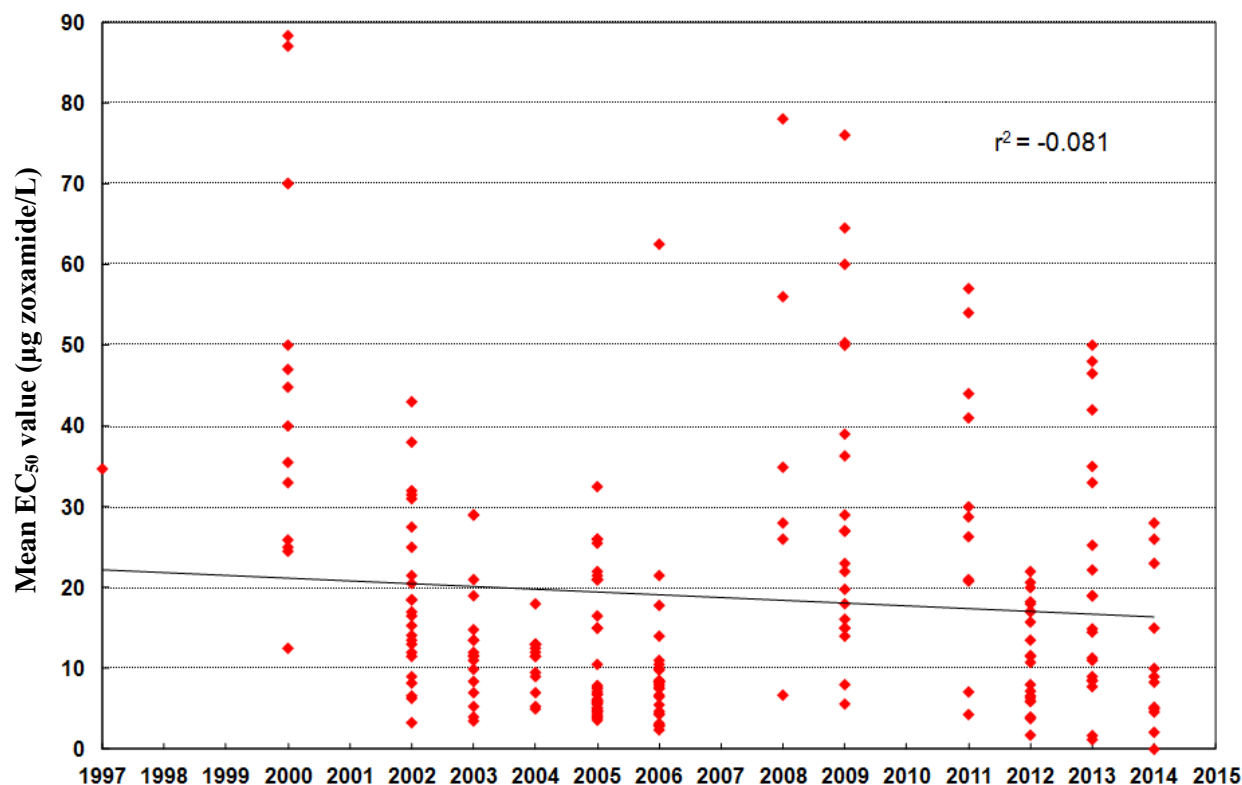
Between tests, the overall sensitivity of PHYTIN isolates from crops treated with zoxamide was no different to that of laboratory isolates and those from crops in untreated plots of field trials that had never been previously exposed to zoxamide.

Zoxamide sensitivity data for PHYTIN isolates from screening carried out across Europe in 1997 (1 isolate) and between 2000 and 2014 using the more reliable *in vitro* test method are summarised by country in Table -2, with data by year presented in graphical form in Figure -1.

Table -2: Summary of zoxamide sensitivity data generated using the *in vitro* method for isolates collected across 12 European countries in 1997 (1 isolate) and between 2000 and 2014

Country of origin – PHYTIN isolates	Years collected	No. of isolates tested (<i>in vitro</i> method)	EC ₅₀ values (µg zoxamide/L)		
			Mean	Min-max	S.D.
Belgium	2013	1	33.0	-	-
France	1997, 2000, 2002, 2003, 2004, 2005, 2006, 2009, 2011, 2012, 2013, 2014	62	19.6	4.3-87	13.84
Germany	2002, 2003, 2004, 2005, 2012	11	10.7	3.3-31.5	9.00
Greece	2003, 2004, 2005	12	8.9	4-19	4.81
Republic of Ireland	2009	6	43.3	15-64.5	20.86
Netherlands	2000, 2004, 2006, 2009, 2014	9	32.4	4.4-70	26.06
Poland	2003	4	6.5	3.5-11.5	3.67
Portugal	2000	3	25.1	24.5-25.9	0.71
Romania	2004, 2005	4	9.1	5.8-13	3.72
Spain	2000	1	12.5	-	-
UK – England	2000, 2003, 2005, 2006, 2012, 2013, 2014	50	14.2	1.2-88.3	14.89
UK – Scotland	2005, 2006, 2013	18	22.9	1.7-62.5	13.41
UK - Wales	2000, 2006, 2009, 2011, 2013, 2014	24	20.9	0.98-76	21.64
UK – Northern Ireland	2003, 2008, 2009	11	30.5	6.7-78	21.05
Jersey	2005	5	5.9	3.6-7.1	1.38

Figure -1: Zoxamide sensitivity (EC_{50} , $\mu\text{g zoxamide/L}$) of *Phytophthora infestans* isolates over time



Data shows that the variation in mean sensitivity levels between individual countries are within the normal sensitivity range for zoxamide and clearly demonstrate that there has been no consistent trend or shift in the sensitivity of PHYTIN isolates to zoxamide in the field over time across Europe.

Based on all presented sensitivity monitoring data and with no evidence of reduced efficacy of products containing zoxamide in the field, it can therefore be concluded that there have been no consistent changes in zoxamide sensitivity amongst field populations of PHYTIN since products containing this active substance were first introduced in Europe.

Plasmopara viticola (PLASVI)

The sensitivity of PLASVI to zoxamide has been tested on a total of 406 isolates from commercial crops and field trials across countries in Europe (343 from France, 13 from Italy, 16 from Portugal, 34 from Spain) in 7 studies carried out between 2013 and 2017.

Fresh sporulations were produced from sampled leaves and sporangia collected into solution which were then inoculated onto Petri dishes and the sensitivity of each isolate tested at rates 1 and 3 mg zoxamide/L, with those that were not sensitive to 3 mg/L then tested at a 3 mg/L rate.

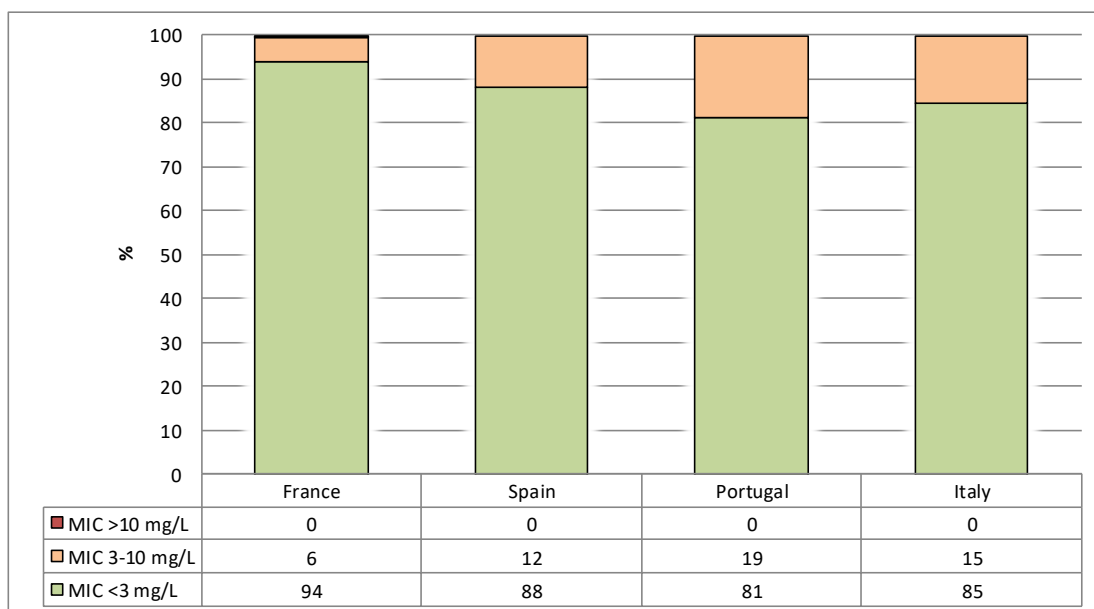
Percentage distributions of the isolates between those for which minimum inhibitory concentrations were <3, 3-10 and >10 mg zoxamide/L for the 406 isolates tested between 2013 and 2017 are presented in graphical form by year in Figure -2 and by country in

Figure -3.

Figure -2: Percentage distribution of PLASVI isolates between those with MIC values of <3, 3-10 and >10 mg zoxamide/L) by year based on data on 406 isolates tested in sensitivity monitoring studies carried out between 2013 and 2017 across 4 main grapevine growing countries in Europe (France, Italy, Portugal, Spain)



Figure -3: Percentage distribution of PLASVI isolates between those with MIC values of <3, 3-10 and >10 mg zoxamide/L) by country based on data on 406 isolates tested in sensitivity monitoring studies carried out between 2013 and 2017 across 4 main grapevine growing countries in Europe



Of the total of 406 isolates tested across these studies carried out between 2013 and 2017, 377 (92.9%) were highly sensitive (MIC of <3 mg/L) to zoxamide and 28 (6.9%) were slightly less sensitive (MIC of 3-10 mg/L). Only 1 of the 406 isolates (0.2%) was indicated to more tolerant (MIC of >10 mg/L) and potentially exhibiting a level of resistance to zoxamide. This isolate was one of those sampled in 2014 from a vineyard in the Charentes region of France. The other 16 isolates from vineyards in the same region in 2014 and also those in the previous year (6 isolates) and following year (8 isolates) were all sensitive. It is therefore considered unlikely that the apparent higher tolerance to zoxamide of the single isolate with was attributable to developed resistance.

There was no consistent trend of the sensitivity of PLASVI isolates to zoxamide changing between 2013 and 2017, with the majority (87-99%) being highly sensitive (MIC of <3 mg/L) in each of the 5 years.

Although the numbers of isolates tested in each of the 4 countries was disproportionate, with far higher numbers tested in France than the other countries, the data shows no consistent differences in sensitivity between countries.

Based on all presented sensitivity monitoring data and with no evidence of reduced efficacy of products containing zoxamide in the field, it can therefore be concluded that there have been no consistent changes in zoxamide sensitivity amongst field populations of PLASVI between 2013 and 2017.

Resistance risk assessment of unrestricted use pattern

According to FRAC Pathogen Risk List[®] 2014, the risk of resistance developing to fungicides for the target diseases can be considered as **medium (2)** for PHYTIN and PHYTSP and **high (3)** for PLASVI.

There is no evidence of resistance of any fungal pathogens to cymoxanil MoA, with the exception of evidence of a shift in sensitivity of PLASVI in some regions of southern Europe. The resistance risk relating to the MoA of cymoxanil is therefore considered to be **medium (4)**.

With the exception of resistance of PHYTCP to zoxamide that was characterised in a laboratory study and from which it was surmised that the potential for resistance occurring to this pathogen in the field was low to medium, there is no evidence of resistance to zoxamide MoA in any other fungal diseases despite widespread use of this active substance against a range of different pathogens in EU countries and other parts of the world for a number of years. The risk of resistance relating to zoxamide is therefore considered to be **low-medium (1-4)**.

As CYMOXANIL 33% + ZOXAMIDE 33% WG is a co-formulated mixture containing two active ingredients with two different modes of action and therefore, the overall risk arising from the use of such a co-formulation is considered to be **low-medium (2)** as they reduce the exposure and hence selection pressure on disease pathogens.

A more complex scheme of risk interactions, involving agronomic risk is determined by the geographical area in which the crop is grown, the crop variety, the expected disease pressure in that area and the disease control practices used, for example, application number and timing. The disease control practices are particularly important because these factors can be modified by growers and advisors and are also influenced by precautionary statements on fungicide labels. Thus use of resistant varieties, crop-rotation, following good agronomic practice and maintaining plant hygiene, reduces the risk of resistance arising. Season-long spray programs are used for control of target diseases of GWN-9823, in which fungicides with different modes of action are used in sequences and mixtures in commercial practice. The risk of resistance relating to agronomic practices is therefore considered as **medium (0.5)**.

Based on available criteria, the overall risk of resistance arising from an 'unrestricted use pattern' of CYMOXANIL 33% + ZOXAMIDE 33% WG is therefore **low (2-3)** with respect to all target diseases (PHYTIN, PHYTSP, PLASVI).

Management strategy

The risk management strategy to reduce the risk of resistance developing to zoxamide from the use of CYMOXANIL 33% + ZOXAMIDE 33% WG is based on Good Agricultural Practices (GAP) and current measures advocated by FRAC.

The risk management strategy to reduce the risk of resistance developing to directly from the use of CYMOXANIL 33% + ZOXAMIDE 33% WG is specifically based on:

- The combination of 2 active substances with different modes of action in the co-formulation
- Application at the label rates for each use, as those giving effective control
- Maximum numbers of applications per season of 2 (France) or 3 (Bulgaria, Croatia, Greece, Italy, Spain, Portugal) in grapevine and 3 in potato, tomato and aubergine
- Use in tank mixture with other fungicides with different modes of action and as part of spray programs in sequences with other fungicides

This should ensure there is no adverse shift in the sensitivity of the target fungal pathogens to the active ingredient included in the product and the overall risk of resistance developing to zoxamide is therefore considered to be low and acceptable for all uses when CYMOXANIL 33% + ZOXAMIDE 33% WG is applied according to label recommendations.

In addition to the preventive management of risk of resistance, the applicant is committed to maintaining its monitoring (investigation of claims of reduced efficacy and suspected resistance, followed by sensitivity testing) and to reporting any developments related to the efficacy of CYMOXANIL 33% + ZOXAMIDE 33% WG based on resistance arising to cymoxanil or zoxamide to the relevant organisations.

3.3.2 Adverse effects on treated crops

The product is currently authorised and the present application is intended for the renewal of the authorisation. Effects are not expected as the product has a long history of safe use and no adverse effects were reported during years.

3.3.3 Observations on other undesirable or unintended side-effects

The product is currently authorised and the present application is intended for the renewal of the authorisation. Undesirable or unintended side-effects are not expected as the product has a long history of safe use and no adverse effects were reported during years.

3.4 Methods of analysis (Part B, Section 5)

Sufficiently sensitive and selective analytical methods are available for the determination of the active substance(s) in the plant protection product and the determination of impurities in the technical active substance material.

3.4.1 Analytical method for the formulation

A HPLC-UV method together with a confirmatory LC-MSMS-method is available for the determination of zoxamide and cymoxanil in the presence of each other and the co-formulants of the WG formulation Cymoxanil 33% + Zoxamide 33 % WG (method no. 24718), which complies with SANCO/3030/99 rev. 5 (2019).

Zoxamide is a racemate comprising equimolar amounts of (R)- and (S)-zoxamide. With this method, it is also possible to check the ratio of the enantiomers of the racemate zoxamide in the formulated product when applying a chiral column.

3.4.2 Analytical methods for residues

All provided analytical methods are acceptable.

It is referred to the EU concluded methods available for the active substances cymoxanil and zoxamide. Besides, the applicant provides a set of pre- and post-authorisation methods for the active substances and – in case of zoxamide – their potentially relevant metabolites.

The pre-authorisation methods to support the plant residue studies are summarised in the following.

Cymoxanil

For cymoxanil the following EU concluded methods are available on EU level :

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	GC-NDP: LOQ = 0.04 mg/kg in potato, grape and tomato 0.1 mg/kg hop GC-NPD: LOQ = 0.05 mg/kg in commodities with high water content (potato, lettuce)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No residue definition is proposed, therefore no analytical method is required
Soil (analytical technique and LOQ)	HPLC-UV: LOQ = 0.01 mg/kg
Water (analytical technique and LOQ)	HPLC-UV: LOQ = 0.1 µg/L (drinking and surface water) An analytical method for IN-KQ960 in surface with an LOQ lower than 0.3 mg/L and in ground water with an LOQ of 0.1 µg/L is required
Air (analytical technique and LOQ)	HPLC-UV: LOQ = 0.46 µg/m ³
Body fluids and tissues (analytical technique and LOQ)	Cymoxanil is not classified as toxic or highly toxic, therefore no analytical method is required

Zoxamide

For zoxamide, the following EU concluded methods are available :

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	<p>Zoxamide in potato (tuber, chips and flakes), grapes (berries, juice, wine and raisins), lettuce, dry bean and oilseed rape seed:</p> <p>QuEChERS multi-residue method, LC-MS/MS.</p> <p>LOQ: 0.01 mg/kg</p> <p>ILV: Potato tuber, grape vine and lettuce – LOQ 0.01 mg/kg</p> <p>RH-141455 and RH-141452 in potato:</p> <p>LC-MS/MS</p> <p>LOQ: 0.01 mg/kg in potato tubers and 0.05 mg/kg in potato chips and flakes for both metabolites</p> <p>ILV: data gap</p>
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Pending, data gaps identified
Soil (analytical technique and LOQ)	LC-MS/MS, LOQ: 0.05 mg/kg determining zoxamide
Water (analytical technique and LOQ)	<p>Drinking and surface water: LC-MS/MS, LOQ: 0.1 µg/L determining zoxamide</p> <p>ILV: Drinking water, LOQ: 0.1 µg/L for determining zoxamide</p>
Air (analytical technique and LOQ)	LC-MS/MS, LOQ: 90 µg/m ³
Body fluids and tissues (analytical technique and LOQ)	Data gap

In addition, a new method for the determination of residues of zoxamide in body fluids (urine) and tissues (bovine liver), with QuEChERS extraction procedure and LC-MS/MS detection has been validated according to SANCO 825/00 rev. 8.1 (2010) in Report No. FF/17/002. The method allows the determination of zoxamide in (human) urine and (bovine liver) tissue with an LOQ of 0.05 mg/L and 0.1 mg/kg, respectively.

A new method for the determination of zoxamide and its metabolites via HPLC-MS/MS and HPLC-HRMS/MS in grape fruit, potato tuber, tomato fruit, cucumber fruit, and onion bulb raw agricultural and relevant processed commodities has been developed and provided (Report No. BPL-STUDY-18-000085). It has been fully validated in compliance with SANCO/825/00 rev. 8.1 and SANCO/3029/99 rev. 4. The extraction efficiency of the analytical method has been verified according to SANTE 2017/10632 rev. 3. With this method, it is possible to determine the analytes zoxamide (sum, R/S), RH-150721 (sum, R/S), RH-129151 (sum, R/S), RH-141288 (sum, R/S), RH-127450 (sum, R/S), RH-149736, RH-149737, RH-24549, RH-139432, RH-141452 and RH-141455. All 5 pairs of chiral analytes were separated to receive their single enantiomers by chiral chromatography. For metabolite RH-129151 - due to the lack of single isomer analytical standards - it was impossible to attribute the absolute configuration (R) and (S) to the measured peaks. Therefore, the 2 enantiomers were assigned in the following as "RH-129151 A" (the first enantiomer eluted in the chromatographic runs) and "RH-129151 B" (the second enantiomer eluted in the chromatographic runs). The metabolites RH-141452, RH-141255 and RH-149737, which are known to form sugar conjugates, can be determined after an additional alkaline hydrolysis step according to the QuEChERS method for the simultaneous determination of acidic pesticides, their esters and conjugates

following alkaline hydrolysis. It allows to quantitatively hydrolyse of potential conjugates of zoxamide metabolites.

This highly specific HPLC-MS/MS method for the determination of zoxamide and its metabolites in grape, potato, tomato, cucumber, and onion has been validated according to SANCO/825/00 rev. 8.1 (2010) and SANCO/3029/99 rev. 4 (2000) at an LOQ of 0.01 mg/kg (for analytes with a chiral centre this limit is referred to the sum of the 2 enantiomers; i.e. the LOQ for each enantiomer is 0.005 mg/kg).

3.5 Mammalian toxicology (Part B, Section 6)

The active substances show the following toxicologically relevant properties:

Common Name	Zoxamide	Cymoxanil
CAS-No.	156052-68-5	57966-95-7
Classification and proposed labelling		
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Skin Sens. 1, H317	Acute Oral Tox. cat.4; Skin Sens. cat.1; STOT RE cat.2; Repr. Cat.2 GHS07; GHS08 Warning H302 H317 H373 H361fd
Additional C&L proposal	--	--
Agreed EU endpoints		
AOEL systemic	0.3 mg/kg bw/d based on a 90-day dog study (60 % oral absorption) and a safety factor of 100	0.01 mg/kg bw/d (corrected for 75% oral absorption)
Reference	EFSA Peer Review Conclusion (2017)	EFSA Scientific Report (2008) 167, 1-116
Acute Acceptable Operator Exposure Level (AAOEL)	Not allocated, not necessary.	Not allocated, not necessary.
Reference	EFSA Peer Review Conclusion (2017)	EFSA Scientific Report (2008) 167, 1-116
Conditions to take into account/critical areas of concern with regard to toxicology		
	None. *	The operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment;
Reference	Final EC Renewal Report (SANTE/10052/2018 rev. 2, 2018)	EFSA Scientific Report (2008) 167, 1-116

3.5.1 Acute toxicity

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat (OECD 401)	1469 mg/kg bw	YES	H302	xxx, 1999; report no. 99R-102

LD ₅₀ dermal, rat (OECD 402)	> 5000 mg/kg bw	YES	None	xxx, 1999; report no. 99R-103
LC ₅₀ inhalation (OECD 403)	> 4.4 mg/L air	YES	None	xxx, 1999; report no. 99R-106
Skin irritation, rabbit (OECD 404)	Non-irritant	YES	None	xxx, 1999; report no. 99R-104
Eye irritation, rabbit (OECD 405)	Non-irritant	YES	None	xxx, 1999; report no. 99R-105
Skin sensitisation, guinea pig (OECD 406, M&K)	Sensitising	YES	H317	xxx, 1999; report no. 99R-107
Supplementary studies for combinations of plant protection products	No data - not required		--	--

3.5.2 Operator exposure

The operator exposure for the intended GAP uses of CYMOXANIL 33% + ZOXAMIDE 33% WG is below the limit of 100% AOEL for single active ingredients and combined (additive) effects if the following PPEs are taken into account:

Potatoes (max. 3x 0.45 kg product/ha in 200 L/ha water at 7 days interval)

- Tractor-mounted boom sprayer, downwards
⇒ Work wear during mixing/loading and application

Assuming the skin sensitizing properties of the formulated product CYMOXANIL 33% + ZOXAMIDE 33%, gloves are generally proposed for mixing loading and maintenance and normal working clothing for application.

zRMS PL: The estimated exposure of operator applying Cymoxanil 33% + Zoxamide 33% WG (Lieto 66 WG) to low crops (potatoes) at dose of 0.45 kg of product/ha (0.1485 kg of each a.s./ha) using tractor-mounted boom spayer and wearing work clothing (long sleeved shirt, long trousers, sturdy boots) during mixing/loading and application to each of the two active substances of Cymoxanil 33% + Zoxamide 33% WG (Reboot) calculated with the EFSA AOEM amounted for zoxamide 0.84 % of AOEL, while for cymoxanil 80.06% of AOEL. Thus, a a combined exposure (sum of exposures to all active substances) expressed as percentage of their AOELs is also below 100%, thus is not posing an unacceptable systemic health risk.

Given the toxicological properties and classification of the formulation Cymoxanil 33% + Zoxamide 33% WG (Lieto 66 WG) according to Regulation 1272/2008/EC), as Skin Sens..1, H317, Repr. 2; H361fd and STOT RE 2; wearing protective gloves and protective clothing is recommended when handling the concentrate

3.5.3 Worker exposure

The worker exposure for the intended GAP uses of CYMOXANIL 33% + ZOXAMIDE 33% WG is below the limit of 100% AOEL for single active ingredients and combined (additive) effects if the following label restrictions are taken into account:

Potatoes (max. 3x 0.45 kg product/ha in 200 L/ha water at 7 days interval)

- ⇒ Work wear (arms, body and legs covered) during all worker re-entry tasks

Assuming the skin sensitizing properties of the formulated product CYMOXANIL 33% + ZOXAMIDE 33%, normal working clothing is generally proposed for all worker re-entry tasks.

zRMS: The exposure of worker not wearing PPE but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of potatoes treated with formulation Cymoxanil 33% + Zoxamide 33% WG (Lieto 66 WG) 3 x 0.45 kg product/ha (0.1485 kg of each a.s./ha) in 200 L/ha water at 7 days interval as foreseen in GAP, calculated with the EFSA AOEM is below a respective AOEL for both active substances. Also a sum of exposures to these active substance expressed as percentage of their AOELs is also below 100%, therefore the application of product Cymoxanil 33% + Zoxamide 33% WG (Lieto 66 WG) does not pose an unacceptable risk to the health of worker for its intended use within good agricultural practice. Re-entering fields of potatoes treated with Cymoxanil 33% + Zoxamide 33% WG (Reboot) by workers for inspection is only allowed when the spray solution has been fully dried out..

3.5.4 Bystander and resident exposure

The calculations according to the EFSA model demonstrate that residents of any age are not at risk during and after application of CYMOXANIL 33% + ZOXAMIDE 33% WG on potatoes in the field. The effects of single active ingredients and combined (additive) effects, calculated for safety reasons, are within the limits of 100 % AOELs for all scenarios. A bystander risk assessment is not re-required for active substances that do not have significant acute toxic effects or the potential to exert toxic effects after a single exposure – which is the case for zoxamide.

zRMS PL: The exposure of resident (adult and child) to each of the active substance (Cymoxanil and Zoxamide) of a formulation Cymoxanil 33% + Zoxamide 33% WG (Lieto 66 WG) applied 3 times per season at 7 days interval at dose of 0.45 kg product/ha (0.1485 kg of each a.s./ha) in 200 L/ha water as foreseen in GAP potatoes, using tractor-mounted boom sprayer and assuming a dermal absorption of Cymoxanil from a diluted formulation as 35%, calculated with the EFSA AOEM demonstrates that such a exposure to Cymoxanil for adult resident is equal respectively to 39 % and for child residents 102.4%, while to Zoxamide for adult resident is equal respectively to 0.72 % and for child residents 1.71 % of respective AOEL. Such exposure to Cymoxanil creates an unacceptable health risk to child residents therefore the refinement of exposure was needed.

Taking into account that dermal absorption of Cymoxanil from dry residue on leaves is 5.7%, and not 35 % as from diluted product a refined calculation resulted in reduction of the exposure to Cymoxanil for adult resident to 17.1 % and for child residents to 63 % of AOEL.

Therefore it is concluded that exposure of adult and child residents to both active substances (Cymoxanil and Zoxamide) of a formulation Cymoxanil 33% + Zoxamide 33% WG (Lieto 66 WG) applied 3 times per season at 7 days interval at dose of 0.45 kg product/ha (0.1485 kg of each a.s./ha) in 200 L/ha water as foreseen in GAP on potatoes, using tractor-mounted boom sprayer is acceptable and does not create a health risk for adult and child residents.

No bystander acute exposure estimation is required since no acute acceptable operator exposure value (AAOEL) has been set for any of these active substances: Cymoxanil and Zoxamide. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for bystanders due to short-term single exposure to Cymoxanil and Zoxamide as a result of application of Cymoxanil 33% + Zoxamide 33% WG (Lieto 66 WG) with accordance with intended use within good agricultural practice.

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

A complete set of data is available to describe the residues of the active substances in the relevant crop

commodities and to demonstrate the safe use of CYMOXANIL 33% + ZOXAMIDE 33% WG for consumers.

EFSA (2017) proposed in their Peer Review Conclusion for zoxamide new residue definitions for risk assessment for plants. Further toxicological and residues data – as requested by EFSA (2017) – are therefore under evaluation by the RMS Latvia and cMSs in an interzonal procedure. However, the data available are considered sufficient for the current risk assessment.

An exceedance of the current MRL of 0.02 mg/kg for zoxamide and of 0.01* mg/kg for cymoxanil in potatoes - as laid down in Reg. (EU) 396/2005 - is not expected.

The chronic intake of zoxamide and chronic and short-term intakes of cymoxanil residues are unlikely to present a public health concern.

Summary for zoxamide

Use-No.*	Crop, **	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Potatoes	Yes	Yes (8 trials [5x 150 or 5x 180 g a.s./ha]); residues ND or < LOQ	Yes	Yes	Yes		No

* 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

The effects of processing on the residues have been investigated. However, these data were not needed for refinement of the risk assessment.

Residues in succeeding crops have been sufficiently investigated, taking into account the specific circumstances of the cGAP use(s) being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake for livestock is expected. Further investigation of residues in commodities of animal origin is therefore not necessary for the renewal of CYMOXANIL 33% + ZOXAMIDE 33% WG.

Summary for cymoxanil

Use-No.*	Crop, **	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
I	Potatoes	Yes	Yes	Yes	Yes	Yes		No

* 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

As residues of Cymoxanil do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake for livestock is expected. Further investigation of residues in commodities of animal origin is therefore not necessary for authorisation of CYMOXANIL 33% + ZOXAMIDE 33% WG

3.6.1 Residues

The present application is intended for the renewal of the authorisation of CYMOXANIL 33% + ZOXAMIDE 33 % WG as a fungicide against downy mildew in grapes, tomato, eggplant and potato.

Data were already available supporting the intended use on potato but, following the renewal of the active ingredient zoxamide, new studies were submitted to comply with the requests of the authorities in order to verify if some of the identified metabolites (no one regarded as toxicologically relevant) could affect the level of residues in the different crops.

The available residues trials, performed according to OECD 509 guidelines, were done for different zoxamide formulations inclusive the here intended WG formulation CYMOXANIL 33% + ZOXAMIDE 33 % WG. However, according to the EC (2019) guidance document SANTE/2019/12752 it is possible to extrapolate since experience shows that emulsifiable concentrates (EC), wettable powders (WP), dispersible granules (WG), and suspension concentrates (SC) formulations usually produce comparable residues

Zoxamide

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. Furthermore, (older) supportive studies are available from the applicant – the studies provided for the authorisation of the product.

Potato: Data are available from the authorisation dossier (4 trials – 2 Northern EU, 2 Southern EU) together with new data performed under Northern (2 trials) and Southern (2 trials) EU growing conditions. All the data are derived from trials with an over-dosed GAP, but residues were either not detectable (i.e. < 0.003 mg/kg) or below the LOQ (< 0.01). Even under these assumptions, and when taking on only the highest available residues (i.e. calculating with LOQ values), no exceedance of the current EU MRL is expected.

Cymoxanil

No new study was submitted for cymoxanil. Sufficient residue data is available. The residues of cymoxanil in potatoes are all below LOQ and below the current EU harmonized MRLs according to Reg. (EC) No. 396/2005.

No further evaluation is required for national re-registration/registration.

3.6.2 Consumer exposure

Zoxamide

Exposure of consumers to zoxamide has been calculated with EFSA PRIMo rev. 3 (EFSA Journal 2018;16(1):5147, 43 pp) based on EU concluded and evaluated input values.

An ARfD for zoxamide was not deemed necessary, an acute consumer risk assessment has therefore not been performed.

With regard to the chronic exposure of consumers, the highest Theoretical Maximum Daily Intake (TMDI) was calculated for The Netherlands' toddler, representing 7 % of the ADI of zoxamide (highest contribution: 4% via spinach). For this calculation, the STMR values derived for the crops under evaluation and the currently available MRL values were considered.

A NEDI calculation has been performed based on the highest STMR values per intended crop from the table above. The National Estimate of Dietary Intake (NEDI) model shows the highest exposure of 15 % via spinaches (9%) for the UK toddler.

Cymoxanil

Exposure of consumers to cymoxanil has been calculated based on EU consolidated input values.

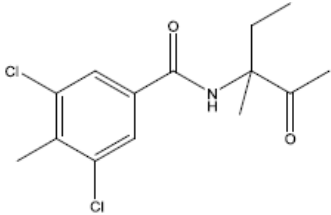
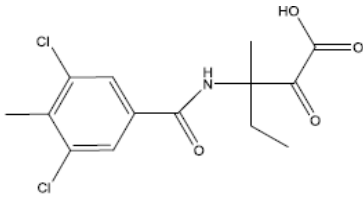
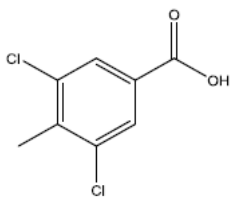
The results of the TMDI calculations with the EFSA model are summarized in section B7. No chronic and acute risk for consumer is expected.

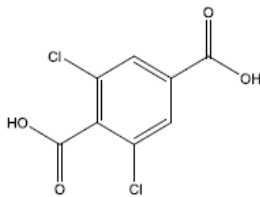
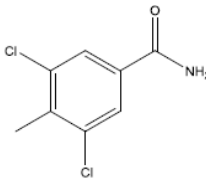
Overall, it can be concluded that the use of the product CYMOXANIL 33% + ZOXAMIDE 33% WG does not lead to unacceptable risks for consumers when applied according to label recommendations.

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

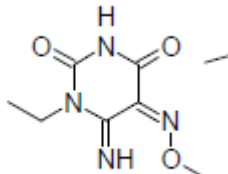
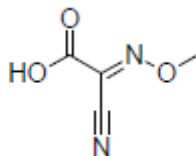
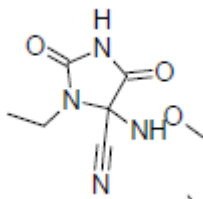
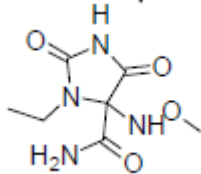
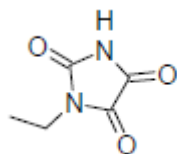
Zoxamide and cymoxanil and their respective metabolites were evaluated and relevant PECs were calculated and presented.

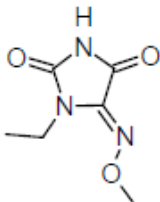
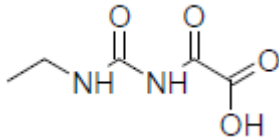
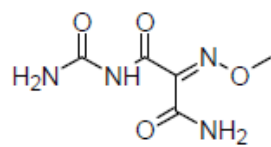
Metabolites of zoxamide potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
RH-127450	302.15		Soil: Max. 15.1% AR after 7 days Water/sediment system: Max. 17.1% AR in surface water (day 28), max. 23.1% AR in sediment, max. 39.3% AR in total system (after incubation at 10°C)	PEC _{gw} : leaching potential to groundwater PEC _{soil} : occurrence in soil PEC _{sw/seq} : occurrence in surface water
RH-163353	332.15		Soil: Max. 15% AR after 3 days Water/sediment: Max. 15.8% AR at day 28 in the water phase, max. 7.4% AR at day 106 in the sediment, max. 20.6% AR (day 56) in the total system	PEC _{gw} : leaching potential to groundwater PEC _{soil} : occurrence in soil PEC _{sw/seq} : occurrence in surface water
RH-24549	205.0		Soil: Max. 33.8% AR after 7 days Water/sediment: Max. 5% AR (whole system)	PEC _{gw} : leaching potential to groundwater PEC _{soil} : occurrence in soil PEC _{sw/seq} : occurrence in surface water

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
RH-141455	235.02		Soil: Max. 8.4% AR after 14 days Water/sediment: Max. 2.1% AR (whole system)	PEC _{gw} : leaching potential to groundwater PEC _{soil} : occurrence in soil PEC _{sw/sed} : occurrence in surface water
RH-139432	204.06		Soil: Max. 4.9% AR after 14 days Surface water: Max. of 21.4% AR (day 28) in surface water of OECD 309 study (max. of 42.4% AR on day 30 in an aquatic photolysis study at pH 4 is regarded as environmentally not relevant).	PEC _{sw/sed} : occurrence in surface water

Metabolites of cymoxanil potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
IN-U3204	198.2		Soil: max 24.7% AR by 0.33 day Water/sediment: max in water 24.7% AR after 0.13 d, max in sediment 0.5% AR after 3 d	PEC _{gw} : leaching potential to groundwater PEC _{soil} : occurrence in soil PEC _{sw/sed} : occurrence in surface water
IN-W3595	128.1		Soil: max 10.1% AR by 1 day Water/sediment: max in water 26.1% AR after 0.25 d, max in sediment 2.3% AR after 1 d	PEC _{gw} : leaching potential to groundwater PEC _{soil} : occurrence in soil PEC _{sw/sed} : occurrence in surface water
IN-JX915	198.2		Soil: 10.9% AR (n=1) Water/sediment: max in water 7.2% AR after 1 d, max in sediment 1.2% AR after 1 d	PEC _{gw} : leaching potential to groundwater PEC _{soil} : occurrence in soil PEC _{sw/sed} : occurrence in surface water
IN-KQ960	216.9		Groundwater: max 6.3% AR by 3 days Water/sediment: max in water 13.0% AR after 1 d, max in sediment 5.5% AR after 30 d	PEC _{gw} : leaching potential to groundwater PEC _{sw/sed} : occurrence in surface water
IN-TA226	142.1		Water/sediment: max in water 11.1% AR after 3 d, max in sediment 1.0% AR after 8 d	PEC _{sw/sed} : occurrence in surface water

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
IN-R3273	171.2		Water/sediment: max in water 5.0% AR after 3 d, max in sediment 0.5% AR after 3 d	PEC _{sw/sed} : occurrence in surface water
IN-KP533	160.1		Water/sediment: max in water 20.5% AR after 10 d, max in sediment 6.5% AR after 1 d	PEC _{sw/sed} : occurrence in surface water
M5	198.2		Water/sediment: max in water 22.9% AR after 1 d, max in sediment 0.0% AR	PEC _{sw/sed} : occurrence in surface water

Cymoxanil: In accordance with article 43 of Regulation (EC) No. 1107/2009, studies on zoxamide, its metabolites and the plant protection product are submitted, while exemption from the submission of studies applies for the active substance cymoxanil and its metabolites. Cymoxanil is currently under renewal on EU level. No unacceptable effects to the environment were identified.

Zoxamide

For zoxamide, additional data to evaluate the degradation behaviour of RH-24549 and the formation fraction of RH-141455 from its precursor RH-24549 were presented and regarded valid for the PEC calculations. The revised endpoints were presented. Besides, EU concluded data were regarded applicable for the risk calculations.

The enantioselective degradation of (R)- and (S)-zoxamide in one soil incubated under aerobic conditions in the dark has been investigated by Kercher (2017). A summary of the study can be found in Appendix 2 of the RR Part B.8. This study has been completed after the peer review of zoxamide data during AIR and considered in the EC Renewal Report (SANTE/10052/2018 rev. 2, dated 23 March 2018). The chemical stability of the chiral carbon of zoxamide and its racemic metabolites has been demonstrated in the study of Kercher (2017) and in a range of further studies and matrices.

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

Maximum and time dependent concentrations for zoxamide and its metabolites were presented for single and multiple applications. As can be seen from the values (PEC_{ini} compared to PEC_{accu} values), soil accumulation of zoxamide - even after multiple year's application on the same field - does not play a role.

PEC_{soil} of the formulated product was calculated for single and multiple applications - considering the same scenarios, crop interception values, soil depths, soil density and GAPs as for the active substance and its metabolites (see above). Single application values of the formulated product are considered relevant for the risk assessment; multiple applications and longer-term PECs are better described by active substance data.

Cymoxanil: In accordance with article 43 of Regulation (EC) No. 1107/2009, studies on zoxamide, its metabolites and the plant protection product are submitted, while exemption from the submission of stud-

ies applies for the active substance cymoxanil and its metabolites. Cymoxanil is currently under renewal on EU level. No unacceptable effects to the environment were identified.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

Zoxamide

For zoxamide, additional data to evaluate the degradation behaviour of RH-24549 and the formation fraction of RH-141455 from its precursor RH-24549 were presented and regarded valid for the PEC calculations. The revised endpoints were presented. Besides, EU concluded data and/or endpoints as required by current guidelines for PEC calculations were regarded applicable for the risk assessment.

PEC_{gw} values simulated with FOCUS PELMO, PEARL and MACRO were performed for all available standard EU scenarios. Independent from the computer model, the crop and the application scenario, the groundwater concentrations for zoxamide, RH-127450, RH-24549, and RH-163353 were <0.001 µg/L.

For metabolite RH-141455 concentrations were simulated below 0.75 µg/L and above the drinking water trigger of 0.1 µg/L. **The maximum relevant concentration derived for Poland was 0.287 µg/L (PELMO, potato, Hamburg).** Thus, no unacceptable risk of groundwater contamination is expected following annual applications of zoxamide and its metabolites for the intended uses.

Cymoxanil: In accordance with article 43 of Regulation (EC) No. 1107/2009, studies on zoxamide, its metabolites and the plant protection product are submitted, while exemption from the submission of studies applies for the active substance cymoxanil and its metabolites. However, Cymoxanil was not predicted to leach into groundwater following a 26-years period after applications of Cymoxanil 33% + Zoxamide 33% WG. For all scenarios, the 80th percentile reporting endpoints for Cymoxanil and its relevant metabolites were below the regulatory threshold value of 0.1 µg/L.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

Zoxamide

Predicted Environmental Concentrations of the parent compound and its relevant metabolites in surface water and sediment (PEC_{sw}, PEC_{sed}) were calculated in a stepwise approach with FOCUS SW following the Guidance of the FOCUS Surface Water Report SANCO/4802/2001- rev. 2 (May 2003) - Aquatic Guidance Document and the Generic Guidance for FOCUS Surface Water Scenarios, version 1.4, May 2015. Step 1+2 calculations were conducted with FOCUS SW Steps 1+2 3.2 for Northern and Southern EU. All FOCUS SW Step 3 scenarios were simulated using the program FOCUS SWASH 5.3⁴ to create the necessary input data for FOCUS MACRO 5.5.4, FOCUS PRZM 4.3.1, SPIN 2.2 and TOXSWA 5.5.3., have been released. The PEC calculations for zoxamide and its relevant metabolites were in general based on EU concluded endpoints. However, there was a single exception with regard to a geometric mean (n=32) foliar half-life of 3.9 d for zoxamide based on residues data recently evaluated in re-port no. GOW1120-1. This substance specific foliar DT₅₀ value was considered for refined FOCUS SW calculations. Beside PEC_{actual} values, PEC_{twa} values were estimated as far as necessary for the aqua-toxicological risk assessment. Both single and multiple applications were taken into account.

Step 4 calculations were carried out as far as applicable with the program SWAN 5, which was developed by members of the FOCUS SW expert group, for the implementation of buffer zones and drift mitigation measures. Besides, drift-reducing measures (i.e. buffer zones and drift reducing equipment for the reduction classes 50%, 75% and 90%, respectively) were considered. The relevant PEC_{sw} values were considered in the aquatox risk assessment.

⁴ FOCUS (2001). "FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC". Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev. 2, 245 pp

Cymoxanil: In accordance with article 43 of Regulation (EC) No. 1107/2009, studies on zoxamide, its metabolites and the plant protection product are submitted, while exemption from the submission of studies applies for the active substance cymoxanil and its metabolites.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

Zoxamide

Due to the properties of zoxamide, the calculation of PEC_{air} is not necessary. The vapour pressure at 25°C of the active substance zoxamide is 1.3×10^{-5} Pa. Thus, according to EVA 3.2h, 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 volatilisation with subsequent deposition is not considered.

Cymoxanil

Cymoxanil has low volatility, as indicated by a low vapour pressure of 1.5×10^{-4} Pa. The Henry's law constant was calculated to be $3.244 \times 10^{-5} \text{ Pa} \times \text{m}^3 \times \text{mol}^{-1}$. Calculations according to the method of Atkinson for indirect photo-oxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half-life estimated at 21.3 hours, indicating that the small proportion of applied Cymoxanil that will volatilise would be unlikely subject to long range atmospheric transport.

3.8 Ecotoxicology (Part B, Section 9)

In accordance with article 43 of Regulation (EC) No. 1107/2009, studies on zoxamide, its metabolites and the plant protection product are submitted, no new study was submitted for the active substance cymoxanil and its metabolites.

3.8.1 Effects on terrestrial vertebrates

Effects of 'Cymoxanil 33% + Zoxamide 33% WG' on birds and mammals were not evaluated as part of the EU reviews of the active substances. Therefore, a risk assessment for 'Cymoxanil 33% + Zoxamide 33% WG' with the proposed use pattern has been provided and is considered adequate.

The assessment of effects on birds and mammals was carried out according to EFSA Guidance on Risk Assessment for Birds and Mammals (EFSA Journal 2009, 7(12):1438) based on EU concluded data for the active substances and data on the formulated product. As a result, an acceptable acute and chronic risk to birds was demonstrated for both active substances as well as for the potentially relevant metabolites of zoxamide and the formulated product 'Cymoxanil 33% + Zoxamide 33% WG'. Secondary poisoning for earthworm and fish-eating birds and via drinking water is not likely.

Information on unacceptable effects to reptiles and amphibians are not available.

3.8.2 Effects on aquatic species

The aquatic risk assessment was carried out according to the EFSA (2013) aquatic guidance document (EFSA Journal 2013;11(7):3290).

New studies are available for zoxamide and its metabolites as well as 'Cymoxanil 33% + Zoxamide 33% WG', which were either requested by EFSA (2017) during AIR zoxamide or are required according to Regulation (EC) No. 284/2013. A comparison of the results for 'Cymoxanil 33% + Zoxamide 33% WG' with the results for the active substances revealed no additive or synergistic effects. Instead, the assessment confirms that zoxamide drives the toxicity of the mixture product. Studies on the toxicity to

aquatic organisms have been carried out with zoxamide and its relevant metabolites. As a result, the metabolites are showing a lower toxicity compared to the parent compound. Therefore, in the following only risk calculations with zoxamide are presented to conclude on a safe use when the formulated product is applied close to surface waters.

Endpoints and effect values relevant for the risk assessment for aquatic organisms – zoxamide and relevant metabolites

Species	Substance	Exposure system	Results	Reference
Fish				
<i>Oncorhynchus mykiss</i>	Zoxamide	96 h, ft	LC ₅₀ = 0.16 mg a.s./L_{mm}	EFSA (2017)
<i>Lepomis macrochirus</i>	Zoxamide	96 h, ft	LC ₅₀ > 0.79 mg a.s./L _{mm}	EFSA (2017)
<i>Pimephales promelas</i>	Zoxamide	96 h, ft	LC ₅₀ > 0.208 mg a.s./L _{mm} [#]	EFSA (2017)
<i>Brachydanio rerio</i>	Zoxamide	96 h, ft	LC ₅₀ > 0.73 mg a.s./L _{mm}	EFSA (2017)
<i>Cyprinodon variegatus</i>	Zoxamide	96 h, ft	LC ₅₀ > 0.85 mg a.s./L _{mm}	EFSA (2017)
<i>Danio rerio</i>	Zoxium 240 SC **	96 h, s	LC ₅₀ = 0.184 mg a.s./L _{mm} LC ₅₀ = 0.865 mg f.p./L _{mm}	EFSA (2017)
<i>Oncorhynchus mykiss</i>	RH-139432	96 h, ft	LC ₅₀ = 2 mg a.s./L_{mm}	EFSA (2017)
<i>Oncorhynchus mykiss</i>	RH-24549	48 h, ss	LC ₅₀ = 23 mg a.s./L_{mm}	EFSA (2017)
<i>Oncorhynchus mykiss</i>	RH-127450	96 h, ss	LC ₅₀ = 4.17 mg a.s./L_{mm}	xxx (2020) / 3202373
<i>Oncorhynchus mykiss</i>	RH-163353	96 h, s	LC ₅₀ > 100 mg a.s./L_{nom}	xxx (2020) / 3202385
<i>Oncorhynchus mykiss</i>	RH-141455	96 h, s	LC ₅₀ > 100 mg a.s./L_{nom}	xxx (2020) / 3202716
<i>Oncorhynchus mykiss</i>	Zoxamide	95 d, ft, ELS	NOEC = 0.00348 mg a.s./L_{mm}	EFSA (2017)
<i>Pimephales promelas</i>	Zoxamide	202 d, ft, FLC	NOEC = 0.06 mg a.s./L _{mm}	EFSA (2017)
<i>Danio rerio</i>	Zoxamide	30 d, post-hatch, ft, ELS	NOEC ≥ 0.12 mg a.s./L _{mm}	EFSA (2017)
<i>Cyprinodon variegatus</i>	Zoxamide	34 d, ft, ELS	NOEC = 0.04 mg a.s./L _{mm} EC ₁₀ = 0.093 mg a.s./L (fish wet weight)	xxx (1998) / 97RC-0078 plus report addendum by xxx (2020)
<i>Lepomis macrochirus</i>	Zoxamide	28 d, ft, bioaccumulation	BCF = 95-136 mg a.s./L _{mm}	EFSA (2017)
Aquatic invertebrates				
<i>Daphnia magna</i>	Zoxamide	48 h, ft	LC ₅₀ > 0.78 mg a.s./L _{mm}	EFSA (2017)
<i>Daphnia magna</i>	Zoxium 240 SC **	48 h, s	EC ₅₀ > 0.69 mg a.s./L _{mm}	EFSA (2017)
<i>Mysidopsis bahia</i>	Zoxamide	96 h, ft	LC ₅₀ = 0.076 mg a.s./L _{mm}	EFSA (2017)
<i>Daphnia magna</i>	RH-139432	48 h, ss	LC ₅₀ = 17 mg a.s./L _{mm}	EFSA (2017)
<i>Americamysis bahia</i>	RH-139432	96 h, s	LC ₅₀ = 6.95 mg a.s./L _{mm}	xxx (2020) / 3202398
<i>Daphnia magna</i>	RH-24549	48 h, s	LC ₅₀ = 40 mg a.s./L _{mm}	EFSA (2017)
<i>Americamysis bahia</i>	RH-24549	96 h, s	LC ₅₀ = 23.2 mg a.s./L	xxx (2020) / 3202394

Species	Substance	Exposure system	Results	Reference
<i>Americamysis bahia</i>	RH-127450	96 h, s	LC ₅₀ = 2.93 mg a.s./L _{mm}	xxx (2020) / 3202374
<i>Daphnia magna</i>	RH-141455	48 h, s	LC ₅₀ > 100 mg a.s./L _{nom}	xxx (2020) / 3202380
<i>Americamysis bahia</i>	RH-141455	96 h, ss	LC ₅₀ > 100 mg a.s./L _{nom}	xxx (2020) / 3202381
<i>Daphnia magna</i>	RH-163353	48 h, s	LC ₅₀ > 100 mg a.s./L _{nom}	xxx (2020) / 3202386
<i>Americamysis bahia</i>	RH-163353	96 h, s	LC ₅₀ > 100 mg a.s./L _{nom}	xxx (2020) / 3202387
<i>Daphnia magna</i>	Zoxamide	21 d, ft	NOEC = 0.039 mg a.s./L _{mm}	EFSA (2017)
<i>Mysidopsis bahia</i>	Zoxamide	27 d, ft	NOEC = 0.0072 mg a.s./L_{mm}	EFSA (2017)
<i>Chironomus riparius</i>	Zoxamide	28 d, ft, spiked water	NOEC _(emergence rate) = 0.38 mg a.s./L^{##} EC ₁₀ (developmental rate) = 0.223 mg a.s./L EC ₁₀ (emergence rate) = 0.318 mg a.s./L	EFSA (2017)
Algae °				
<i>Selenastrum capricornutum</i>	Zoxamide	72, 96, 120 h, s	72-96 h-ErC ₅₀ = 0.01413 mg a.s./L_{mm} 120 h-EbC ₅₀ = 0.023 mg a.s./L _{mm}	RAR (2017) Ziegler T.A., Stewart S. (1996) / 94RC-0238
<i>Anabaena flos-aquae</i>	Zoxamide	96 h, s	ErC ₅₀ > 0.86 mg a.s./L _{mm} EbC ₅₀ > 0.86 mg a.s./L _{mm}	RAR (2017) Drottar, K.R., Sutherland, C.A., Krueger, H.O. (1998) / 97RC-0130
<i>Scenedesmus subspicatus</i>	Zoxamide	96 h, s	ErC ₅₀ = 0.018 mg a.s./L _{mm} EbC ₅₀ = 0.011 mg a.s./L _{mm}	RAR (2017) Drottar, K.R., Sutherland, C.A., Krueger, H.O. (1998) / 97RC-0133
<i>Navicula pelliculosa</i>	Zoxamide	96 h, s	ErC ₅₀ > 0.93 mg a.s./L _{mm} EbC ₅₀ > 0.93 mg a.s./L _{mm}	RAR (2017) Drottar, K.R., Sutherland, C.A., Krueger, H.O. (1998) / 97RC-0131
<i>Skeletonema costatum</i>	Zoxamide	96 h, s	ErC ₅₀ > 0.91 mg a.s./L _{mm} EbC ₅₀ > 0.91 mg a.s./L _{mm}	RAR (2017) Drottar, K.R., Sutherland, C.A., Krueger, H.O. (1998) / 97RC-0132
<i>Selenastrum capricornutum</i>	RH-117,281 2F **	96 h, s	ErC ₅₀ = 0.0582 mg a.s./L _{mm} * EbC ₅₀ = 0.0514 mg a.s./L _{mm} *	EFSA (2017)
<i>Scenedesmus subspicatus</i>	RH-139432	72 h, s	ErC ₅₀ > 30 mg a.s./L_{mm} EbC ₅₀ = 26 mg a.s./L _{mm}	RAR (2017) Hoberg, J.R. (2002) / 12550.6288
<i>Desmodesmus subspicatus</i>	RH-24549	72 h, s	ErC ₅₀ > 60 mg a.s./L_{nom} EbC ₅₀ > 60 mg a.s./L _{nom}	EFSA (2017)
<i>Pseudokirchneriella subcapitata</i>	RH-141455	72 h, s	EC ₅₀ > 100 mg a.s./L_{nom}	EFSA (2017)

Species	Substance	Exposure system	Results	Reference
<i>Raphidocelis subcapitata</i>	RH-127450	72 h, s	$E_rC_{50} > 6.60 \text{ mg a.s./L}_{\text{mm}}$ $E_yC_{50} = 5.98 \text{ mg a.s./L}_{\text{mm}}$	Hugill, E. (2020) / 3202375
<i>Raphidocelis subcapitata</i>	RH-163353	72 h, s	$E_rC_{50} > 100 \text{ mg a.s./L}$ $E_yC_{50} > 100 \text{ mg a.s./L}$	Jarrom, R. (2020) / 3202388
Aquatic plants °				
<i>Lemna gibba</i>	Zoxamide	14 d, ss	$7 \text{ d } EC_{50} > 0.018 \text{ mg a.s./L}_{\text{mm}}$ $14 \text{ d } EC_{50} = 0.017 \text{ mg a.s./L}_{\text{mm}}$ $NOEC = 0.009 \text{ mg a.s./L}_{\text{mm}}$	EFSA (2017)
<i>Lemna gibba</i>	Zoxamide	7 d, ss	$E_rC_{50} = 0.0237 \text{ mg a.s./L}_{\text{nom}}$ $E_yC_{50} = 0.0122 \text{ mg a.s./L}_{\text{mm}}$	Juckeland D. (2020) 18 48 ALE 0005
Higher-tier studies (micro- or mesocosm studies)				

s: static; ss: semi-static; ft: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

* endpoints expressed as mg formulation/L are converted to mg a.s./L considering the purity of the formulation (21.24 %, w/w)

** RH-117,281 2F is a very similar formulation to Zoxium 240 SC. Refer to Document J-CP for details of both formulations. However, the toxicity endpoints for RH-117,281 2F / Zoxium 240 SC are not relevant for the risk assessment of 'CYMOXAN-IL 33% + ZOXAMIDE 33% WG'.

Mistake in the EFSA Peer Review Conclusion (2017), which has been corrected based on Drott K.R. & Krueger H.O. (1998): RH-117,281 Technical: A flow-through life-cycle toxicity test with the fathead minnow (*Pimephales promelas*), report no. 97RC-0079, and based on the study summary in the RAR (2017).

In line with the risk calculation during AIR / in the RAR (2017).

° According to the EFSA (2013) guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters, growth rate endpoints (E_rRC_{50} values) are preferred.

bold = worst-case endpoint taken forward for the aquatic risk assessment

Ratios between predicted environmental concentrations in surface water bodies (PEC_{SW} , PEC_{SED}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group and are presented below. Worst-case PEC values from single and multiple applications were considered.

For Poland the relevant scenarios are D3, D4 and R1. These scenarios are highlighted in the tables below in **green**.

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for zoxamide for each organism group based on FOCUS Steps 1, 2 and 3 calculations (worst-case PECs) for the use of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ in potatoes

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plant
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	Geomean of available data*	<i>Mysidopsis bahia</i>	<i>Selenastrum capricornutum</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>
Endpoint (µg/L)		LC ₅₀ 160	NOEC 3.48	EC ₅₀ 229	NOEC 7.2	ErC ₅₀ 14.13	NOEC 380	ErC ₅₀ 23.7
AF		100	10	100	10	10	10	10
RAC (µg/L)		1.6	0.348	2.29	0.72	1.413	38	2.37
FOCUS Scenario	PEC _{gl-max} (µg/L)							
Step 1								
	61.834	38.646	177.684	27.002	85.881	43.761	1.627	26.090
Step 2								
N-Europe	3.669	2.293	10.543	1.602	5.096	2.597	0.097	1.548
S-Europe	6.802	4.251	19.546	2.970	9.447	4.814	0.179	2.870
Step 3								
D3/ditch	0.565	0.353	1.624	0.247	0.785	0.400	0.015	0.238
D4/pond	0.058	0.036	0.167	0.025	0.081	0.041	0.002	0.024
D4/stream	0.454	0.284	1.305	0.198	0.631	0.321	0.012	0.192
D6 1 st /ditch	0.563	0.352	1.618	0.246	0.782	0.398	0.015	0.238
D6 2 nd /ditch	0.559	0.349	1.606	0.244	0.776	0.396	0.015	0.236
R1/pond	0.087	0.054	0.250	0.038	0.121	0.062	0.002	0.037
R1/stream	0.534**	0.334	1.534	0.233	0.742	0.378	0.014	0.225
R2/stream	0.524	0.328	1.506	0.229	0.728	0.371	0.014	0.221
R3/stream	0.688**	0.430	1.977	0.300	0.956	0.487	0.018	0.290

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration;

* See par. 9.5.1.1 for details; ** single application

PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Further PEC/RAC ratios were calculated based on FOCUS SW Step 4 PEC values, taking into account more realistic scenarios and a substance specific geometric mean DT₅₀ value (n=32) for zoxamide on leaves. For PEC values see Part B.8 chapter 8.9.2.1.

Aquatic organisms: PEC/RAC ratios for zoxamide based on the RAC for fish prolonged and FOCUS SW Step 4 calculations with mitigation of plant DT₅₀, spray drift and run-off for the use of ‘CYMOXANIL 33% + ZOXAMIDE 33% WG’ in potatoes, multiple applications

Intended use		Potatoes, multiple applications				
Active substance		Zoxamide				
Application rate (g/ha)		3 x 148.5				
RAC (µg/L) fish prolonged		0.348				
Nozzle reduction	No-spray buffer (m)	1/3	5	10	15	20
	Vegetated filter strip (m)	FOCUS default	5	10	15	20
None	D3 ditch	1.624	0.523	0.273	0.187	0.141
50%		0.813	0.261	0.138	0.092	0.069
75%		0.405	0.129	0.069	0.046	0.034
90%		0.164	0.052	0.029	0.017	0.014
None	D4 pond	0.167	0.149	0.106	0.083	0.069
50%		0.083	0.075	0.052	0.043	0.034
75%		0.040	0.037	0.026	0.020	0.017
90%		0.017	0.014	0.011	0.009	0.006
None	D4 stream	1.305	0.540	0.284	0.193	0.147
50%		0.652	0.270	0.141	0.095	0.072
75%		0.328	0.135	0.072	0.049	0.037
90%		0.129	0.055	0.029	0.020	0.014
None	D6 ditch 1 st	1.618	0.520	0.273	0.184	0.141
50%		0.810	0.259	0.135	0.092	0.069
75%		0.405	0.129	0.069	0.046	0.034
90%		0.161	0.052	0.026	0.017	0.014
None	D6 ditch 2 nd	1.606	0.514	0.270	0.184	0.138
50%		0.802	0.259	0.135	0.092	0.069
75%		0.402	0.129	0.069	0.046	0.034
90%		0.161	0.052	0.026	0.017	0.014
None	R1 pond	0.250	0.210	0.138	0.106	0.083
50%		0.172	0.141	0.086	0.069	0.052
75%		0.132	0.106	0.063	0.049	0.034
90%		0.109	0.086	0.049	0.037	0.026
None	R1 stream	1.534	1.213	0.698	0.534	0.365
50%		1.534	1.213	0.698	0.534	0.365
75%		1.534	1.213	0.698	0.534	0.365
90%		1.534	1.213	0.698	0.534	0.365
None	R2 stream	1.503	0.790	0.448	0.342	0.233
50%		1.006	0.790	0.448	0.342	0.233

75%	R3 stream	1.006	0.790	0.448	0.342	0.233
90%		1.006	0.790	0.448	0.342	0.233
None		1.977	1.560	0.897	0.687	0.468
50%		1.977	1.560	0.897	0.687	0.468
75%		1.977	1.560	0.897	0.687	0.468
90%		1.977	1.560	0.897	0.687	0.468

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration;
PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

Aquatic organisms: PEC/RAC ratios for zoxamide based on the RAC for fish prolonged and FOCUS SW Step 4 calculations with mitigation of plant DT₅₀, spray drift and run-off for the use of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' in potatoes; single application

Intended use		Potatoes, single application				
Active substance		Zoxamide				
Application rate (g/ha)		148.5				
RAC (µg/L) fish prolonged		0.348				
Nozzle reduction	No-spray buffer (m)	1/3	5	10	15	20
	Vegetated filter strip (m)	FOCUS default	5	10	15	20
None	D3 ditch	2.236	0.733	0.388	0.264	0.201
50%		1.118	0.365	0.195	0.132	0.101
75%		0.557	0.184	0.098	0.066	0.052
90%		0.224	0.072	0.040	0.026	0.020
None	D4 pond	0.089	0.080	0.057	0.046	0.037
50%		0.046	0.040	0.029	0.023	0.020
75%		0.023	0.020	0.014	0.011	0.009
90%		0.009	0.009	0.006	0.006	0.003
None	D4 stream	1.744	0.736	0.391	0.267	0.201
50%		0.874	0.368	0.195	0.132	0.101
75%		0.437	0.184	0.098	0.066	0.052
90%		0.175	0.075	0.040	0.026	0.020
None	D6 ditch 1 st	2.210	0.724	0.385	0.261	0.198
50%		1.106	0.362	0.193	0.132	0.101
75%		0.552	0.181	0.095	0.066	0.049
90%		0.221	0.072	0.037	0.026	0.020
None	D6 ditch 2 nd	2.193	0.718	0.382	0.261	0.198
50%		1.098	0.359	0.190	0.129	0.098
75%		0.549	0.181	0.095	0.066	0.049
90%		0.218	0.072	0.037	0.026	0.020
None	R1 pond	0.149	0.124	0.078	0.060	0.046
50%		0.112	0.089	0.055	0.040	0.032
75%		0.092	0.072	0.043	0.032	0.023
90%		0.080	0.063	0.034	0.026	0.017

None	R1 stream	1.549	0.897	0.517	0.397	0.270
50%		1.135	0.897	0.517	0.397	0.270
75%		1.135	0.897	0.517	0.397	0.270
90%		1.135	0.897	0.517	0.397	0.270
None	R2 stream	2.046	0.862	0.457	0.313	0.239
50%		1.023	0.431	0.230	0.155	0.118
75%		0.511	0.267	0.152	0.118	0.080
90%		0.342	0.267	0.152	0.118	0.080
None	R3 stream	2.181	0.920	0.489	0.333	0.253
50%		1.092	0.460	0.244	0.167	0.126
75%		0.546	0.264	0.152	0.118	0.080
90%		0.336	0.264	0.152	0.118	0.080

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration;
PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

For the intended GAP use of zoxamide on potato fields with **3 x 0.45 kg prod./ha** the implementation of the following measure is necessary during spray application close to surface waters :

- For potatoes a 10 m vegetated buffer zone.

3.8.3 Effects on bees

The bee risk assessment is based on the EPPO (2010) bee guidance (EPPO Standard PP3/10 (3) Environmental risk assessment scheme for plant protection products. Chapter 10: Honeybees), as updated from the EPPO 2001 guidance, which is referred to in the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

For zoxamide, cymoxanil and ‘Cymoxanil 33% + Zoxamide 33% WG’ the HQ values for acute oral and contact toxicity to adult honeybees are below the relevant trigger of 50, indicating that no unacceptable risk is expected following the application of ‘Cymoxanil 33% + Zoxamide 33% WG’ according to the intended use pattern in the field.

Additional studies with zoxamide and the formulated product on the chronic adult honey bee and honey bee larvae toxicity are available or are submitted with this dossier, but without risk assessment. The EFSA bee guidance document (2014) is not yet voted and therefore not taken into account. However, two honey bee field studies from 2018 and 2019 with additional assessments on colony and brood development are available, which have been performed under southern EU (Spanish) and central EU (German) conditions. As a result, two consecutive foliar applications of ‘Cymoxanil 33% + Zoxamide 33% WG’ at a rate of each 1.35 kg product/ha (the 3-fold max. single application rate of 0.45 kg product/ha) with an interval of 7 days under field conditions on full-flowering *Phacelia tanacetifolia* caused no adverse effects on honeybee behaviour, mortality, foraging activity, colony weight development, colony strength, conditions of the colonies, overall bee brood development as well as detailed brood development over two consecutive investigated brood cycles.

3.8.4 Effects on arthropod species other than bees

The evaluation of the risk for non-target arthropods 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), and in consideration of the recommendations of

the guidance document ESCORT 2 (Candolfi et al., 2000)⁵. It is based on the hazard quotient (HQ) approach, assessing the risk to non-target arthropods in-field and off-field and considering either the LR₅₀ (lethal rate) or the ER₅₀ (effect rate) on reproduction

Based on the results of extended laboratory studies with *T. pyri*, *Aphidius*, *Chrysoperla* and *Orius* the PER_{in-field} was below the rate with ≤ 50 % effect for all representative uses. Therefore, also off-field no risk to non-target arthropods is expected from the intended uses of 'CYMOXANIL 33% + ZOXAMIDE 33% WG'. The risk assessment for the off-field area is therefore covered by the risk assessment for the in-field area.

In addition, the aged residue test carried out with the product on *Typhlodromus pyri* (Colli M., 2006; report no. BT031/06) showed no adverse effects at the rate of 2.25 kg product/ha after 7 days, indicating an acceptable potential of re-colonisation/recovery within an ecologically relevant period.

It is therefore possible to conclude that the GAP uses of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' do not pose any risk to non-target arthropods.

The product 'CYMOXANIL 33% + ZOXAMIDE 33% WG' shows in general a low toxicity to non-target arthropods.

3.8.5 Effects on soil organisms

The risk assessment was conducted according to the 'Guidance document on terrestrial ecotoxicology under Council Directive 91/414/EEC' (Anonymous 2002)⁶ and the requirements of Regulation (EC) No. 284/2013 for the plant protection product 'Cymoxanil 33% + Zoxamide 33% WG'.

The risk assessment was conducted according to the Guidance Document on Terrestrial Ecotoxicology (2002).

New data on zoxamide and its metabolites are provided within this submission in order to fulfill requests of EFSA (2017). Moreover, new studies with 'CYMOXANIL 33% + ZOXAMIDE 33% WG' have been performed in order to fulfil the data requirements for plant protection products in accordance with Regulation (EC) No 1107/2009.

All acute and chronic TER values for earthworms and other non-target soil organisms (meso- and macrofauna) exposed to zoxamide and its relevant soil metabolites are greater than the Commission Regulation (EU) No. 546/2011 triggers of 10 and 5 – even if considering worst-case assumptions.

For 'CYMOXANIL 33% + ZOXAMIDE 33% WG', the TER values for the chronic earthworm, *Folsomia* and *Hypoaspis aculeifer* risk assessment are above the trigger of 5 for the potato uses. For these calculations, PEC_{soil,accu} values considering single applications were taken into account; multiple applications and long-term PECs are better described by active substance data.

In addition, the overall toxicity of zoxamide and its metabolite and of zoxamide, cymoxanil and their metabolites on earthworms has been assessed in field earthworm studies with Zoxium 240 SC and 'CYMOXANIL 33% + ZOXAMIDE 33% WG', respectively. In these studies, potential effects of field populations of earthworms after spray application of Zoxium 240 SC and 'CYMOXANIL 33% + ZOXAMIDE 33% WG' to bare soils at exaggerated application pattern did not show any statistically significant effects on single species, ecological groups and total earthworm abundance or biomass one

⁵ Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods: from the ESCORT 2 Workshop (European standard characteristics of non-target arthropod regulatory testing): a joint BART, EPPO/CoE, OECD, and IOBC Workshop organised in conjunction with SETAC Europe and EC: held at Wageningen International Conference Centre, Wageningen, the Netherlands : 21-23 March 2000.

⁶ Guidance document on terrestrial ecotoxicology under Council Directive 91/414/EEC, SANCO/10329/2002 rev. 2 dated 17th October 2002

year after application (Schulz L. 2020, Report No. 18 48 FEW 0001 and Schulz L. 2020, Report No. 19 48 FEW 0003).

Overall, the risk to earthworms and other non-target soil organisms (meso- and macrofauna) is acceptable following use of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' according to the proposed use pattern.

The risk of 'Cymoxanil 33% + Zoxamide 33% WG', zoxamide, cymoxanil and their relevant metabolites to soil micro-organisms was evaluated by comparison of no-effect concentrations, derived from laboratory tests, with PEC_{soil} values.

Since the formulated product at a soil concentration higher than expected after the use of 'Cymoxanil 33% + Zoxamide 33% WG' had no effects $\geq 25\%$ on the N transformation processes in soil at the end of a 28-day incubation period in the laboratory, the intended GAP uses of 'Cymoxanil 33% + Zoxamide 33% WG' can be regarded as safe for soil micro-organisms and their function in the field. The effects were below the trigger of 25% given in Commission Regulation (EU) no. 546/2011.

3.8.6 Effects on non-target terrestrial plants

The risk assessment was conducted according to the 'Guidance document on terrestrial ecotoxicology The risk assessment was conducted according to the Guidance Document on Terrestrial Ecotoxicology (2002).

During AIR of zoxamide, only screening data on terrestrial vascular plants were considered relevant and sufficient (see RAR zoxamide, 2017). No adverse effects were seen at dose rates up to 500 g a.s./ha. Therefore, no studies on seedling emergence and vegetative vigour were regarded to be required. Moreover, as the active substance is not an herbicide and/or plant growth regulator, Tier I studies examining the effects on seedling emergence and vegetative vigour were not requested.

To assess the effects of 'CYMOXANIL 33% + ZOXAMIDE 33% WG' on terrestrial plants, a vegetative vigour test on different species of non-target-plants was carried out. This study showed that application of 1.35 kg formulation/ha (equivalent to 0.4455 kg a.s./ha) had no significant phytotoxic effects on two mono- and four dicotyledon species of plants. The only significant effect observed was a 16% decrease in dry biomass with *P. sativum*. The EC_{50} was therefore assumed to be higher than 0.4455 kg a.s./ha. Thus, no effects over 50% were observed at an application rate three times higher than the single rate proposed for 'CYMOXANIL 33% + ZOXAMIDE 33% WG'. It is therefore possible to conclude that 'CYMOXANIL 33% + ZOXAMIDE 33% WG' poses no unacceptable risk to terrestrial non-target plants in off-crop areas following the proposed uses.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No additional data is available or necessary.

3.9 Relevance of metabolites (Part B, Section 10)

Zoxamide metabolite

The zoxamide metabolite RH-141455 is not appearing $> 0.1 \mu\text{g/L}$ (the drinking water limit) after the use of CYMOXANIL 33% + ZOXAMIDE 33% WG on tomatoes and vines early. However, it is appearing $> 0.1 \mu\text{g/L}$ (but $< 0.75 \mu\text{g/L}$) in EU groundwater scenarios after the use of CYMOXANIL 33% + ZOXAMIDE 33% WG on vines late and potatoes early and late and therefore has been considered in an assessment of its toxicological relevance according to EC guidance document SANCO/221/2000 –rev. 10. The relevance of the groundwater metabolite RH-141455 of the active substance zoxamide has already been assessed at EU level (see RAR 2017 and EFSA Peer Review Conclusion 2017) for different GAP

uses with higher seasonal application rates. As a result, RH-141455 was regarded as not relevant according to Step 5 of the EC guidance document SANCO/221/2000 –rev.10 (see RAR 2017). However, EFSA (2017) requested further toxicological data in their Peer Review Conclusion - such as a repeated dose toxicity study for RH141455 - to set a reference value for the metabolite RH-141455. Meanwhile, this study has been performed and provided to the RMS Latvia and cMSs for interzonal evaluation. It confirms the low toxicity of RH-141455 with a NOAEL > 1000 mg/kg bw/d.

For the actual GAP uses with lower seasonal application rates of zoxamide (compared to the GAP uses defended on EU level), the max. predicted concentrations in the groundwater/drinking water are > 0.01 µg/L but < 0.75 µg/L. Thus, a Step 4 exposure assessment according to EC guidance document SANCO/221/2000 –rev.10 has been performed.

During AIR (see RAR, 20017), the ADI for zoxamide was confirmed at 0.5 mg/kg bw/day and it was concluded that it is not necessary to allocate an ARfD – as for the first EU approval of zoxamide. As a conservative approach for the risk assessment on EU level, an additional assessment factor of 10 was applied to the ADI for zoxamide to establish an ADI for the metabolite RH-141455 of 0.05 mg/kg bw/day (50 µg/kg bw/day). However, a new 90-d dietary toxicity study in rats is now available to derive an ADI in case applicable (report no. U-19102). Based on the REACH guidance (Table R 8-5)⁷ a factor of 200 can be applied, which leads to a more realistic ADI for RH-141455 of 5.0 mg/kg bw/d.

Resulting exposure calculations for a 5-kg bottle-fed infant, a 10-kg child and a 60-kg adult confirm no undue risks for consumers from the maximum predicted RH-141455 concentrations in the drinking water.

RH-141455 is also a metabolite which might be found in potatoes and has therefore been regarded as potentially relevant by EFSA (2017) in their Peer Review Conclusion. However, in supervised field trials with potatoes performed in accordance with actual worst-case GAP uses, residues in potato tubers were <0.01 mg/kg (the LOQ for the analytical method). Therefore, the contribution to the dietary intake of RH-141455 via potatoes is not relevant.

As a result, RH-141455 is considered to be not relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.

Cymoxanil: No metabolite is predicted to occur in groundwater at concentrations > 0.1 µg/L, so no further relevance evaluation is required.

zRMS: The application of the formulation CYMOXANIL 33% + ZOXAMIDE 33% (Lieto 66 WG) in line with GAP does not pose a health risk for consumers of water due to potential occurrence of metabolite RH-141455 or other not toxicologically relevant metabolites of zoxamide in ground water. No metabolite of cymoxanil occurs in ground water at concentration > 0.1 µg/L, thus they are not posing health risk to potential consumers of ground water.

^{7,2} Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.8: Characterization of Dose [Concentration]-Response for Human Health, dated Nov. 2012

Appendix 1 Copy of the product authorisation

MS assessor to insert details of the product authorization for MS country.
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Appendix 2 Copy of the product label

MS assessor to present a copy of the approved product label for MS country.

Appendix 3 Letter of Access

Please refer to the Letter of Access of the company Sipcam-Oxon SpA, which is regarded to include trade and secret information of the company Gowan. It is therefore provided as a separate document and should be handled as confidential information.

Appendix 4 Lists of data considered for national authorisation

List of data submitted by the applicant and relied on

Data point ²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 2.1	Lucini, L.	2006	Cymoxanil 33 % + Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A.* Gowan	R-163/2015 (Poland)
KCP 2.1	Mori, V.	2008	Cymoxanil 33 % + Zoxamide 33 % WG Shelf life at room temperature. Sipcam Oxon, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006 GLP Not Published => Filed under KCP 2.7.5	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.1	De Ryckel, B.	2019	Validation of analytical method of cymoxanil and zoxamide content and Physico-chemical properties and storage stability of Cymoxanil 33% + Zoxamide 33% WG Gowan Crop Protection Ltd., UK Walloon Agricultural Research Centre (CRA-W), Belgium, Report No. 24718 GLP Not published => Filed under KCP 2.7.1	N	Y	Data/study report never submitted before to Country	GW1 Sipcam Oxon S.p.A.	--
KCP 2.2.1	Lucini, L.	2006	Cymoxanil 33 % + Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 2.2.2	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.3.2	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.3.3	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.4.2	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.4.2	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Sipcam Oxon, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006 GLP Not Published => Filed under KCP 2.7.5	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)

Data point ²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 2.6.2	Lucini, L.	2006	Cymoxanil 33 % + Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.6.2	De Ryckel, B.	2019	Validation of analytical method of cymoxanil and zoxamide content and Physico-chemical properties and storage stability of Cymoxanil 33% + Zoxamide 33% WG Gowan Crop Protection Ltd., UK Walloon Agricultural Research Centre (CRA-W), Belgium, Report No. 24718 GLP Not published => Filed under KCP 2.7.1	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	--
KCP 2.7.1	Lucini, L.	2006	Cymoxanil 33 % + Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.7.1	De Ryckel, B.	2019	Validation of analytical method of cymoxanil and zoxamide content and Physico-chemical properties and storage stability of Cymoxanil 33% + Zoxamide 33% WG Gowan Crop Protection Ltd., UK Walloon Agricultural Research Centre (CRA-W), Belgium, Report No. 24718 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	

Data point ²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 2.7.3	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.7.5	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Sipcam Oxon, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006 GLP Not Published	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.8.1	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.8.1	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Sipcam Oxon, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006 GLP Not Published => Filed under KCP 2.7.5	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.8.2	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)

Data point ²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 2.8.2	Mori, V.	2008	Cymoxanil 33 % + Zoxamide 33 % WG Shelf life at room temperature. Sipcam Oxon, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006 GLP Not Published => Filed under KCP 2.7.5	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.8.2	De Ryckel, B.	2019	Validation of analytical method of cymoxanil and zoxamide content and Physico-chemical properties and storage stability of Cymoxanil 33% + Zoxamide 33% WG Gowan Crop Protection Ltd., UK Walloon Agricultural Research Centre (CRA-W), Belgium, Report No. 24718 GLP Not published => Filed under KCP 2.7.1	N	Y	Data/study report never submitted before to Country	GW I Sipcam Oxon S.p.A.	--
KCP 2.8.3.1	Lucini, L.	2006	Cymoxanil 33 % + Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.8.3.1	Mori, V.	2008	Cymoxanil 33 % + Zoxamide 33 % WG Shelf life at room temperature. Sipcam Oxon, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006 GLP Not Published => Filed under KCP 2.7.5	N	Y	Data/study report never submitted before to Country	Sipcam Oxon Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)

Data point ²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 2.8.3.2	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.8.3.2	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Sipcam Oxon, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006 GLP Not Published => Filed under KCP 2.7.5	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.8.5.1.1	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.8.5.1.2	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.8.5.1.2	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Sipcam Oxon, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006 GLP Not Published => Filed under KCP 2.7.5	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)

Data point ²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 2.8.5.2.1	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.8.5.2.1	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Sipcam Oxon, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006 GLP Not Published => Filed under KCP 2.7.5	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.8.5.2.2	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.8.5.3/	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP No Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.8.5.3	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Sipcam Oxon, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006 GLP Not Published => Filed under KCP 2.7.5	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 2.8.7.1	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Sipcam Oxon, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP No Published => Filed under KCP 2.1	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCP 2.9.1	Harant, H.	2014	Evaluation of the physical compatibility of a tank mixture of Cymoxanil 33% + Zoxamide 33% WG and Aliette WG under field conditions Gowan Comércio Internacional e Servicos, Limitada, Portugal/Sipcam Oxon S.p.A., Italy BioChem agrar, Germany, Report No. 13 10 47 044 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	--
KCP 12	Anonymous	2020	Material Safety Data Sheet REBOOT, HARPON, LIETO, PAJO, ELECTIS PLUS, ELECTIS CX, Cymoxanil 33% + Zoxamide 33%, dated 22.12.2020 Gowan Crop Protection, Ltd., UK No GLP Not published	N	Y	Data/study report never submitted before to Country	GWI	--
KCP 5.1.1	Diogo, A.	2003	Analytical Method and Validation for the Determination of Cymoxanil and Zoxamide in Harpon XF – 98083 Formulation Dow AgroSciences Industrial Ltda., Brazil, Report no. DAS–AM–02–051 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI	R-163/2015 (Poland)
KCP 5.1.1	De Ryckel, B.	2018	Validation of analytical method of cymoxanil and zoxamide content and Physico-chemical properties and storage stability of Cymoxanil 33% + zoxamide 33% WG Gowan Crop Protection Ltd., UK Walloon Agricultural Research Centre (CRA-W), Belgium, Report No. 24718 GLP No Published	N	Y	Data/study report never submitted before to Country	GWI	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1 (KCA 4.1)	Peterek, S.	2020	Magnitude of the residues of zoxamide and its metabolites in grapevine (RAC bunches) and processed fractions, following applications of Zoxium 240 SC, Northern Europe – 2018 Gowan Crop Protection Ltd., UK Staphyt GmbH, Germany, Report No. AB2-18-35355 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GW I	--
KCP 5.1 (KCA 4.1)	Sala, A.	2020	Determination of zoxamide and its metabolites in raw agricultural commodity wine grape (berries) and processed fractions (juice, wine) following five applications of Zoxium 240 SC (GWN-9790 EU) in open field condition, 2 harvest trials, Northern Europe, year 2017 – final report amendment no. 1 Gowan Crop Protection Ltd., UK LabAnalysis, Italy, Report No. BPL-STUDY-19-000041 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GW I	--
KCP 5.1 (KCA 4.1)	Thomas-Delille, E.	2020	RH-150721 Residues in wine grape and processed fractions following five foliar applications with Zoxium 240 SC under field conditions in Northern Europe in 2017 – amended final report Gowan Crop Protection Ltd., UK Anadiag, France, Report No. B7284 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GW I	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1 (KCA 4.1)	Sala, A.	2020	Determination of Zoxamide and its metabolites in raw agricultural commodity wine grape (berries) and processed fractions (juice, wine) following five applications of Zoxium 240 SC (GWN-9790 EU) in open field condition 2 harvest trials, Southern Europe, year 2017 - final report amendment no. 1 Gowan Crop Protection Ltd., UK LabAnalysis, Italy, Report No. BPL-STUDY-19-000051 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GWl	--
KCP 5.1 (KCA 4.1)	Casalinuovo, L.	2020	Determination of zoxamide and his metabolite RH-150721 residues in raw agricultural commodity red grapes and processed fraction following five applications of Zoxium 240 SC (Zoxamide 240 g/L) (South Europe - 2 trials year 2017) plus amendment no. 1 to final report Gowan Crop Protection Ltd., UK Biotechnologie B.T., Italy, Report No. BIU-005-17 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GWl	--
KCP 5.1 (KCA 4.1)	Longhi, D.	2020	Determination of zoxamide and its metabolites in raw agricultural commodity of grape wine in open field following five and three applications of the formulated product GWN 9790 EU (North Europe - 4 trials year 2019) Gowan Crop Protection Ltd., UK LabAnalysis, Italy, Report No. BPL-STUDY-19-000057 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GWl	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1 (KCA 4.1)	Longhi, D.	2020	Determination of zoxamide and its metabolites in raw agricultural commodity of table grape and processed (raisin) in open field following five and three applications of the formulated product GWN 9790 EU (South Europe – 1 trial year 2019) Gowan Crop Protection Ltd., UK LabAnalysis, Italy, Report No. BPL-STUDY-19-000058 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GW	--
KCP 5.1 (KCA 4.1)	Maccaferri, L.	2020	Magnitude of the residues of zoxamide in table grape bunches and in raisins processed fraction, following applications of Zoxium 240 SC. One harvest trial, Southern Europe – 2018 Gowan Crop Protection Ltd., UK Renolab S.r.l., Italy, Report No. 18097-03R GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GW	--
KCP 5.1 (KCA 4.1)	Maccaferri, L.	2019	Determination of the residues of zoxamide and/or phosphorous acid in table grape raw agricultural commodity following five applications of GOW F 716, Zoxium 240 SC, GOW F 316 in open field conditions (one harvest trial, Italy 2017) Gowan Crop Protection Ltd., UK Renolab S.r.l., Italy, Report No. 17120-01R GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1 (KCA 4.1)	Maccaferri, L.	2019	Determination of the residues of zoxamide and/or phosphorous acid in raw agricultural commodity of grapevine and processed commodities (juice, must, young wine and bottled wine) following five applications of GOW F 716, Zoxium 240 SC, GOW F 316 in open field conditions (one harvest trial, Italy 2017) Gowan Crop Protection Ltd. UK Renolab S.r.l., Italy, Report No. 17120-02R GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GWl	--
KCP 5.1 (KCA 4.1)	Maccaferri, L.	2020	Magnitude of residues of zoxamide enantiomers and metabolites in grapes and processed commodities (juice, must, young wine and bottled wine) following five applications of GOW F 716 and Zoxium 240 SC in open field condition (Italy 2017) Gowan Crop Protection Ltd., UK Renolab S.r.l, Italy, Report No. 19200-01R GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GWl	--
KCP 5.1 (KCA 4.1)	Luciani, G.P.	2016	Determination of zoxamide and benalaxyl-m residues after three applications of GWN-10392 on wine grapes under field conditions – Italian trial, year 2015 Gowan Comercio Internacional et Servicos Lda., Portugal Tentamus AgriParadigma S.r.l., Italy, Report No. AGRI 009/15 GLP HAR GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GWl	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1 (KCA 4.1)	Perboni, A.	2017	Determination of benalaxyl-m and zoxamide residues in raw agricultural commodity grapes (wine and table) and processed commodity (must, fermenting must, wine and aged wine) following three applications of GWN-10392 (benalaxyl-m 150 g/L + zoxamide 225 g/L) in open field condition (3 harvest trials, Northern and Southern Europe, year 2015) Gowan Crop Protection Ltd., UK Biotechnologie BT, Italy, Report No. RAU-049-15 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GWI	--
KCP 5.1	Romanini, M	2011	Determination of cymoxanil and zoxamide residues at harvest in raw and processed agricultural commodity grape (bunch, must young and bottled wine) Following five applications of HARPON WG (Cymoxanil 33% + Zoxamide 33% WG) - Four trials, Northern Eu-rope 2010 Gowan Comercio Internacional e Servicos Limitada, Portugal Research Centre "E. Gagliardini", Italy, Report No. CREG2117 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GWI	R-163/2015 (Poland)
KCP 5.1	Romanini, M.	2011	Determination of cymoxanil and zoxamide residues at harvest in raw and processed agricultural commodity grape (bunch, must young and bottled wine) following five applications of HARPON WG (Cymoxanil 33% + Zoxamide 33% WG) - Four trials, Northern Eu-rope 2010 Gowan Comercio Internacional e Servicos Limitada, Portugal Research Centre "E. Gagliardini", Italy, Report No. CREG2120 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GWI	R-163/2015 (Poland)

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1 (KCA 4.1)	Longhi, D.	2020	Determination of (R) and (S) zoxamide residues and its metabolites RH-150721, RH-129151, RH-141452, RH-141288, RH-24549 in raw agricultural commodity of industrial tomato and its processed products (juice, puree and peeled tomatoes) following five applications of formulated product Zoxium 240 SC (sponsor code GWN-9790 EU) in open field (South Europe – 4 trials years 2018) Gowan Crop Protection Ltd., UK LabAnalysis, Italy, Report No. BPL-STUDY-18-000014 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GWI	--
KCP 5.1 (KCA 4.1)	Longhi, D.	2020	Determination of (R) and (S) zoxamide residues and its metabolites RH-150721, RH-129151, RH-141452, RH-141288, RH-24549 in fresh market tomato raw agricultural commodity following five applications of the formulated product Zoxium 240 SC (sponsor code GWN-9790 EU) in greenhouse (South Europe – 4 trials years 2018) - final report amendment no. 1 Gowan Crop Protection Ltd., UK LabAnalysis, Italy, Report No. BPL-STUDY-18-000015 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GWI	--
KCP 5.1 (KCA 4.1)	Longhi, D.	2020	Determination of zoxamide and its metabolites in raw agricultural commodity of industrial tomato in open field following five applications of the formulated product GWN 9790 EU (South Europe - 4 trials year 2019) Gowan Crop Protection Ltd., UK LabAnalysis, Italy, Report No. BPL-STUDY-19-000059 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GWI	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1 (KCA 4.1)	Pandolfi, A.	2020	Determination of zoxamide residues and its metabolites in raw agricultural commodity tomato (fruits) following five applications of Zoxium 240 SC (sponsor code GWN-9790 EU) in protected condition (Italy - Southern Europe - 4 trials year 2019) Gowan Crop Protection Ltd., UK RES AGRARIA, Italy, Report No. RA 19 043 BPL GW GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GW I	--
KCP 5.1 (KCA 4.1)	Tetuan, B.	2016	Determination of residues at harvest of zoxamide, benalaxyl-m and cymoxanil in tomato, following three broadcast applications of GWN-10392, GWN-9823 and IR6141-copper oxychloride-copper hydroxide 5-15-15 WG under greenhouse conditions and determination of residues at harvest of zoxamide and benalaxyl-m in industry tomato and its processed products (canned tomatoes, puree and juice), following three broadcast applications of GWN-10392 under open field conditions - South Europe - season 2015 Gowan Comercio Internacional et Servicios Ltd., Portugal Promovert Crop Services SL, Spain, Report No. 15 F CL GW P/A GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GW I	--
KCP 5.1	Romanini, M.	2011	Determination of cymoxanil and zoxamide residues at harvest in raw and processed agricultural commodity tomato (fruit, juice, puree and canned) following five applications of HAR-PON WG (Cymoxanil 33% + zoxamide 33% WG) - Four trials, Italy 2010 Gowan Comercio Internacional e Servicios Limitada, Portugal Research Centre "E. Gagliardini", Italy, Report No. CREG2118 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GW I	R-163/2015 (Poland)

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1	Devine, H.C.	2006	Residues of Mancozeb and Zoxamide in field and protected tomatoes at intervals and at harvest following multiple applications of Electis, Northern France and the United Kingdom – 2006 Dow Agrosiences, UK CEM Analytical Services Ltd (CEMAS), UK, Report No. GHE-P-11604, CEMS-2967 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GW I	--
KCP 5.1	Tetuan, B.	2011	Determination of residues at harvest in potatoes, following six broadcast applications of Harpon WG, under field conditions - Northern Europe - season 2010 Gowan Comercio Internacional & Servicos Ltda, Portugal PROMO-VERT, France, Report No. 10 F PT GW P/A, PROMO/ZOX-CYM/10.01 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GW I	R-163/2015 (Poland)
KCP 5.1	Tetuan, B.	2011	Determination of residues at harvest in potatoes, following five broadcast applications of HARPON WG, under field conditions - Southern Europe - season 2010 Gowan Comercio Internacional & Servicos Ltda, Portugal PROMO-VERT, France, Report No. 10 F PT GW P/ B, PROMO/ZOX-CYM/10.01 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GW I	R-163/2015 (Poland)

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1	Terranegra, A.	2020	Magnitude of residue of zoxamide and metabolite RH-1452 and RH-1455 in potatoes (RAC tubers) and processed fractions, following 5 applications of GWN 9790 EU in two trials (2 HS), Northern Europe (France and Poland) – 2017 – amended Final Report GOWAN Crop Protection Ltd., UK Staphyt Italia S.r.l., Italy, Report No. ATA-18-30694, BPL-STUDY-19-0000065 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GW I	--
KCP 5.1	Pandolfi, A.	2020	Determination of the residues of zoxamide (R), (S) and sum and its metabolites in raw agricultural commodity potato (tubers) and its processed fractions (chips, baked/cooked, fried and flakes) following five applications of Zoxium 240 SC (sponsor code GWN-9790 EU) in open field condition (Italy - Southern Europe - 2 trials year 2018) Gowan Crop Protection Ltd., UK Res Agraria S.r.l., Italy, Report No. RA 18 051 BPL GW, BPL-STUDY-19-000025 GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GW I	--
KCP 5.1 (KCA 4.1)	Luciani, G.P.	2012	Determination of zoxamide and dimethomorph residues after two applications of Zoxium 240 SC and GWN-9963 on lettuce, rocket salad and endive under field conditions - Italian trial year 2012 Gowan Italia Spa, Italy AgriParadigma Srl, Italy, Report No. AGRI 013/12 GLP DEC GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GW I	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1 (KCA 4.1)	Luciani, G.P.	2012	Determination of zoxamide and dimethomorph residues after two applications of Zoxium 240 SC and GWN-9963 on lettuce and rocket - Italian trial, year 2012 Gowan Italia Spa, Italy AgriParadigma Srl, Italy, Report No. AGRI 014/12 GLP DEC GLP Not published ⇒ Filed under KCA 6.3	N	Y	Data/study report never submitted before to Country	GW	--
KCP 5.1 (KCA 4.1)	Longhi, D.	2019	RH-141452: Hydrolysis under simulated processing conditions Gowan Crop Protection Ltd., UK LabAnalysis s.r.l., Italy, Report No. BPL-STUDY-18-000092 GLP Not published ⇒ Filed under KCA 6.5.1	N	Y	Data/study report never submitted before to Country	GW	
KCP 5.1 (KCA 4.1)	Longhi, D.	2019	RH-141455: Hydrolysis under simulated processing conditions Gowan Crop Protection Ltd., UK LabAnalysis s.r.l., Italy, Report No. BPL-STUDY-19-000009 GLP Not published ⇒ Filed under KCA.6.5.1	N	Y	Data/study report never submitted before to Country	GW	
KCP 5.1 (KCA 4.1)	xxx.	2020	RH-163353: Fish, acute toxicity test Gowan Crop Protection Ltd., UK xxx, Report No. 3202385 GLP Not published ⇒ Filed under KCP 10.2.1	Y	Y	Data/study report never submitted before to Country	GW	
KCP 5.1 (KCA 4.1)	Jarrom, R.	2020	RH-163353: Acute toxicity to Daphnia magna Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202386 GLP Not published ⇒ Filed under KCP 10.2.1	N	Y	Data/study report never submitted before to Country	GW	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1 (KCA 4.1)	Jarrom, R.	2020	RH-163353: Mysid acute toxicity test Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202387 GLP Not published ⇒ Filed under KCP 10.2.1	N	Y	Data/study report never submitted before to Country	GW	
KCP 5.1 (KCA 4.1)	Jarrom, R.	2020	RH-163353: Inhibition of growth to the alga Raphidocelis subcapitata Gowan Crop Protection Ltd., UK Smithers ESG Ltd., UK, Report No. 3202388 GLP Not published ⇒ Filed under KCP 10.2.1	N	Y	Data/study report never submitted before to Country	GW	
KCP 5.1 (KCA 4.1)	xxx	2020	RH-141455: Fish, acute toxicity test Gowan Crop Protection Ltd., UK xxx, Report No. 3202716 GLP Not published ⇒ Filed under KCP 10.2.1	Y	Y	Data/study report never submitted before to Country	GW	
KCP 5.1 (KCA 4.1)	Hugill, E.	2020	RH-141455: Acute toxicity to Daphnia magna Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202380 GLP Not published ⇒ Filed under KCP 10.2.1	N	Y	Data/study report never submitted before to Country	GW	
KCP 5.1 (KCA 4.1)	Hugill, E.	2020	RH-141455: Mysid acute toxicity test Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202381 GLP Not published ⇒ Filed under KCP 10.2.1	N	Y	Data/study report never submitted before to Country	GW	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1 (KCA 4.1)	xxx	2020	RH-127450: Fish, acute toxicity test Gowan Crop Protection Ltd., UK xxx, Report No. 3202373 GLP Not published ⇒ Filed under KCP 10.2.1	Y	Y	Data/study report never submitted before to Country	GW I	
KCP 5.1 (KCA 4.1)	xxx	2019	RH-127450: Mysid acute toxicity test Gowan Crop Protection Ltd., UK xxx, Report No. 3202374 GLP Not published ⇒ Filed under KCP 10.2.1	N	Y	Data/study report never submitted before to Country	GW I	
KCP 5.1 (KCA 4.1)	Hugill, E.	2019	RH-127450: Inhibition of growth on the alga Raphidocelis subcapitata Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202375 GLP Not published ⇒ Filed under KCP 10.2.1	N	Y	Data/study report never submitted before to Country	GW I	
KCP 5.1 (KCA 4.1)	Hugill, E.	2019	RH-24549: Mysid acute toxicity test Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202394 GLP Not published ⇒ Filed under KCP 10.2.1	N	Y	Data/study report never submitted before to Country	GW I	
KCP 5.1 (KCA 4.1)	Hugill, E.	2019	RH-139432: Mysid acute toxicity test Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK Report No. 3202398 GLP Not published ⇒ Filed under KCP 10.2.1	N	Y	Data/study report never submitted before to Country	GW I	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1 (KCA 4.1)	Juckeland, D.	2018	Effects of Zoxium 240 SC on Lemna gibba in a growth inhibition test under semi-static test conditions Gowan Crop Protection Ltd., UK BioChem agrar, Germany, Report No. 18 48 ALE 0005 GLP Not published ⇒ Filed under KCP 10.2.1	N	Y	Data/study report never submitted before to Country	GW	--
KCP 5.1	xxx	2007	Acute toxicity of Cymoxanil 33% + Zoxamide 33% WG to rainbow trout (Oncorhynchus mykiss), determined under flow-through conditions Sipcam Oxon S.p.A., Italy xxx, Report No. CH-E-023/2006 GLP Not published ⇒ Filed under KCP 10.2.1	Y	Y	Data/study report never submitted before to Country	GW Sipcam Oxon S.p.A.	R-163/2015 (Poland)
KCP 5.1	xxx	2007	Acute toxicity of Cymoxanil 33% + Zoxamide 33 % WG to Daphnia magna in a 48-hour immobilization test under semi-static exposure-limit test Sipcam Oxon S.p.A., Italy xxx, Report No. CH-001/2007 GLP Not published ⇒ Filed under KCP 10.2.1	Y	Y	Data/study report never submitted before to Country	GW Sipcam Oxon S.p.A.	R-163/2015 (Poland)
KCP 5.1	xxx	2007	Toxicity of Cymoxanil 33% + Zoxamide 33% WG to green algae Pseudokirchneriella subcapitata determined in a growth inhibition study Sipcam Oxon S.p.A., Italy xxx, Report No. CH-002/2007 GLP Not published ⇒ Filed under KCP 10.2.1	Y	Y	Data/study report never submitted before to Country	GW Sipcam Oxon S.p.A.	R-163/2015 (Poland)

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1 (KCA 4.1)	xxx	2020	xxx, 2020: Final report addendum for RH-117,281 technical: An early life-stage toxicity test with the sheepshead minnow (Cyprinodon variegatus) Gowan Crop Protection Ltd., UK xxx, USA, Report No. 129A-143A GLP Not published ⇒ Filed under KCP 10.2.2	N	Y	Data/study report never submitted before to Country	GW I	
KCP 5.1 (KCA 4.1)	xxx	1998	RH-117,281 technical: An early life-stage toxicity test with the sheepshead minnow (Cyprinodon variegatus) xxx, Report No. 97RC-0078 Gowan Crop Protection Ltd., UK xxx, Report No. 129A-143A GLP Not published ⇒ Filed under KCP 10.2.2	Y	Y	Data/study report never submitted before to Country	GW I	
KCP 5.1	Garofani, S.	2007	Cymoxanil 33% + Zoxamide 33% WG: validation of the analytical method for the determination of the content of zoxamide in water samples from the aquatic ecotoxicological studies Sipcam Oxon S.p.A., Italy ChemService S.r.l., Italy., Report No. CH-156/2006 GLP Not published	N	Y	Data/study report never submitted before to Country	GW I Sipcam Oxon S.p.A.	R-163/2015 (Poland)
KCP 5.1 (KCA 4.1)	Kercher, S.	2017	Enantioselective degradation of (R)-Zoxamide and (S)-Zoxamide in one soil incubated under aerobic conditions Gowan Crop Protection Ltd., UK RLP AgroScience GmbH, Germany, Report No. AS520 GLP Not published ⇒ Filed under KCP 9.1.1.1	N	Y	Data/study report never submitted before to Country	GW I	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1 (KCA 4.1)	Friedrich, S.	2018	Effects of Zoxium 240 SC on the reproduction of the earthworm <i>Eisenia andrei</i> in artificial soil with 5 % peat content Gowan Crop Protection Ltd., UK BioChem agrar, Germany, Report No. 17 48 TEC 0009 GLP Not published ⇒ Filed under KCP 10.4.1.1	N	Y	Data/study report never submitted before to Country	GW I	
KCP 5.1 (KCA 4.1)	Schulz, L.	2020	Effects of Zoxium 240 SC on earthworms under field conditions Gowan Crop Protection Ltd., UK, BioChem agrar, Germany, Report No.18 48 FEW 0001 GLP Not published ⇒ Filed under KCP 10.4.1.2	N	Y	Data/study report never submitted before to Country	GW I	--
KCP 5.1 (KCA 4.1)	Parsons, Ch	2020	Zoxium 240 SC - A laboratory test to determine the effects of fresh residues on the springtail <i>Folsomia candida</i> (Collembola, Isotomidae) in artificial soil substrate Gowan Crop Protection Ltd., UK Mambo-Tox Ltd., UK, Report No. GOW-17-13 GLP Not published ⇒ Filed under KCP 10.4.2	N	Y	Data/study report never submitted before to Country	GW I	--
KCP 5.1 (KCA 4.1)	Parsons, Ch	2020	Zoxium 240 SC – A laboratory test to determine the effects of fresh residues on the predatory soil mite <i>Hypoaspis aculeifer</i> (Acari, Laelapidae) in an artificial soil substrate Gowan Crop Protection Ltd., UK Mambo-Tox Ltd., UK, Report No. GOW-17-14 GLP Not published ⇒ Filed under KCP 10.4.2	N	Y	Data/study report never submitted before to Country	GW I	--
KCP 5.1	Thomas, H.	2020	Validation of a HPLC-MS-MS method for the determination of Cymoxanil and Zoxamide in soil Gowan Crop Protection Ltd., UK, SIPCAM OXON S.p.A. BioChem agrar, Germany, Report No.18 35 CRX 0033 GLP Not Published	N	Y	Data/study report never submitted before to Country	GW I Sipcam Oxon S.p.A	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1	Friedrich, S.	2020	Effects of Cymoxanil 33 % + Zoxamide 33 % WG on the reproduction of the earthworm <i>Eisenia andrei</i> in artificial soil Gowan Crop Protection Ltd., UK, SIPCAM OXON S.p.A., Italy BioChem agrar, Germany, Report No.17 48 TEC 0008, 18 35 CRX 0029 GLP Not Published ⇒ Filed under KCP 10.4.1.2	N	Y	Data/study report never submitted before to Country	GW Sipcam Oxon S.p.A	--
KCP 5.1	Schulz, L.	2020	Effects of Cymoxanil 33% + Zoxamide 33% WG on earthworms under field conditions Gowan Crop Protection Ltd., UK, SIPCAM OXON S.p.A., Italy BioChem agrar, Germany, Report No.19 48 FEW 0003, 19 35 CRX 0030 GLP Not published ⇒ Filed under KCP 10.4.1.2	N	Y	Data/study report never submitted before to Country	GW Sipcam Oxon S.p.A	--
KCP 5.1	Parson, Ch.	2020	Cymoxanil 33% + Zoxamide 33 % WG (GWN-9823) – A laboratory test to determine the effects of fresh residues on the springtail <i>Folsomia candida</i> (Collembola, Isotomidae) in an artificial soil substrate Gowan Crop Protection Ltd., UK, SIPCAM OXON S.p.A, Italy Mambo-Tox Ltd., UK, Report No. GOW-17-3, 18 35 CRX 0026 GLP Not Published ⇒ Filed under KCP 10.4.2	N	Y	Data/study report never submitted before to Country	GW Sipcam Oxon S.p.A	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1	Parson, Ch.	2020	Cymoxanil 33% + Zoxamide 33 % WG (GWN-9823) – A laboratory test to determine the effects of fresh residues on the predatory soil mite <i>Hypoaspis aculeifer</i> (Acari, Laelapidae) in an artificial soil substrate Gowan Crop Protection Ltd., UK, SIPCAM OXON S.p.A, Italy Mambo-Tox Ltd., UK, Report No. GOW-17-4; 18 35 CRX 0027 GLP Not published ⇒ Filed under KCP 10.4.2	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A	--
KCP 5.1 (KCA 4.1)	Gray, J.	2020	RH-163353: Effect on reproduction in the earthworm <i>Eisenia fetida</i> Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No.3202389 GLP Not published ⇒ Filed under KCP 10.4.1.1	N	Y	Data/study report never submitted before to Country	GWI	
KCP 5.1 (KCA 4.1)	Gray, J.	2020	RH-163353: Collembolan reproduction test in soil Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202390 GLP Not published ⇒ Filed under KCP 10.4.2	N	Y	Data/study report never submitted before to Country	GWI	
KCP 5.1 (KCA 4.1)	Gray, J	2020	RH-163353: Effect on reproduction of <i>Hypoaspis</i> (<i>Geolaelaps</i>) <i>aculeifer</i> Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202391 GLP Not published ⇒ Filed under KCP 10.4.2	N	Y	Data/study report never submitted before to Country	GWI	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1 (KCA 4.1)	Gray, J.	2020	RH-127450: Effect on reproduction in the earthworm <i>Eisenia fetida</i> Gowan Crop Protection Ltd., UK Smithers ERS Ltd, UK, Report No.3202376 GLP Not published ⇒ Filed under KCP 10.4.1.1	N	Y	Data/study report never submitted before to Country	GW	
KCP 5.1 (KCA 4.1)	Gray, J.	2019	RH-24549: Effect on reproduction in the earthworm <i>Eisenia fetida</i> Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No.3202395 GLP Not published ⇒ Filed under KCP 10.4.1.1	N	Y	Data/study report never submitted before to Country	GW	
KCP 5.1 (KCA 4.1)	Gray, J.	2020	RH-141455: Collembolan reproduction study Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202382 GLP Not published ⇒ Filed under KCP 10.4.2	N	Y	Data/study report never submitted before to Country	GW	
KCP 5.1 (KCA 4.1)	Gray, J.	2020	RH-141455: Effect on reproduction of <i>Hypoaspis (Geolaelaps) aculeifer</i> Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202383 GLP Not published ⇒ Filed under KCP 10.4.2	N	Y	Data/study report never submitted before to Country	GW	
KCP 5.1 (KCA 4.1)	xxx	2020	RH-141455: 90-day oral dietary toxicity study with toxicokinetics and 28-day recovery period in Sprague Dawley rats Gowan Crop Protection Ltd., UK xxx, Report No. U-19102 GLP Not published ⇒ Filed under KCP 7.4	Y	Y	Data/study report never submitted before to Country	GW	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1 (KCA 5.8.1)	xxx	2020	RH-141455: 2-day oral dietary pharmacokinetic study in Sprague Dawley rats Gowan Crop Protection Ltd, UK xxx, Report No. U-19044 No GLP Not published ⇒ Filed under KCP 7.4	Y	Y	Data/study report never submitted before to Country	GW	
KCP 5.1 (KCA 5.8.1)	xxx	2020	RH-141455: 14-day oral dietary dose range finding study in Sprague Dawley rats Gowan Crop Protection Ltd, UK xxx, Report No. U-19071 No GLP Not published ⇒ Filed under KCP 7.4	Y	Y	Data/study report never submitted before to Country	GW	
KCP 5.1 (KCA 4.1)	xxx	2020	RH-150721: 2-day oral dietary pharmacokinetic study in Sprague Dawley rats Gowan Crop Protection Ltd., UK xxx, Report No. U-19134 No GLP Not published ⇒ Filed under KCP 7.4	Y	Y	Data/study report never submitted before to Country	GW	
KCP 5.1 (KCA 4.1)	xxx	2020	Analytical method validation for the estimation of RH-150721 in rat feed by reverse phase high performance Liquid Chromatography Gowan Crop Protection Ltd., UK xxx, Report No. U-19162 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	
KCP 5.1 (KCA 4.1)	xxx	2019	RH-141455: Analytical method validation for the estimation of RH-141455 in rat feed by reverse phase high performance liquid chromatography was used for the dose formulation analysis Gowan Crop Protection Ltd., UK xxx, Report No. U-19069 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1 (KCA 4.1)	Picard, Ch.R.	2018	Zoxamide: Honey bee (<i>Apis mellifera</i> L.) larval toxicity, repeated exposure Exigent LLC, A Gowan Group Company, USA Smithers Viscient, USA, Report No. 12791.6307 GLP Not published ⇒ Filed under KCP 10.3.1.3	N	Y	Data/study report never submitted before to Country	GW I	
KCP 5.1	Ruhland, S.	2018	Chronic toxicity of Cymoxanil 33% + Zoxamide 33% WG to the honey bee <i>Apis mellifera</i> L. under laboratory conditions Gowan Crop Protection Ltd., UK, Sipcam Oxon S.p.A, Italy BioChem agrar, Germany, Report No. 17 48 BAC 0005, 17 35 CRB 0009 GLP Not Published ⇒ Filed under KCP 10.3.1.2	N	Y	Data/study report never submitted before to Country	GW I Sipcam Oxon S.p.A	--
KCP 5.1	Scheller, K.	2020	Cymoxanil 33% + Zoxamide 33% WG - Repeated exposure of honey bee (<i>Apis mellifera</i> L.) larvae under laboratory conditions (in vitro) Gowan Crop Protection Ltd., UK, SIPCAM OXON S.p.A., Italy BioChem agrar, Germany, Report No. 17 48 BLC 0005, 17 35 CRB 0010 GLP Not published ⇒ Filed under KCP 10.3.1.3	N	Y	Data/study report never submitted before to Country	GW I Sipcam Oxon S.p.A	--
KCP 5.1	Schnurr, A.	2020	Effects of Cymoxanil 33% + Zoxamide 33% WG on the honeybee <i>Apis mellifera</i> L. under field conditions with additional assessments on colony and brood development Gowan Crop Protection Ltd., UK, SIPCAM OXON S.p.A., Italy BioChem agrar, Germany, Report No. 18 48 BFB 0001 GLP Not published ⇒ Filed under KCP 10.3.1.6	N	Y	Data/study report never submitted before to Country	GW I Sipcam Oxon S.p.A	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.1	Schnurr, A.	2020	Effects of Cymoxanil 33% + Zoxamide 33% WG on the honeybee <i>Apis mellifera</i> L. under field conditions in Spain (Southern zone) with additional assessments on colony and brood development Gowan Crop Protection Ltd., UK, SIPCAM OXON S.p.A., Italy BioChem agrar, Germany, Report No. 19 48 BFB 0001 GLP Not published ⇒ Filed under KCP 10.3.1.6	N	Y	Data/study report never submitted before to Country	GW Sipcam Oxon S.p.A	--
KCP 5.2	Witte, A.	2020	Validation of an analytical method for the determination of residues of R/S-Isomers of Zoxamide and metabolites RH-141452 and RH-141455 in 4 different matrices: potato tubers (water containing matrix), potato flakes (dry matrix), potato chips (fat containing matrix) and pickled silver skin onions (acidic matrix) Gowan Crop Protection Ltd., UK CIP Pforzheim, Germany., Report No. 18G10186-01-VMPL GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCP 5.2 (KCA 4.2)	Sala, A.	2020	Validation of an analytical method to determine zoxamide residues in grape, potato, tomato, cucumber, and onion raw agricultural and processed commodities Gowan Crop Protection Ltd., UK LabAnalysis, Italy, Report No. BPL-STUDY-18-000085 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCP 5.2 (KCA 4.2)	Coleman, H.	2017	Validation of an analytical method for the determination of zoxamide in body fluid and tissue Gowan Crop Protection Ltd., UK Battelle UK Ltd., Essex, UK, Report No. FF/17/002 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 5.2	Freschi, G.	2001	Validation of analytical method for determination of residues of Cymoxanil in tomato (whole fruit) Sipcam Oxon S.p.A., Italy Sipcam S.p.A, Italy, Report No. SIP1278 GLP Not Published	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A	R-163/2015 (Poland)
KCP 5.2	Freschi, G.	2001	Validation of analytical method for determination of residues of Cymoxanil in grapes (bunches) Sipcam Oxon S.p.A., Italy Sipcam S.p.A, Italy, Report No. SIP1276 GLP Not Published	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A	R-163/2015 (Poland)
KCP 5.2	Leak, T.	2010	Analytical method for the determination of Cymoxanil and IN-KQ960 in water (pond, stream, well and tap) using LC/MS/MS Sipcam Oxon S.p.A., Italy ChemService, Italy, Report No. DuPont-27500/ ABC-65072 rev.2, GLP, Not Published	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A	R-163/2015 (Poland)
KCP 5.2	Cermak, J.	2013	Independent Laboratory Validation for the Determination of residues of Cymoxanil and IN-KQ960 in water (drinking and stream) using LC/MS/MS Sipcam Oxon S.p.A., Italy Research Institute for Organic Syntheses, Inc., Czech Republic, Report No. 2556-256/12/48 (DuPont-35792), GLP, Not published	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A	R-163/2015 (Poland)
KCP 7.1.1	xxx	1999	RH – 7281/Cymoxanil 66% DG Blend (1:1) Acute oral toxicity study in male and female rats xxx, Report No. 99R – 102 GLP Not published	Y	Y	Data/study report never submitted before to Country	GW Sipcam Oxon S.p.A	R-163/2015 (Poland)
KCP 7.1.2	xxx	1999	RH – 7281/Cymoxanil 66% DG Blend (1:1) Acute dermal toxicity study in male and female rats xxx, Report No. 99R – 103 GLP Not published	Y	Y	Data/study report never submitted before to Country	GW Sipcam Oxon S.p.A	R-163/2015 (Poland)

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 7.1.3	xxx	1999	RH – 7281/Cymoxanil 66% DG Blend (1:1) Acute inhalation toxicity study in rats xxx, Report No. 99R – 106 GLP Not published	Y	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A	R-163/2015 (Poland)
KCP 7.1.4	xxx	1999	RH – 7281/Cymoxanil 66% DG Blend (1:1) Skin irritation study in rabbits xxx, Report No. 99R – 104 GLP Not published	Y	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A	R-163/2015 (Poland)
KCP 7.1.5	xxx	1999	RH – 7281/Cymoxanil 66% DG Blend (1:1) Eye irritation study in rabbits xxx, Report no. 99R – 105 GLP Not published	Y	Y	Data/study report never submitted before to Country	GWI	R-163/2015 (Poland)
KCP 7.1.6	xxx	1999	RH – 7281/Cymoxanil 66% DG Blend (1:1) Dermal sensitization study in guinea pigs xxx Report no. 99R – 107 GLP Not published	Y	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A	R-163/2015 (Poland)
KCP 7.2/01	Jullian E.	2014	Quantification of dislodgeable foliar residues following five applications of Vitene Ultra to grapevines in northern France and Italy, 2013 Report number: S13-01291 Laboratory: Eurofins Agrosience Services, Ltd. Owner: SIPCAM OXON S.p.A GLP: Y Published: N	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 7.2/02	Jullian E.	2014	Quantification of dislodgeable foliar residues following six applications of Vitene Ultra to potato in the United Kingdom, 2013 Report number: S13-01293 Laboratory: Eurofins Agroscience Services, Ltd. Owner: SIPCAM OXON S.p.A GLP: Y Published: N	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A	--
KCP 7.3/01	Prisk, L.	2018	The in vitro percutaneous absorption of radiolabelled Cymoxanil and radiolabelled zoxamide in the concentrate and one in-use dilution through human skin Gowan Crop Protection Ltd., UK & Sipcam Oxon SpA Charles River Laboratories Edinburgh Ltd., UK, Report No. 38683 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	--
KCP 7.3/02	Maas W.,	2020	The in vitro percutaneous absorption of radiolabelled cymoxanil from a transferred dried surface residue through human split-thickness skin Sipcam Oxon S.p.A, Italy Charles River Laboratories Den Bosch BV, The Netherlands Report No. 20211644, GLP, Not published	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A	--
KCP 7.4 (KCA 5.8.1)	Schreib, G.	2019	Reverse mutation assay using bacteria (Salmonella typhimurium and Escherichia coli) with RH-24549 Gowan Crop Protection Ltd, UK Eurofins BioPharma Product Testing Munich GmbH, Germany, Report No. STUGC19AA1580-1 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 7.4 (KCA 5.8.1)	Schreib, G.	2019	Reverse mutation assay using bacteria (Salmonella typhimurium and Escherichia coli) with RH-129151 Gowan Crop Protection Ltd, UK Eurofins BioPharma Product Testing Munich GmbH, Germany, Report No.188626 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	
KCP 7.4 (KCA 5.8.1)	Voges, Y.	2020	In vitro mammalian cell gene mutation test (HPRT-locus) in Chinese Hamster V79 cells with RH-129151 Gowan Crop Protection Ltd, UK Eurofins BioPharma Product Testing Munich GmbH, Germany, Report No. 188628 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	
KCP 7.4 (KCA 5.8.1)	Voges, Y.	2020	In vitro Mammalian cell gene mutation test (HPRT-Locus) in Chinese Hamster V79 Cells with RH-141452 Gowan Crop Protection Ltd, UK Eurofins BioPharma Product Testing Munich GmbH, Germany, Report No. 188620 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	
KCP 7.4 (KCA 5.8.1)	Schreib, G.	2017	In vitro mammalian cell gene mutation assay (Thymidine Kinase Locus/TK+/-) in mouse lymphoma L5178Y cells with RH-150721 Gowan Crop Protection Ltd, UK Eurofins BioPharma Product Testing Munich GmbH, Germany, Report No. 171360 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	
KCP 7.4 (KCA 5.8.1)	Donath, C.	2020	In vitro Mammalian micronucleus assay in Chinese Hamster V79 cells with RH-129151 Gowan Crop Protection Ltd, UK Eurofins BioPharma Product Testing Munich GmbH, Germany, Report No. 188627 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 7.4 (KCA 5.8.1)	Donath, C.	2019	In vitro mammalian micronucleus assay in Chinese Hamster V79 cells with RH-141452 Gowan Crop Protection Ltd, UK Eurofins BioPharma Product Testing Munich GmbH, Germany, Report No. 188616 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	
KCP 7.4 (KCA 5.8.1)	Donath, C.	2017	In vitro mammalian micronucleus assay in Chinese Hamster V79 cells with RH-150721 Gowan Crop Protection Ltd, UK Eurofins BioPharma Product Testing Munich GmbH, Germany, Report No. 171361 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	
KCP 7.4 (KCA 5.8.1)	xxx	2020	RH-141455: 2-day oral dietary pharmacokinetic study in Sprague Dawley rats Gowan Crop Protection Ltd, UK xxx, Report No. U-19044 No GLP Not published	Y	Y	Data/study report never submitted before to Country	GW	
KCP 7.4 (KCA 5.8.1)	xxx	2020	RH-141455: 14-day oral dietary dose range finding study in Sprague Dawley rats Gowan Crop Protection Ltd, UK xxx, Report No. U-19071 No GLP Not published	Y	Y	Data/study report never submitted before to Country	GW	
KCP 7.4 (KCA 5.8.1)	xxx	2020	RH-141455: 90-day oral dietary toxicity study with toxicokinetics and 28-day recovery period in Sprague Dawley rats Gowan Crop Protection Ltd, UK xxx, Report No. U-19102 GLP Not published	Y	Y	Data/study report never submitted before to Country	GW	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 7.4 (KCA 5.8.1)	xxx	2020	RH-150721: 2-day oral dietary pharmacokinetic study in Sprague Dawley rats Gowan Crop Protection Ltd, UK xxx, Report No. U-19134 No GLP Not published	Y	Y	Data/study report never submitted before to Country	GW	
KCP 7.4 (KCA 5.8.1)	xxx	2020	RH-150721: 14-day oral dietary dose range finding study in Sprague Dawley rats Gowan Crop Protection Ltd., UK xxx, Report No. U-19189 GLP Not published	Y	Y	Data/study report never submitted before to Country	GW	
KCP 7.4 (KCA 5.8.1)	xxx	2020	RH-150721: 90-day oral dietary toxicity study and 28-day recovery period in Sprague Dawley rats Gowan Crop Protection Ltd, UK xxx, Report No. U-19235 GLP Not published	Y	Y	Data/study report never submitted before to Country	GW	
KCP 7.4 (KCA 5.8.1)	Strupp, Ch.	2020	Zoxamide metabolite RH-150721 - proposal of ADI setting for dietary risk assessment Gowan Crop Protection Ltd, UK, Report No. CS13072020 No GLP Not published	N	Y	Data/study report never submitted before to Country	GW	
KCP 9.1.1.1 (KCA 7.1.1)	Derz, K.	2020	Aerobic degradation of RH-24549 in three soils according to the OECD 106 Gowan Crop Protection Ltd., UK Fraunhofer IME, Germany, Report No. MKC-004/5-30 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	
KCP 9.1.1.1 (KCA 7.1.1)	Klein, J., Mendel-Kreusel, R.	2020	Re-calculation of the degradation of RH-141455 and RH-24549 in soil based on the study data of Derz K. (2020): Aerobic degradation of RH-24549 in three soils Gowan Crop Protection Ltd., UK Mendel-Kreusel Consult, Germany, Report No. GOW0720-1 No GLP Not published	N	Y	Data/study report never submitted before to Country	GW	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 9.1.1.1 (KCA 7.1.1.)	Kercher, S.	2017	Enantioselective degradation of (R)-Zoxamide and (S)-Zoxamide in one soil incubated under aerobic conditions Gowan Crop Protection Ltd., UK RLP AgroScience, Germany, Report No. AS520 GLP Not published	N	Y	Data/study report never submitted before to Country	GW I	
KCP 9.1.1.1	Clark, B.	2010	14C-IN-KQ960: Rate of degradation in five soils ABC Laboratories, Inc. Columbia, Missouri. USA, report no. Du Pont 28466/ ABC 65143 GLP Not published AIIA study on the active substance Cymoxanil	N	Y	Data/study report never submitted before to Country	GW I Sipcam Oxon S.p.A	R-163/2015 (Poland)
KCP 9.1.2	Clark, B.	2010	14C-IN-KQ960: Batch equilibrium (adsorption/desorption) in five soils ABC Laboratories Inc. Columbia, Missouri. USA Report No. DuPont 28467/ ABC 65144 GLP Not published AIIA study on the active substance Cymoxanil	N	Y	Data/study report never submitted before to Country	GW I Sipcam Oxon S.p.A	R-163/2015 (Poland)
KCP 9.2.5	Klein, J., Klein, M., Mendel-Kreusel, R.	2020	Residue dissipation of Zoxamide on/in salad plants in the open field in Southern Europe and indoor Gowan Crop Protection Ltd., UK Mendel-Kreusel Consult, Germany, Report No. GOW1020-1 No GLP Not published	N	Y	Data/study report never submitted before to Country	GW I	--
KCP 9.2.5	Appeltauer, A.	2020	Determination of Residues of Zoxamide on/in Typical Feed Items of Herbivorous Birds and Mammals after Two Applications of Zoxium 240 SC on Sugar Beet and Wheat in Germany 2017 Gowan Crop Protection Ltd., UK Eurofins GmbH, Germany, Report No. S16-05375 GLP Not published	N	Y	Data/study report never submitted before to Country	GW I	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 9.2.5	Appeltauer, A.	2020	Determination of Residues of Zoxamide on/in Typical Feed Items of Herbivorous Birds and Mammals after Two Applications of the test item on Sugar Beet and Wheat in The Netherlands in 2019 Gowan Crop Protection Ltd., UK Eurofins GmbH, Germany, Report No. S19-01450 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCP 9.2.5	Appeltauer, A.	2020	Determination of Residues of Zoxamide on/in Typical Feed Items of Herbivorous Birds and Mammals after Two Applications of Zoxium 240 SC on Sugar Beet and Wheat in Southern Europe 2017 Gowan Crop Protection Ltd., UK Eurofins GmbH, Germany, Report No. S16-05376 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCP 9.2.5	Appeltauer, A.	2020	Determination of Residues of Zoxamide on/in Typical Feed Items of Herbivorous Birds and Mammals after Two Applications of the test item on Sugar Beet and Wheat in Italy in 2020 Gowan Crop Protection Ltd., UK Eurofins GmbH, Germany, Report No. S19-23773 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCP 9.2.5	Klein, J., Mendel-Kreusel, R.	2020	Residue dissipation of zoxamide on/in plants Gowan Crop Protection Ltd., UK Mendel-Kreusel Consult, Germany, Report No. GOW1120-1 No GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCA 6.1	Sala A.	2021	Interim Report – Storage stability of Zoxamide residues under frozen conditions (-18°C) in potato tubers, potato flakes and fried potatoes LabAnalysis, Italy, Report No. BPL-STUDY-18-000047 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.1	Longhi D.	2021	Evaluation of the stability of the analyte RH-129151 in the final extract of the following commodities and processed: grape, grape juice, wine, raisin, potato, fried potato, potato fries, tomato peeled tomato, cucumber LabAnalysis, Italy, Report No. GLP-STUDY-20-77 GLP Not published	N	Y	Data/study report never submitted before to Country	GW I	--
KCA 6.1	Lucini L.	2006	Freezer storage stability of cymoxanil residue in grape bunches Sipcam SpA, Italy Report no. SIP 1380 GLP, Unpublished	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A.	R-163/2015 (Poland)
KCA 6.1	Lucini L.	2006	Freezer storage stability of cymoxanil in whole and processed tomatoes Sipcam SpA, Italy Report no. SIP 1381 GLP, Unpublished	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A.	R-163/2015 (Poland)
KCA 6.2.1	Melkebeke, T., van Noorloos, B.	2003	Metabolism, distribution, and expression of Cymoxanil residues in tomato NOTOX B.V., 's-Hertogenbosch, The Netherlands Report no 257783 GLP, Unpublished	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A.	R-163/2015 (Poland)
KCA 6.3 KCA 6.5.1	Romanini M.	2011	Determination of cymoxanil and zoxamide residues at harvest in raw and processed agricultural commodity grape (bunch, must, young and bottled wine) following five applications of Harpon WG (cymoxanil 33% + zoxamide 33% WG) - four trials, Italy 2010 CREG, Research Centre "E. Gagliardini", SIPCAM S.p.A., 26857 Salerano sul Lambro (LO), ITALY Report no CREG2117 GLP, Unpublished	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3	Romanini M.	2011	Determination of cymoxanil and zoxamide residues at harvest in raw and processed agricultural commodity grape (bunch, must, young and bottled wine) following five applications of Harpon WG (cymoxanil 33% + zoxamide 33% WG) - four trials, Northern Europe, 2010. CREG, Research Centre “E. Gagliardini”, SIPCAM S.p.A., 26857 Salerano sul Lambro (LO), ITALY Report no CREG2120 GLP, Unpublished	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCA 6.3 KCA 6.5.3	Peterek, S.	2020	Magnitude of the residues of zoxamide and its metabolites in grapevine (RAC bunches) and processed fractions, following applications of Zoxium 240 SC, Northern Europe – 2018 Gowan Crop Protection Ltd., UK Staphyt GmbH, Germany, Report No. AB2-18-35355; 18097-01R GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCA 6.3 KCA 6.5.3	Sala, A.	2020	Determination of zoxamide and its metabolites in raw agricultural commodity wine grape (berries) and processed fractions (juice, wine) following five applications of Zoxium 240 SC (GWN-9790 EU) in open field condition, 2 harvest trials, Northern Europe, year 2017 – final report amendment no. 1 Gowan Crop Protection Ltd., UK LabAnalysis, Italy, Report No. BPL-STUDY-19-000041 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCA 6.3 KCA 6.5.3	Thomas-Delille, E.	2020	RH-150721 Residues in wine grape and processed fractions following five foliar applications with Zoxium 240 SC under field conditions in Northern Europe in 2017 – amended final report Gowan Crop Protection Ltd., UK Anadiag, France, Report No. B7284 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3 KCA 6.5.3	Sala, A.	2020	Determination of Zoxamide and its metabolites in raw agricultural commodity wine grape (berries) and processed fractions (juice, wine) following five applications of Zoxium 240 SC (GWN-9790 EU) in open field condition 2 harvest trials, Southern Europe, year 2017 - final report amendment no. 1 Gowan Crop Protection Ltd., UK LabAnalysis, Italy, Report No. BPL-STUDY-19-000051 GLP Not published	N	Y	Data/study report never submitted before to Country	GWl	--
KCA 6.3 KCA 6.5.3	Casalinuovo, L.	2020	Determination of zoxamide and his metabolite RH-150721 residues in raw agricultural commodity red grapes and processed fraction following five applications of Zoxium 240 SC (Zoxamide 240 g/L) (South Europe - 2 trials year 2017) plus amendment no. 1 to final report Gowan Crop Protection Ltd., UK Biotechnologie B.T., Italy, Report No. BIU-005-17 GLP Not published	N	Y	Data/study report never submitted before to Country	GWl	--
KCA 6.3	Longhi, D.	2020	Determination of zoxamide and its metabolites in raw agricultural commodity of grape wine in open field following five and three applications of the formulated product GWN 9790 EU (North Europe - 4 trials year 2019) Gowan Crop Protection Ltd., UK LabAnalysis, Italy, Report No. BPL-STUDY-19-000057 GLP Not published	N	Y	Data/study report never submitted before to Country	GWl	--
KCA 6.3 KCA 6.5.3	Longhi, D.	2020	Determination of zoxamide and its metabolites in raw agricultural commodity of table grape and processed (raisin) in open field following five and three applications of the formulated product GWN 9790 EU (South Europe – 1 trial year 2019) Gowan Crop Protection Ltd., UK LabAnalysis, Italy, Report No. BPL-STUDY-19-000058 GLP Not published	N	Y	Data/study report never submitted before to Country	GWl	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3 KCA 6.5.3	Maccaferri, L.	2020	Magnitude of the residues of zoxamide in table grape bunches and in raisins processed fraction, following applications of Zoxium 240 SC. One harvest trial, Southern Europe – 2018 Gowan Crop Protection Ltd., UK Renolab S.r.l., Italy, Report No. 18097-03R GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCA 6.3 KCA 6.5.3	Maccaferri, L.	2019	Determination of the residues of zoxamide and/or phosphorous acid in table grape raw agricultural commodity following five applications of GOW F 716, Zoxium 240 SC, GOW F 316 in open field conditions (one harvest trial, Italy 2017) Gowan Crop Protection Ltd., UK Renolab S.r.l., Italy, Report No. 17120-01R GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCA 6.3 KCA 6.5.3	Maccaferri, L.	2019	Determination of the residues of zoxamide and/or phosphorous acid in raw agricultural commodity of grapevine and processed commodities (juice, must, young wine and bottled wine) following five applications of GOW F 716, Zoxium 240 SC, GOW F 316 in open field conditions (one harvest trial, Italy 2017) Gowan Crop Protection Ltd. UK Renolab S.r.l., Italy, Report No. 17120-02R GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCA 6.3 KCA 6.5.3	Maccaferri, L.	2020	Magnitude of residues of zoxamide enantiomers and metabolites in grapes and processed commodities (juice, must, young wine and bottled wine) following five applications of GOW F 716 and Zoxium 240 SC in open field condition (Italy 2017) Gowan Crop Protection Ltd., UK Renolab S.r.l., Italy, Report No. 19200-01R GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3 KCA 6.5.3	Luciani, G.P.	2016	Determination of zoxamide and benalaxyl-m residues after three applications of GWN-10392 on wine grapes under field conditions – Italian trial, year 2015 Gowan Comercio Internacional et Servicos Lda., Portugal Tentamus AgriParadigma S.r.l., Italy, Report No. AGRI 009/15 GLP HAR GLP Not published	N	Y	Data/study report never submitted before to Country	GWl	--
KCA 6.3 KCA 6.5.3	Perboni, A.	2017	Determination of benalaxyl-m and zoxamide residues in raw agricultural commodity grapes (wine and table) and processed commodity (must, fermenting must, wine and aged wine) following three applications of GWN-10392 (benalaxyl-m 150 g/L + zoxamide 225 g/L) in open field condition (3 harvest trials, Northern and Southern Europe, year 2015) Gowan Crop Protection Ltd., UK Biotechnologie BT, Italy, Report No. RAU-049-15 GLP Not published	N	Y	Data/study report never submitted before to Country	GWl	--
KCA 6.3 KCA 6.5.1	Romanini M.	2011	Determination of cymoxanil and zoxamide residues at harvest in raw and processed commodity tomato (fruit, juice, puree and canned) following five applications of Harpon WG (cymoxanil 33% + zoxamide 33% WG) - four trials, Italy 2010. CREG, Research Centre “E. Gagliardini”, SIPCAM S.p.A., 26857 Salerano sul Lambro (LO), ITALY Report no: CREG2118 GLP, Unpublished	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A. Gowan	R-163/2015 (Poland)
KCA 6.3	Devine, H.C.	2008	Residues of mancozeb and zoxamide in field and protected tomatoes at intervals and at harvest following multiple applications of Electis, Northern France and The United Kingdom – 2006 Dow Agrosciences Ltd., UK CEM Analytical Services Ltd (CEMAS), UK, Report No. CEMS-2967, GHE-P-11604 GLP Not published	N	Y	Data/study report never submitted before to Country	GWl	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3 KCA 6.5.3	Longhi, D.	2020	Determination of (R) and (S) zoxamide residues and its metabolites RH-150721, RH-129151, RH-141452, RH-141288, RH-24549 in raw agricultural commodity of industrial tomato and its processed products (juice, puree and peeled tomatoes) following five applications of formulated product Zoxium 240 SC (sponsor code GWN-9790 EU) in open field (South Europe – 4 trials years 2018) Gowan Crop Protection Ltd., UK LabAnalysis, Italy, Report No. BPL-STUDY-18-000014 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCA 6.3	Longhi, D.	2020	Determination of (R) and (S) zoxamide residues and its metabolites RH-150721, RH-129151, RH-141452, RH-141288, RH-24549 in fresh market tomato raw agricultural commodity following five applications of the formulated product Zoxium 240 SC (sponsor code GWN-9790 EU) in greenhouse (South Europe – 4 trials years 2018) - final report amendment no. 1 Gowan Crop Protection Ltd., UK LabAnalysis, Italy, Report No. BPL-STUDY-18-000015 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCA 6.3	Longhi, D.	2020	Determination of zoxamide and its metabolites in raw agricultural commodity of industrial tomato in open field following five applications of the formulated product GWN 9790 EU (South Europe - 4 trials year 2019) Gowan Crop Protection Ltd., UK LabAnalysis, Italy, Report No. BPL-STUDY-19-000059 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3	Pandolfi, A.	2020	Determination of zoxamide residues and its metabolites in raw agricultural commodity tomato (fruits) following five applications of Zoxium 240 SC (sponsor code GWN-9790 EU) in protected condition (Italy - Southern Europe - 4 trials year 2019) Gowan Crop Protection Ltd., UK RES AGRARIA, Italy, Report No. RA 19 043 BPL GW GLP Not published	N	Y	Data/study report never submitted before to Country	GWI	--
KCA 6.3 KCA 6.5.3	Tetuan, B.	2016	Determination of residues at harvest of zoxamide, benalaxyl-m and cymoxanil in tomato, following three broadcast applications of GWN-10392, GWN-9823 and IR6141-copper oxychloride-copper hydroxide 5-15-15 WG under greenhouse conditions and determination of residues at harvest of zoxamide and benalaxyl-m in industry tomato and its processed products (canned tomatoes, puree and juice), following three broadcast applications of GWN-10392 under open field conditions - South Europe - season 2015 Gowan Comercio Internacional et Servicos Ltd., Portugal Promovert Crop Services SL, Spain, Report No. 15 F CL GW P/A GLP Not published	N	Y	Data/study report never submitted before to Country	GWI	--
KCA 6.3	Tetuan B.	2011	Determination of residues at harvest in potatoes following six broadcast applications of Harpon WG under field conditions- Northern Europe, season 2010. Promovert Report no.10 F PT GW P/A GLP, Unpublished	N	Y	Data/study report never submitted before to Country	GWI	R-163/2015 (Poland)
KCA 6.3	Tetuan B.	2011	Determination of residues at harvest in potatoes following six broadcast applications of Harpon WG under field conditions- Southern Europe, season 2010. Promovert Report no.10 F PT GW P/B GLP, Unpublished	N	Y	Data/study report never submitted before to Country	GWI	R-163/2015 (Poland)

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3 KCA 6.5.3	Terranegra A.	2020	Magnitude of residue of zoxamide and metabolite RH-1452 and RH-1455 in potatoes (RAC tubers) and processed fractions, following 5 applications of GWN 9790 EU in two trials (2 HS), Northern Europe (France and Poland) – 2017 – amended Final Report Staphyt Italia S.r.l., Italy, Report No. ATA-18-30694 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCA 6.3 KCA 6.5.3	Pandolfi A.	2020	Determination of the residues of zoxamide (R), (S) and sum and its metabolites in raw agricultural commodity potato (tubers) and its processed fractions (chips, baked/cooked, fried and flakes) following five applications of Zoxium 240 SC (sponsor code GWN-9790 EU) in open field condition (Italy - Southern Europe - 2 trials year 2018) Res Agraria S.r.l., Italy, Report No. RA 18 051 BPL GW GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCA 6.3	Luciani, G.P.	2012	Determination of zoxamide and dimethomorph residues after two applications of Zoxium 240 SC and GWN-9963 on lettuce, rocket salad and endive under field conditions - Italian trial year 2012 Gowan Italia Spa, Italy AgriParadigma Srl, Italy, Report No. AGRI 013/12 GLP DEC GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCA 6.3	Luciani, G.P.	2012	Determination of zoxamide and dimethomorph residues after two applications of Zoxium 240 SC and GWN-9963 on lettuce and rocket - Italian trial, year 2012 Gowan Italia Spa, Italy AgriParadigma Srl, Italy, Report No. AGRI 014/12 GLP DEC GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3	Lucini L.	2008	Determination of cymoxanil residues in raw agricultural commodity tomato (fruit) following application of SIP40936 (CYMOXANIL 33% + ZOXAMIDE 33% WG) SIPCAM S.p.A., Italy Report SIP 1551 GLP, Unpublished AIIA study on the active substance Cymoxanil	N	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A.	R-163/2015 (Poland)
KCA 6.5.1	Grist, A.	2018	Zoxamide: Hydrolysis under simulated processing conditions Gown Crop Protection Ltd., UK Envigo CRS Ltd., UK, Report No. RB66JN GLP Not published	N	Y	Data/study report never submitted before to Country	GW	
KCA 6.5.1	Longhi, D.	2019	RH-141452: Hydrolysis under simulated processing conditions Gown Crop Protection Ltd., UK LabAnalysis s.r.l., Italy, Report No. BPL-STUDY-18-000092 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	
KCA 6.5.1	Longhi, D.	2019	RH-141455: Hydrolysis under simulated processing conditions Gown Crop Protection Ltd., UK LabAnalysis s.r.l., Italy, Report No. BPL-STUDY-19-000009 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	
KCA 6.5.1	Völkl S.	2000	14C-RH-117281: Processing of tomatoes Rohm and Haas Comp., USA, Report No. 34-01-25, DERBI 92297 RCC Ltd, Switzerland, Report No. 34P-99-25 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.7.1	Cashmore, A.	2019	RH-141288: Partition coefficient (n-octanol/water) Shake flask method Gowan Crop Protection Ltd., Uk Smithers ERS Ltd, Uk, Report No. 3202371 GLP Not published	N	Y	Data/study report never submitted before to Country	GWl	--
KCA 6.10	Poráčzki, K.	2020	Magnitude of residues of zoxamide in Phacelia (Phacelia tanacetifolia BENTH.) honey after three applications of GWN-9790EU under semi-field conditions in Northern and Southern Europe Gowan Crop Protection Ltd, UK BioChem agrar, Germany, Report No. 19 48 BTR 0003 GLP Not published	N	Y	Data/study report never submitted before to Country	GWl	--
KCP 10.1.1.1 (KCA 8.	xxx	2006	CYMOXANIL 33% + ZOAXAMIDE 33% WG (SIP 40936): an acute oral toxicity study with the northern bobwhite. Sipcam Oxon S.p.A., Italy xxx, Report No. 613-103 GLP Not published	Y	Y	Data/study report never submitted before to Country	GWl Sipcam Oxon S.p.A.	R-163/2015 (Poland)
KCP 10.1.2.2	xxx	2011	Magnitude of cymoxanil residues in grasses weeds in a non-crop field area after one spray application of CYMOXANIL 45% WG xxx - SIPCAM S.p.A. - xxx Report no. CREG 2142 GLP, Unpublished IIA study on the active substance	Y	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A.	R-163/2015 (Poland)
KCP 10.1.2.2	xxx	2011	Cymoxanil – higher tier vole risk assessments for cymoxanil uses in Europe xxx Report no R11406 No GLP, Unpublished IIA study on the active substance	Y	Y	Data/study report never submitted before to Country	Sipcam Oxon S.p.A.	R-163/2015 (Poland)

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 10.2.1 (KCA 8.2.1)	xxx	2020	RH-163353: Fish, acute toxicity test Gowan Crop Protection Ltd., UK xxx, Report No. 3202385 GLP Not published	Y	Y	Data/study report never submitted before to Country	GWl	
KCP 10.2.1 (KCA 8.2.1)	xxx	2020	RH-141455: Fish, acute toxicity test Gowan Crop Protection Ltd., UK xxx, Report No. 3202716 GLP Not published	Y	Y	Data/study report never submitted before to Country	GWl	
KCP 10.2.1 (KCA 8.2.1)	xxx	2020	RH-127450: Fish, acute toxicity test Gowan Crop Protection Ltd., UK xxx, Report No. 3202373 GLP Not published	Y	Y	Data/study report never submitted before to Country	GWl	
KCP 10.2.1 (KCA 8.2.4.1)	xxx	2020	RH-163353: Acute toxicity to Daphnia magna Gowan Crop Protection Ltd., UK xxx, Report No. 3202386 GLP Not published	Y	Y	Data/study report never submitted before to Country	GWl	
KCP 10.2.1 (KCA 8.2.4.1)	xxx	2020	RH-141455: Acute toxicity to Daphnia magna Gowan Crop Protection Ltd., UK xxx, Report No. 3202380 GLP Not published	Y	Y	Data/study report never submitted before to Country	GWl	
KCP 10.2.1 (KCA 8.2.4.2)	xxx	2020	RH-127450: Mysid acute toxicity test Gowan Crop Protection Ltd., UK xxx, Report No. 3202374 GLP Not published	Y	Y	Data/study report never submitted before to Country	GWl	
KCP 10.2.1 (KCA 8.2.4.2)	xxx	2020	RH-24549: Mysid acute toxicity test Gowan Crop Protection Ltd., UK xxx, Report No. 3202394 GLP Not published	Y	Y	Data/study report never submitted before to Country	GWl	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 10.2.1 (KCA 8.2.4.2)	xxx	2020	RH-139432: Mysid acute toxicity test Gowan Crop Protection Ltd., UK xxx, Report No. 3202398 GLP Not published	Y	Y	Data/study report never submitted before to Country	GW	
KCP 10.2.1 (KCA 8.2.4.2)	xxx	2020	RH-163353: Mysid acute toxicity test Gowan Crop Protection Ltd., UK xxx, Report No. 3202387 GLP Not published	Y	Y	Data/study report never submitted before to Country	GW	
KCP 10.2.1 (KCA 8.2.4.2)	xxx	2020	RH-141455: Mysid acute toxicity test Gowan Crop Protection Ltd., UK xxx, Report No. 3202381 GLP Not published	Y	Y	Data/study report never submitted before to Country	GW	
KCP 10.2.1 (KCA 8.2.6)	xxx	2020	RH-127450: Inhibition of growth on the alga Raphidocelis subcapitata Gowan Crop Protection Ltd., UK xxx, Report No. 3202375 GLP Not published	Y	Y	Data/study report never submitted before to Country	GW	
KCP 10.2.1 (KCA 8.2.6)	xxx	2020	RH-163353: Inhibition of growth to the alga Raphidocelis subcapitata Gowan Crop Protection Ltd., UK xxx, Report No. 3202388 GLP Not published	Y	Y	Data/study report never submitted before to Country	GW	
KCP 10.2.1 (KCA 8.2.7)	xxx	2020	Effects Zoxamide technical on Lemna gibba in a growth inhibition test under semi-static test conditions Gowan Crop Protection Ltd., UK xxx, Report No. 18 48 ALE 0005 GLP Not published	Y	Y	Data/study report never submitted before to Country	GW	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 10.2.1 (KCA 8.2.1)	xxx	2007	Acute toxicity of Cymoxanil 33% + Zoxamide 33% WG to rainbow trout (<i>Oncorhynchus mykiss</i>), determined under flow-through conditions Sipcam Oxon S.p.A., Italy xxx, Report No. CH-E-023/2006 GLP Not published	Y	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	R-163/2015 (Poland)
KCP 10.2.1 (KCA 8.2.1)	Croce V.	2007	Acute toxicity of Cymoxanil 33% + Zoxamide 33 % WG to <i>Daphnia magna</i> in a 48-hour immobilization test under semi-static exposure-limit test Sipcam Oxon S.p.A., Italy ChemService S.r.l., Italy, Report No. CH-001/2007 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	R-163/2015 (Poland)
KCP 10.2.1 (KCA 8.2.6)	Croce V.	2007	Toxicity of Cymoxanil 33% + Zoxamide 33% WG to green algae <i>Pseudokirchneriella subcapitata</i> determined in a growth inhibition study Sipcam Oxon S.p.A., Italy ChemService S.r.l. Italy, Report No. CH-002/2007 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	R-163/2015 (Poland)
KCP 10.2.2 (KCA 8.2.2.1)	xxx	2020	Final report addendum for RH-117,281 technical: An early life-stage toxicity test with the sheepshead minnow (<i>Cyprinodon variegatus</i>) Gowan Crop Protection Ltd., UK xxx, Report No. 129A-143A GLP Not published	Y	Y	Data/study report never submitted before to Country	GWI	
KCP 10.2.2 (KCA 8.2.2.1)	xxx	1998	RH-117,281 technical: An early life-stage toxicity test with the sheepshead minnow (<i>Cyprinodon variegatus</i>) xxx, Report No. 97RC-0078 xxx, Report No. 129A-143A GLP Not published	Y	Y	Data/study report never submitted before to Country	GWI	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 10.3.1.1	Colli M.	2006	Effects, acute oral and acute contact toxicity of CYMOXAN-IL 33% + ZOXAMIDE 33% WG on the honeybee, Apis mellifera, L., in laboratory (Limit test). Sipcam Oxon S.p.A., Italy Biotechnologie BT S.r.l, Italy, Report No BT026/06 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	R-163/2015 (Poland)
KCP 10.3.1.1	Amsel, K.	2017	Acute toxicity of Cymoxanil 33% + Zoxamide 33% to the bumblebee Bombus terrestris L. under laboratory conditions Gowan Crop Protection Ltd., UK, Sipcam Oxon S.p.A, Italy Biochem Agrar, Gerichshain, Germany, Report No. 17 48 BBA 0003 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	--
KCP 10.3.1.2	Ruhland, S.	2018	Chronic toxicity of Cymoxanil 33% + Zoxamide 33% WG to the honey bee Apis mellifera L. under laboratory conditions Gowan Crop Protection Ltd., UK, Sipcam Oxon S.p.A, Italy BioChem agrar, Germany, Report No. 17 48 BAC 0005 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	--
KCP 10.3.1.3 (KCA 8.3.1.3)	Picard, Ch.R.	2018	Zoxamide: Honey bee (Apis mellifera L.) larval toxicity, repeated exposure Exigent LLC, A Gowan Group Company, USA Smithers Viscient, USA, Report No. 12791.6307 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI	
KCP 10.3.1.3	Scheller, K.	2019	Reboot - Repeated exposure of honey bee (Apis mellifera L.) larvae under laboratory conditions (in vitro) Gowan Crop Protection Ltd., UK, SIPCAM OXON S.p.A, Italy BioChem agrar; Germany, Report No. 17 48 BLC 0005 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 10.3.1.6	Schnurr, A.	2020	Effects of Cymoxanil 33% + Zoxamide 33% WG on the honeybee <i>Apis mellifera</i> L. under field conditions with additional assessments on colony and brood development Gowan Crop Protection Ltd., UK, SIPCAM OXON S.p.A, Italy BioChem agrar, Germany, Report No. 18 48 BFB 0001 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	--
KCP 10.3.1.6	Schnurr, A.	2020	Effects of Cymoxanil 33% + Zoxamide 33% WG on the honeybee <i>Apis mellifera</i> L. under field conditions in Spain (Southern zone) with additional assessments on colony and brood development Gowan Crop Protection Ltd., UK, SIPCAM OXON S.p.A., Italy BioChem agrar, Germany, Report No. 19 48 BFB 0001 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	--
KCP 10.3.2.2	Colli M.	2006	Effects of CYMOXANIL 33% ÷ ZOXAMIDE 33% WG on the Aphid Parasitoid, <i>Aphidius rhopalosiphi</i> De Stefani Perez (Hymenoptera, Braconidae) in Laboratory (Limit test). Sipcam Oxon S.p.A., Italy Biotechnologie BT S.r.l, Italy, Report No BT028/06 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	R-163/2015 (Poland)
KCP 10.3.2.2	Colli M.	2011	Effects of CYMOXANIL 33% + ZOXAMIDE 33% WG on the Predatory Mite, <i>Typhlodromus pyri</i> Scheuten (Acari Phytoseiidae) under extended laboratory conditions (Rate response test). Sipcam Oxon S.p.A., Italy Biotechnologie BT S.r.l, Italy, Report No. BT031/06 (second edition) GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	R-163/2015 (Poland)

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 10.3.2.2	Vinall, S.	2018	Cymoxanil 33% + Zoxamide 33% WG – A rate-response extended laboratory test to evaluate the effects of fresh residues on the predatory bug <i>Orius laevigatus</i> (Hemiptera; Anthocoridae) Gowan Crop Protection Ltd., UK, Sipcam Oxon S.p.A, Italy Mambo-Tox, Southampton, UK, Report No. GOW-17-2 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	--
KCP 10.3.2.2	Vaughan, R.	2017	Reboot (GWN-9823) – A rate-response extended laboratory test to evaluate the effects of fresh residues on the green lacewing, <i>Chrysoperla carnea</i> (Neuroptera, Chrysopidae) Gowan Crop Protection Ltd., UK, Sipcam Oxon S.p.A, Italy Mambo-Tox, Southampton, UK, Report No. GOW-17-1 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	--
KCP 10.4.1.1 (KCA 8.4.1.)	Friedrich, S.	2019	Effects of Zoxium 240 SC on the reproduction of the earthworm <i>Eisenia andrei</i> in artificial soil with 5 % peat Gowan Crop Protection Ltd., UK BioChem agrar, Germany, Report No. 17 48 TEC 0009 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI	
KCP 10.4.1.1 (KCA 8.4.1)	Gray, J.	2020	RH-127450: Effect on reproduction in the earthworm <i>Eisenia fetida</i> Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202376 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI	
KCP 10.4.1.1 (KCA 8.4.1)	Gray, J.	2020	RH-24549: Effect on reproduction in the earthworm <i>Eisenia fetida</i> Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202395 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI	

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KCP 10.4.1.1 (KCA 8.4.1)	Gray, J.	2020	RH-163353: Effect on reproduction in the earthworm <i>Eisenia fetida</i> Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202389 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI	
KCP 10.4.1.1 (KCA 8.4.1.)	Colli M.	2006	Acute toxicity of CYMOXANIL 33% + ZOXAMIDE 33% WG on Earthworms, <i>Eisenia fetida</i> , using an artificial soil test Sipcam Oxon S.p.A., Italy Biotechnologie BT S.r.l, Italy, Report No. BT027/06 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	R-163/2015 (Poland)
KCP 10.4.1.1	Friedrich, S.	2020	Effects of Cymoxanil 33 % + Zoxamide 33 % WG on the reproduction of the earthworm <i>Eisenia andrei</i> in artificial soil with 5 % peat Gowan Crop Protection Ltd., UK, SIPCAM OXON S.p.A, Italy BioChem agrar, Germany, Report No. 17 48 TEC 0008 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	--
KCP 10.4.1.2 (KCA 8.4.1)	Schulz, L.	2020	Effects of Zoxium 240 SC on earthworms under field conditions Gowan Crop Protection Ltd., UK BioChem agrar, Germany, Report No. 18 48 FEW 0001 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI	--
KCP 10.4.1.2	Schulz, L.	2020	Effects of Cymoxanil 33% + Zoxamide 33% on earthworms under field conditions Gowan Crop Protection Ltd., UK, SIPCAM OXON S.p.A, Italy BioChem agrar, Germany, Report No. 19 48 FEW 0003 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 10.4.2 (KCA 8.4.2)	Parsons, Ch	2020	Zoxium 240 SC - A laboratory test to determine the effects of fresh residues on the springtail Folsomia candida (Collembola, Isotomidae) in artificial soil substrate Gowan Crop Protection Ltd., UK Mambo-Tox Ltd., UK, Report No. GOW-17-13 GLP Not published	N	Y	Data/study report never submitted before to Country	GWl	--
KCP 10.4.2 (KCA 8.4.2)	Parsons, Ch	2020	Zoxium 240 SC – A laboratory test to determine the effects of fresh residues on the predatory soil mite Hypoaspis aculeifer (Acari, Laelapidae) in an artificial soil substrate Gowan Crop Protection Ltd., UK Mambo-Tox Ltd., UK, Report No. GOW-17-14 GLP Not published	N	Y	Data/study report never submitted before to Country	GWl	--
KCP 10.4.2 (KCA 8.4.2)	Gray, J.	2020	RH-163353: Collembolan reproduction test in soil Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202390 GLP Not published	N	Y	Data/study report never submitted before to Country	GWl	
KCP 10.4.2 (KCA 8.4.2)	Gray, J.	2020	RH-141455: Collembolan reproduction study Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202382 GLP Not published	N	Y	Data/study report never submitted before to Country	GWl	
KCP 10.4.2 (KCA 8.4.2)	Gray, J.	2020	RH-163353: Effect on reproduction of Hypoaspis (Geolaelaps) aculeifer Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202391 GLP Not published	N	Y	Data/study report never submitted before to Country	GWl	
KCP 10.4.2 (KCA 8.4.2)	Gray, J.	2020	RH-141455: Effect on reproduction of Hypoaspis (Geolaelaps) aculeifer Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202383 GLP Not published	N	Y	Data/study report never submitted before to Country	GWl	

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KCP 10.4.2	Parsons, Ch..	2020	Cymoxanil 33% + Zoxamide 33% WG – a laboratory test to determine the effects of fresh residues on the springtail <i>Folsomia candida</i> (Collembola, Isotomidae). Gowan Crop Protection Ltd., UK, SIPCAM OXON S.p.A, Italy Mambo-Tox Ltd., UK, Report No. GOW-17-3 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	--
KCP 10.4.2	Parsons, Ch..	2020	Cymoxanil 33% + Zoxamide 33% – A laboratory test to determine the effects of fresh residues on the predatory mite <i>Hypoaspis aculeifer</i> (Acari: Laelapidae) Gowan Crop Protection Ltd, UK, SIPCAM OXON S.p.A, Italy Mambo-Tox Ltd., U.K., Report No. GOW-17-4 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI Sipcam Oxon S.p.A.	--
KCP 10.5 (KCA 8.5)	Jarrom, R.	2019	RH-127450: Soil nitrogen transformation test Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202377 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI	
KCP 10.5 (KCA 8.5)	Jarrom, R.	2019	RH-24549: Soil nitrogen transformation test Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No. 3202396 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI	
KCP 10.5 (KCA 8.5)	Jarrom, R.	2020	RH-163353: Soil nitrogen transformation test Gowan Crop Protection Ltd., UK Smithers ERS Ltd., UK, Report No.3202392 GLP Not published	N	Y	Data/study report never submitted before to Country	GWI	

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCP 10.5	Schulz, L.	2017	Effects of Cymoxanil 33% + Zoxamide 33% WG on the activity of soil microflora (Nitrogen transformation test) Gowan Crop Protection Ltd., UK Biochem Agrar, Germany, Report No. 17 48 SMO 0004 GLP Not published	N	Y	Data/study report never submitted before to Country	GW	--
KCP 10.6.2	xxx	2007	Vegetative vigour limit test for non-target plants following single rate application of CYMOXANIL 33% + ZOXAMIDE 33% WG Sipcam Oxon S.p.A., Italy xxx, Report No. BT034/06 GLP Not published	Y	Y	Data/study report never submitted before to Country	GW Sipcam Oxon S.p.A.	R-163/2015 (Poland)

*Formerly Oxon Italia SpA

In addition, please consider the reference list with confidential data and documents in the appendix to the Part C (confidential) document.

Under Article 59 of Regulation 1107/2009/EC, the Sponsor Company claims data protection for all Gowan studies for which data protection claimed is reported as YES.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 4.1.2	Weber, H.	2012	Validation of an enforcement method (“QuEChERS”) for the determination of residues of zoxamide in grapes and potatoes and their processed products using LC-MS/MS Eurofins AgroScience Services Chem GmbH, Report No. S12-03949, November 30, 2012 GLP Not published	N	Y	To ensure that the validation data comply with current requirements	GW	--
KCA 4.1.2	Weber, H., Giesau, A.	2013	Validation of analytical method for the determination of residues of the zoxamide metabolite RH-150721 in grapes and processing fractions using LC-MS/MS Eurofins AgroScience Services Chem GmbH, Report No. S12-03950 GLP Not published	N	Y	To ensure that the validation data comply with current requirements.	GW	--
KCA 4.1.2	Weber, H., Giesau, A.	2013	Validation of analytical method for the determination of residues of the zoxamide metabolites RH-1452 and RH- 1455 in potatoes and processing fractions using LCMS/MS Eurofins AgroScience Services Chem GmbH, Report No. S12-03951, May 2, 2013 GLP Not published	N	Y	To ensure that the validation data comply with current requirements.	GW	--
KCA 4.1.2	Luciani, G.P.	2010	Determination of zoxamide residues after five applications of ELECTIS MZ and ZOXIUM 240 SC on potato under field conditions – Italian trial Agri Paradigma S.r.l., Report No. AGRI 012/10 GLP DEC, October 29 2010 GLP Not published	N	Y	To ensure that the validation data comply with current requirements.	GW	--
KCA 4.1.2	Nixon, W.B., Sulairman, M.W.	1997	The analysis of RH-117,281 technical in filtered saltwater in support Rohm and Haas, Report No. 95RC-0275, May 15, 1999 Wildlife International Ltd, Report No. 129A-136 GLP Not published	N	Y	To ensure that the validation data comply with current requirements.	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 4.1.2	Kendall, T. Z.	1998	The analysis of RH-117,281 technical in filtered saltwater Rohm and Haas, Report No. 97RC-0077, June 17, 1998 Wildlife International Ltd, Report No. 129A-142 GLP Not published	N	Y	To ensure that the validation data comply with current requirements.	GW	--
KCA 4.1.2	Aversa, S	2010	Validation of an analytical method for the determination of zoxamide in solutions of aquatic toxicity test with GOW 008 Biotechnologie BT Srl, Report No. BT102/10, November 18, 2010 GLP Not published	N	Y	To ensure that the validation data comply with current requirements.	GW	--
KCA 4.1.2	Weber, H., Zetzsch, A., Giesler, W.	2016	Storage Stability of residues of Zoxamide, RH-150721, RH-1452 and RH-1455 in Grape and Processed Products and Potato Eurofins AgroScience Services Chem GmbH, Report No. S12-03952, February 15, 2016 GLP Not published	N	Y	Data required to supplement existing storage stability data	GW	--
KCA 4.1.2	Luciani, G.P.	2010	Determination of Zoxamide residues after five application of ELECTIS MZ and ZOXIUM 240 SC on Wine grape and Table grape – Italian trial, year 2010 Research Centre “Agri Paradigma S.r.l”, Report No. AGRI 010/10 GLP DEC, October 29, 2010 GLP Not published	N	Y	Data not available for first Annex I inclusion and bridge to support use of new formulation and modified GAP	GW	--
KCA 4.1.2	Wais, A.	2001	Determination of residues of RH-117,281 and mancozeb in/on vine grapes (RAC grapes and processing products) following treatment with RH-7281/mancozeb 75WG from a field trial (semi residue decline study) in Italy; 1999 Rohm and Haas, Report No. ER ref R 77.10 RCC Ltd., Report No. 734580 GLP Not published	N	Y	Data not available for first Annex I inclusion	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 4.1.2	Hein, W.	2014	Extraction Efficiency of [phenyl-UL-14C] Zoxamide from Plant Metabolism Samples (Pea) RLP AgroScience GmbH, Report No. AS362, June 25, 2014 GLP Not published	N	Y	Data not available for first Annex I inclusion	GW	--
KCA 4.2	Weber, H.	2012	Validation of an enforcement method ("QuEChERS") for the determination of residues of zoxamide in grapes and potatoes and their processed products using LC-MS/MS Eurofins AgroScience Services Chem GmbH, Report No. S12-03949, November 30, 2012 GLP Not published	N	Y	To ensure that the validation data comply with current requirements.	GW	--
KCA 4.2	Richter, S.	2014	Validation of the QuEChERS Multi-Residue Method for the Determination of Zoxamide in Various Crop Types PTRL Europe, Report No. P 3114G, February, 2010 GLP Not published	N	Y	To ensure that the validation data comply with current requirements	GW	--
KCA 4.2	Schlewitz, P.	2014	Independent Laboratory Validation of the Analytical Method for the Determination of Zoxamide Residues in Lettuce Anadiag, Report No. R B4023, May, 23/2014 GLP Not published	N	Y	To ensure that the validation data comply with current requirements	GW	--
KCA 4.2	Jooß, S.	2013	Development and validation of a residue method for the determination of zoxamide in soil PTRL Europe, Report No. P 3051 G, October 21, 2013 GLP Not published	N	Y	To ensure that the validation data comply with current requirements	GW	--
KCA 4.2	Jooß, S.	2013	Development and Validation of a Residue Method for the Determination of Zoxamide in Drinking and in Surface Water PTRL Europe, Report No. P 3050 G GLP Not published	N	Y	To ensure that the validation data comply with current requirements	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 4.2	Schlewitz, P.	2014	Independent Laboratory Validation of a Residue Method for the Determination of Zoxamide in Drinking Water Anadiag, Report No. R B4049, July 1, 2014 GLP Not published	N	Y	To ensure that the validation data comply with current requirements	GW	--
KCA 4.2	Miller, C.	2014	Zoxamide: Validation of Methodology for the Determination of Residues in Air Huntingdon Life Sciences, Report No. FRK0048, January 29, 2014 GLP Not published	N	Y	To ensure that the validation data comply with current requirements	GW	--
KCA 5.1.1	Scullion, P.	2013	A study to compare the metabolite profile of 14C-zoxamide in cryopressed human, dog, rat and mouse hepatocytes. CXR Biosciences, Report No. CXR1237, October 29, 2013 GLP Not published	N	Y	New data requirement.	GW	--
KCA 5.1.1	Powrie, R.H.	2014	A study to investigate the presence of a specific metabolite of zoxamide, RH-150721, in analytical data from previous study CXR1237 CXR Biosciences, Report No. CXR1416, July 17, 2014 GLP Not published	N	Y	New data requirement.	GW	--
KCA 5.1.1	xxx	1998	14C-RH-117,281: Pharmacokinetic and metabolism study in rats xxx, Report No. 94R-235; ER Ref No. 24.1; US Ref No. 94R-235, GLP Not published	Y	Y	NA	GW	--
KCA 5.1.1	xxx	1998	Distribution of 14C-RH-117,281 to the bone marrow of mice xxx, Report No. 97R-173, October 15, 1998, ER Ref No. 24.2 GLP Not published	Y	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 5.1.1	xxx	2001	Identification of RH-139432 from zoxamide (RH-117281) rat pharmacokinetic study samples xxx, Report No. 34-00-105, February 26, 2001, ER Ref No. 45.3 GLP Not published	Y	Y	NA	GW	--
KCA 5.2.1	xxx	1996	RH-117,281 technical: acute oral toxicity study in male and female rats xxx, Report No. 95R-268, June 26, 1996, ER Ref No. 1.3 GLP Not published	Y	Y	NA	GW	--
KCA 5.2.1	xxx	1998	RH-117,281 technical: Acute oral toxicity study in male and female mice xxx, Report No. 98R-165, December 4, 1998, ER Ref No. 24.3 GLP Not published	Y	Y	NA	GW	--
KCA 5.2.2	xxx	1996	RH-117,281 technical: Acute dermal toxicity study in male and female rats xxx, Report No. 95R-269, ER Ref No. 1.4 GLP Not published	Y	Y	NA	GW	--
KCA 5.2.3	xxx	1996	RH-117,281 Technical: acute inhalation toxicity study in rats xxx, Report No. 95R-266, ER Ref No. 2.2, US Ref No. 95R-266 GLP Not published	Y	Y	NA	GW	--
KCA 5.2.4	xxx	1996	RH-117,281 technical: skin irritation study in rabbits xxx, Report No. 95R-270, ER Ref No. 1.5, US Ref No. 95R-270 GLP Not published	Y	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 5.2.5	xxx	1996	RH-117,281 Technical: eye irritation study in rabbits xxx, Report No. 95R-271, ER Ref No. 1.6, US Ref No. 95R-271 GLP Not published	Y	Y	NA	GWI	--
KCA 5.2.6	xxx	1997	Dermal sensitization study of RH-117,281 Technical in guinea pigs - maximization test xxx, Report No. 6228-112 xxx, Report No. 95RC-170, ER Ref No. 4.2, US Ref No. 95RC-170 GLP No published	Y	Y	NA	GWI	--
KCA 5.2.6	xxx		RH-117,281 Technical: Delayed contact hypersensitivity study in guinea pigs xxx Report No. 97R-074, ER Ref No. 23.2, US Ref No. 97R-074 GLP Not published	Y	Y	NA	GWI	--
KCA 5.2.6	xxx	1998	RH-117,281 Technical: Delayed contact hypersensitivity (dilution) study in guinea pigs xxx Report No. 98R-154, ER Ref No. 24.4, US Ref No. 98R-154 GLP Not published	Y	Y	NA	GWI	--
KCA 5.2.7	Heppenheimer, A.	2014	Zoxamide: Cytotoxicity assay in vitro with Balb/c 3T3 cells: Natural red test at simultaneous irradiation with artificial sunlight Harlan Cytotest Cell Research GmbH, Report No. 1641200 GLP Not published	N	Y	New data requirement.	GWI	--
KCA 5.3.1	xxx	1996	RH-117,281 Technical: four-week range-finding toxicity study in dogs xxx, Report No. 94R-234, April 15, 1996, ER Ref No. 2.3 GLP Not published	Y	Y	NA	GWI	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 5.3.2	xxx	1996	RH-117,281: three-month dietary toxicity study in mice xxx, Report No. 94R-075, February 9, 1996, ER Ref No.5.3 GLP Not published	Y	Y	NA	GWI	--
KCA 5.3.2	xxx	1996	RH-117,281: three-month dietary toxicity/neurotoxicity study in rats xxx, Report No. 94R-233, March 22, 1996, ER Ref No. 3.1 GLP Not published	Y	Y	NA	GWI	--
KCA 5.3.2	xxx	1997	RH-117,281 Technical: three-month dietary toxicity study in dogs xxx, Report No. 96R-030, October 8, 1997, ER Ref No. 9.1 GLP Not published	Y	Y	NA	GWI	--
KCA 5.3.2	xxx	1998	RH-117,281 Technical: one-year chronic dietary toxicity study in dogs xxx, Report No. 95R-277, June 9, 1998, ER Ref No. 25.1 GLP Not published	Y	Y	NA	GWI	--
KCA 5.3.3	xxx	1998	RH-117,281 Technical: twenty-eight-day dermal toxicity study in rats xxx, Report No. 97R-075, October 16, 1998, ER Ref No. 23.3 GLP Not published	Y	Y	NA	GWI	--
KCA 5.4.1	Sames, J.S., Ciaccio, P.C.	1996	RH-117,281 Technical: Salmonella Typhimurium gene mutation assay (Ames test) Rohm and Haas Co., Report No. 95R-262, October 25, 1996, ER Ref No. 2.7 GLP Not published	N	Y	NA	GWI	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 5.4.1	Riley, S.	1998	RH-117,281: Test for chemical induction of chromosome aberrations in cultured Chinese Hamster ovary (CHO) cells Covance Laboratories Ltd., Study No. 616/20-D5140 Rohm and Haas Co., Report No. 96RC-125, December 1998, ER Ref No. 23.6 GLP Not published	N	Y	NA	GWI	--
KCA 5.4.1	Pant, K.	1994	RH-117,281: Test for chemical induction of gene mutation at the HGPT locus in cultured Chinese Hamster ovary cells with and without metabolic activation. SITEK Research Laboratories, Report No. 0282-2510 Rohm and Haas Co., Report No. 94RC-077, November 16, 1994, ER Ref No. 23.4 GLP Not published	N	Y	NA	GWI	--
KCA 5.4.2	Sames, J.S., Vandenberghe, Y.L.	1996	RH-117,281 Technical: micronucleus assay in CD-1 mouse bone marrow cells Rohm and Haas Co., Report No. 95R-264, October 29, 1996, ER Ref No. 1.9 GLP Not published	N	Y	NA	GWI	--
KCA 5.4.2	xxx	1998	Distribution of 14C-RH-117,281 to the bone marrow of mice xxx, Report No. 97R-173, July 24, 1998, ER Ref No. 24.2 GLP Not published	Y	Y	NA	GWI	--
KCA 5.4.2	Yound, D.H.	1998	Mechanism of action of the oomycete fungicides RH-54032 and RH-117281 on Phytophthora capsici, tobacco, mouse lymphoma cells and isolated bovine tubulin Rohm and Haas Co., Report No. 98R-1098, November 30, 1998, ER Ref No. 23.5 GLP Not published	N	Y	NA	GWI	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 5.5	xxx	1998	RH-117,281 Technical: 24-month dietary chronic/oncogenicity study in rats xxx, Report No. 417-505 xxx, Report No. 94RC-236, November 3, 1998, ER Ref No. 21.1 GLP Not published	Y	Y	NA	GW	--
KCA 5.5	xxx	1998	RH-117,281 Technical: Eighteen-month dietary oncogenicity study in mice (photomicrographs) xxx, Report No. 96R-094, September 24, 1998, ER Ref No. 20.1 GLP Not published	Y	Y	NA	GW	--
KCA 5.6.1	xxx	1998	RH-117,281 Technical: Two generation reproductive toxicity study in rats xxx, Report No. 95R-272, December 10, 1998, ER Ref No. 26.1 GLP Not published	Y	Y	NA	GW	--
KCA 5.6.2	xxx	1995b	RH-7281 Technical: oral (gavage) developmental toxicity study in rats xxx, Report No. 94R-079, September 15, 1995, ER Ref No. 6.1 GLP Not published	Y	Y	NA	GW	--
KCA 5.6.2	xxx	1997	RH-117,281 Technical: oral (gavage) developmental study in rabbits xxx, Report No. 95R-267, April 8, 1997; ER Ref No. 8.2 GLP Not published	Y	Y	NA	GW	--
KCA 5.7.1	xxx	1997	RH-117,281 Technical: acute oral (gavage) neurotoxicity study in rats xxx, Report No. 95R-182, January 6, 1997, ER Ref No. 10.1 GLP Not published	Y	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 5.7.1	xxx	1996	RH-117,281: three-month dietary toxicity/neurotoxicity study in rats xxx, Report No. 94R-233, March 22, 1996, ER Ref No. 3.1 GLP Not published	Y	Y	NA	GWI	--
KCA 5.7.1	xxx	1995	Carbaryl and DDT: Neurotoxicity evaluation of positive control substances in rats xxx, Report No. 94R-224, ER Ref No. 27.5 GLP Not published	Y	Y	NA	GWI	--
KCA 5.7.1	xxx	1995	d-Amphetamine and Chlorpromazine: Motor activity assessment of positive control substances in rats xxx, Report No. 94R-225, ER Ref No. 27.6 GLP Not published	Y	Y	NA	GWI	--
KCA 5.7.1	xxx	1995	Triethyltin and Acrylamide: Neurotoxicity evaluation of positive control substances in rats xxx, Report No. 94R-211; ER Ref No. 28.1 GLP Not published	Y	Y	NA	GWI	--
KCA 5.8.1	Woods, I.	2014	RH-141455: In vitro mutation test using mouse lymphoma L5178Y Huntingdon Life Sciences Eye Research Centre, Report No. FRK0049, July 8, 2014 GLP Not published	N	Y	To demonstrate that the metabolite is not of toxicological relevance.	GWI	--
KCA 5.8.1	Woods, I.	2014	RH-141455: In vitro micronucleus test in human lymphocytes Huntingdon Life Sciences Eye Research Centre, UK, Report No. FRK0050, July 8, 2014 GLP Not published	N	Y	To demonstrate that the metabolite is not of toxicological relevance.	GWI	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 5.8.1	Sokolowski, A.	2013	RH-150,721: Salmonella typhimurium reverse mutation assay Harlan CCR, Report No. 1549300, October 7, 2013 GLP Not published	N	Y	To address potential toxicity of metabolite found in wine.	GWI	--
KCA 5.8.1	Thandi, K.	2013	DEREK evaluation of the toxicities of zoxamide and metabolite RH-150,721 LSR Associates Ltd., Study No: FRK0046, May 17, 2013 GLP Not published	N	Y	To address potential toxicity of metabolite found in wine.	GWI	--
KCA 5.8.1	xxx	1998	14C-RH-141,452: Rat metabolism study, Tier I testing xxx., Report No. RPT00410 xxx, Report No. 97RC-154, November 19, 1998, ER Ref No: 27.1 GLP Not published	Y	Y	NA	GWI	--
KCA 5.8.1	xxx	1998	RH-141,452: Acute oral toxicity study in male and female mice xxx, Report No. 98R-049, September 24, 1998, ER Ref No. 25.2 GLP Not published	Y	Y	NA	GWI	--
KCA 5.8.1	xxx	1998	RH-141,452: Salmonella typhimurium gene mutation assay (Ames test) xxx, Report No. 98R-050, October 1, 1998, ER Ref No. 25.3 GLP Not published	Y	Y	NA	GWI	--
KCA 5.8.1	xxx	1998	14C-RH-141,455: Rat metabolism study, Tier I testing xxx, Report No. 98RC-017, ER Ref No. 27.2 xxx, Report No. RPT00411 GLP Not published	Y	Y	NA	GWI	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 5.8.1	xxx	1998	RH-141,455: Acute oral toxicity study in male and female mice xxx, Report No. 98R-047, September 24, 1998, ER Ref No. 27.3 GLP Not published	Y	Y	NA	GWI	--
KCA 5.8.1	xxx	1998	RH-141,455: Salmonella typhimurium gene mutation assay (Ames test) xxx, Report No. 98R-048, September 23, 1998, ER Ref No. 27.4 GLP Not published	Y	Y	NA	GWI	--
KCA 6.1	Ross, J.R.	1998	Storage stability of RH-117281 Residues in Grapes, Grape Juice, Raisins and Potatoes under Conditions of Frozen Storage Rohm and Haas, McKenzie Laboratories, Enviro Test Laboratories, Report No. 34-98-161, December 15, 1998, ER R61.1 GLP Not published	N	Y	NA	GWI	--
KCA 6.1	Ross, J.R.	1998	Storage stability of RH-141,455 and RH-141,452 Residues in Potatoes, Potato Chips and Potato Flakes under Conditions of Frozen Storage Rohm and Haas, McKenzie Laboratories, Enviro Test Laboratories, Report No. 34-98-162, December 15, 1998, ER R61.2 GLP Not published	N	Y	NA	GWI	--
KCA 6.1	Reibach, P.H.	2000	Storage Stability of RH-117,281 Residue in Potato Samples under Conditions of Frozen Storage: Supplement to TR34-98-161 (ER 61.1) Rohm and Haas, Report No. 34-00-80, ER R77.11 GLP Not published	N	Y	NA	GWI	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.1	Weber, H., Hissmann, H.	2014	Storage Stability of residues of Zoxamide, RH-150721, RH-1452 and RH-1455 in Grape and Processed Products and Potato Eurofins AgroScience Services Chem GmbH, Report No. S12-03952, February 15, 2016 GLP Not published	N	Y	Data required to supplement existing storage stability data	GW	--
KCA 6.2.1	Reibach, P.H., Spencer W.O.	1998	14C-RH-117,281: Nature of the Residue in Fruiting Grape Plants Rohm and Haas, American Agricultural Services, Inc. (AA-SI), Report No. 34-98-49, ER R14.5 GLP Not published	N	Y	NA	GW	--
KCA 6.2.1	Reibach, P.H., Spencer W.O.	1998	14C-RH-117,281: Nature of the Residue in Potato Rohm and Haas, American Agricultural Services, Inc. (AASI), Report No. 34-98-50, September 17, 1998, ER R14.3 GLP Not published	N	Y	NA	GW	--
KCA 6.2.1	Graves, D.D., Reibach, P.H.	2000	Consideration of the Difference in the Magnitude of the Residues of RH-7281 in Grapes from Supervised Field Residue Trials Compared to the 14C Grape Metabolism Study ER 14.5 Rohm and Haas, Report No. 34-00-83, ER R76.6 GLP Not published	N	Y	NA	GW	--
KCA 6.2.1	Staffa, C., Möndel, M.	2014	14C-phenyl UL Zoxamide: Plant Metabolism in Grape RLP AgroScience GmbH, Report No. AS209, July 15, 2014 GLP Not published	N	Y	Data required to supplement existing storage stability data	GW	--
KCA 6.2.1	Sharma, A.K.	1999	RH-117,281: Nature of Residue in fruiting Tomato Plants Rohm and Haas, Grayson Research, LLC, Report No. 34-99-159, December 14, 1999 GLP Not published	N	Y	Data not available for first Annex I inclusion	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.2.1	Sharma, A.K.	1999	RH-117,281: Nature of Residue in cucurbits (Cucumber) Rohm and Haas, Grayson Research, LLC, Report No. 34-99-57, November 30, 1999 GLP Not published	N	Y	Data not available for first Annex I inclusion	GW	--
KCA 6.2.1	Hein, W.	2014	[Phenyl-UL-14C] Zoxamide: Plant Metabolism in Pea RLP AgroScience GmbH, Report No. AS290, June 12, 2014 GLP Not published	N	Y	Data not available for first Annex I inclusion	GW	--
KCA 6.2.1	Hein, W.	2014	Extraction Efficiency of [phenyl-UL-14C] Zoxamide from Plant Metabolism Samples (Pea) RLP AgroScience GmbH, Report No. AS362, June 25, 2014 GLP Not published	N	Y	Data not available for first Annex I inclusion	GW	--
KCA 6.2.1	Wolf, S.	2001	Determination of RH-0721 Residues in/on Grape (RAC Grape) from Field Trials in Europe (1997/1999) - to support ER 14.5 Rohm and Haas, RCC Ltd., Report No. 799773 March 16, 2001, ER ref. no. R 79.1 GLP Not published	N	Y	NA	GW	--
KCA 6.2.3	xxx	1998	Metabolism of 14C-RH-117,281 in lactating goats xxxx, Report No. 34-97-166, September 10, 1998, ER R16.1 xxx., Report No. RPT00299 GLP Not published	Y	Y	NA	GW	--
KCA 6.3.1	Wais, A.	1999	Determination of residues of RH-117,281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane/RH-117,281 75DG blend from field trials in Germany, 1996 Rohm and Haas, Report No. 649776, April 12, 1999, ER R66.4 RCC Ltd., Report No. 553002 GLP Not published	N	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3.1	Wais, A.	1999	Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-72812F and Dithane/RH-117,281 75 DG Blend from field trials in the United Kingdom; 1996 Rohm and Haas, Report No. 649811, April 16, 1999, ER R70.3 RCC Ltd., Report No. 553300 GLP Not published	N	Y	NA	GW	--
KCA 6.3.1	Grolleau, G.	1999	Magnitude of the Residue of RH-7281 and its metabolites RH-1452 and RH-1455 in Potato Raw Agricultural Commodity Rohm and Haas, Report No. EA960112, April 6, 1999, ER R63.3 RCC Ltd, Report No. 714925 GLP Not published	N	Y	NA	GW	--
KCA 6.3.1	Wais, A.	1999	Determination of residues of RH-117,281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane/RH-117,281 75DG blend from field trials in Italy, 1996 Rohm and Haas, Report No. 649800, April 13, 1999, ER R67.5/67.6 RCC Ltd., Switzerland, Report No. 553103 GLP Not published	N	Y	NA	GW	--
KCA 6.3.1	Wais, A.	1999	Determination of residues of RH-117,281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane/RH-117,281 75DG blend from field trials in Germany, 1997 Rohm and Haas, RCC Ltd., Report No. 652252, March 18, 1999, ER R64.4/65.5 GLP Not published	N	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3.1	Wais, A.	1999	Determination of residues of RH-117,281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane/RH-117,281 75DG blend from field trials in the UK, 1997 Rohm and Haas, RCC Ltd., Report No. 652263, March 23, 1999, ER R65.5/65.6 GLP Not published	N	Y	NA	GWI	--
KCA 6.3.1	Grolleau, G.	1999	Magnitude of the Residue of RH-7181 and its metabolites RH-1452 and RH-1455 in Potato Raw Agricultural Commodity - Northern and Southern France – 1997 Rohm and Haas, Report No. EA970131, April 6, 1999, ER R64.1 RCC Ltd., Report No. 714936 GLP Not published	N	Y	NA	GWI	--
KCA 6.3.1	Wais, A.	1999	Determination of residues of RH-117,281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane/RH-117,281 75DG blend from field trials in Italy, 1997 Rohm and Haas, RCC Ltd., Report No. 652285, March 25, 1999, ER R65.3/65.4 GLP Not published	N	Y	NA	GWI	--
KCA 6.3.1	Wais, A.	1999	Determination of residues of RH-117,281 and mancozeb in/on potatoes (RAG tubers) following treatment with RH-7281 2F and Dithane/RH-117,281 75DG blend from field trials in Greece, 1997 Rohm and Haas, RCC Ltd., Report No. 652307, March 17, 1999, ER R64.2/64.3 GLP Not published	N	Y	NA	GWI	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3.1	Wais, A.	1999	Determination of Residues of RH-117,281 and Mancozeb in/on Potato (RAC Tubers) Following Treatment with Dithane/RH-117,281 75DG (Blend (8:1) and Dithane/RH-117,281 75WP Blend (8:1) from Two Field Trials (Semi Residue Decline Studies) in Germany; 1998 Rohm and Haas, RCC Ltd., Report No. 688904, April 13, 1999, ER R68.1/68.2 GLP Not published	N	Y	NA	GW	--
KCA 6.3.1	Wais, A.	1999	Determination of residues of RH-117,281 and mancozeb in/on potato (RAC tubers) following treatment with Dithane/RH-117,281 75DG blend (8:1) and Dithane/RH-117,281 75WP blend (8:1) from two field trials (semi residue decline studies) in UK, 1998 Rohm and Haas, RCC Ltd., Report No. 688937, April 13, 1999, ER R68.3/68.4 GLP Not published	N	Y	NA	GW	--
KCA 6.3.1	Wais, A.	1999	Determination of residues of RH-117,281 in/on potato (RAC tubers) following treatment with Dithane/RH-117,281 75DG blend (8:1) and Dithane/RH-117,281 75WP blend (8:1) from four field trials (semi residue decline studies) in Spain, 1998 Rohm and Haas, RCC Ltd., Report No. 688926, April 13, 1999, ER R66.6/66.7 GLP Not published	N	Y	NA	GW	--
KCA 6.3.1	Wais, A.	2000	Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH-141,455 in/on potato (RAC tubers) following treatment with RH-7281/mancozeb 75WG from a field trial (semi residue decline studies) in the Netherlands, 1999 Rohm and Haas, RCC Ltd., Report No. 734567, January 31, 2000, ER R72.5 GLP Not published	N	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3.1	Wais, A.	2000	Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH-141,455 in/on potato (RAC tubers and processing products) following treatment with RH-7281/mancozeb 75WG from a field trial (semi residue decline studies) in Northern France, 1999 Rohm and Haas, RCC Ltd., Report No. 734556, February 21, 2000, ER R72.9 GLP Not published	N	Y	NA	GW	--
KCA 6.3.1	Wais, A.	2000	Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH-141,455 in/on potato (RAC tubers) following treatment with RH-7281/mancozeb 75WG from a field trial (semi residue decline studies) in Northern France, 1999 Rohm and Haas, RCC Ltd., Report No. 739001, March 15, 2000 ER R72.4 GLP Not published	N	Y	NA	GW	--
KCA 6.3.1	Wais, A.	2000	Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH-141,455 in/on potato (RAC tubers and processing products) following treatment with RH-7281/mancozeb 75WG from a field trial (semi residue decline studies) in Italy, 1999 Rohm and Haas, RCC Ltd., Report No. 734545, March 15, 2000, ER R73.2 GLP Not published	N	Y	NA	GW	--
KCA 6.3.1	Luciani, G.P.	2010	Determination of Zoxamide residues after five application of Electis MZ and Zoxium 240 SC on Potato-Italian trial, year 2010 Res Agraria s.r.l, AgriParadigma s.r.l., Report No. AGRI 012/010 GLP DEC, October 29, 2010 GLP Not published	N	Y	Data not available for first Annex I inclusion and bridge to support use of new formulation and modified GAP	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3.2	Wais, A.	1999	Determination of residues of RH-117281 and mancozeb in/on vine (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75DG Blend from field trials in Germany, 1996 Rohm and Haas, Report No. 649765, April 16, 1999, ER R69.4/69.5 RCC Ltd., Report No. 553001 GLP Not published	N	Y	NA	GW	--
KCA 6.3.2	Grolleau, G.	1999	Magnitude of the Residue of RH-7281 and Mancozeb in Grape Raw Agricultural Commodity and of RH-7281 in Wine and Processed Fractions Rohm and Haas, Report No. EA960110, March 15, 1999, ER R60.1 ANADIAG, Report No R6055 GLP Not published	N	Y	NA	GW	--
KCA 6.3.2	Wais, A.	1999	Determination of residues of RH-117281 and mancozeb in/on vine (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Italy; 1996 Rohm and Haas, Report No. 649787, April 16, 1999, ER R70.1/70.2 RCC Ltd, Report No. 553101 GLP Not published	N	Y	NA	GW	--
KCA 6.3.2	Wais, A.	1999	Determination of residues of RH-117,281 and mancozeb in/on table grapes (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG blend from field trials in Italy, 1996 Rohm and Haas, Report No. 649798, April 16, 1999, ER R71.3/71.4 RCC Ltd, Report No. 553102 GLP Not published	N	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3.2	Wais, A.	1999	Determination of residues of RH-117281 and mancozeb in/on table grapes (RAC grapes) following treatment with RH-7281 2F and Dithane /RH-117,281 75 DG Blend from field trials in Spain; 1996 Rohm and Haas, Report No. 620875, April 16, 1999, ER R70.5/70.6 RCC Ltd, Report No. 553200 GLP Not published	N	Y	NA	GW	--
KCA 6.3.2	Wais, A.	1999	Determination of residues of RH-117281 and mancozeb in/on vine (RAC grapes) following treatment with RH-7281 2F and Dithane /RH-117,281 75 DG Blend from field trials in Germany; 1997 Rohm and Haas, RCC Ltd, Report No. 652241, April 16, 1999, ER R71.1/71.2 GLP Not published	N	Y	NA	GW	--
KCA 6.3.2	Grolleau, G.	1999	Magnitude of the Residue of RH-7281 and Mancozeb in Grape Raw Agricultural Commodity and of RH-7281 in Wine Rohm and Haas, Report No. EA970130, March 15, 1999, ER R62.3 ANADIAG, Report No. R7097 GLP Not published	N	Y	NA	GW	--
KCA 6.3.2	Wais, A.	1999	Determination of residues of RH-117281 and mancozeb in/on vine (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Italy; 1997 Rohm and Haas, RCC Ltd, Report No. 652274, April 14, 1999, ER R68.5/68.6 GLP Not published	N	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3.2	Wais, A.	1999	Determination of residues of RH-117281 and mancozeb in/on vine (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Greece; 1997 Rohm and Haas, RCC Ltd, Report No. 652296, April 14, 1999, ER R69.2/69.3 GLP Not published	N	Y	NA	GW	--
KCA 6.3.2	Wais, A.	1999	Determination of residues of RH-117281 and mancozeb in/on table grapes (RAC grapes) following treatment with RH-117281 2F and dithane/RH-117281 75 DG blend from field trials in Italy; 1997. Rohm and Haas, RCC Ltd, Report No. 660688, March 19, 1999, ER R65.1/65.2 GLP Not published	N	Y	NA	GW	--
KCA 6.3.2	Wais, A.	1999	Determination of residues of RH-117281 and mancozeb in/on vine grapes (RAC grapes) following treatment with dithane/RH-117281 75 DG blend (8:1), dithane/RH-117281 75 WP blend (8:1) and RH-117281 2F experimental fungicide from four field trials (semi residue decline studies) in Germany; 1998. Rohm and Haas, RCC Ltd, Report No. 688893, April 13, 1999, ER R67.2/67.3 GLP Not published	N	Y	NA	GW	--
KCA 6.3.2	Grolleau, G.	1999	Magnitude of the Residue of RH-7281 and mancozeb (as CS2) in Grape Raw Agricultural Commodity. Rohm and Haas, Report No. EA980117, March 15, 1999, ER R63.1 ANADIAG, Report No. R8153 GLP Not published	N	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3.2	Wais, A.	1999	Determination of residues of RH-117281 and mancozeb in/on vine grapes (RAC grapes) following treatment with dithane/RH-117281 75 DG blend (8:1) and dithane/RH-117281 75 WP blend (8:1) from two field trials (semi residue decline studies) in Italy; 1998 Rohm and Haas, RCC Ltd, Report No. 688961, April 12, 1999, ER R66.2/66.3 GLP Not published	N	Y	NA	GW	--
KCA 6.3.2	Wais, A.	1999	Determination of residues of RH-117281 and mancozeb in/on vine grapes (RAC grapes) following treatment with dithane/RH-117,281 75 DG blend (8:1) from two field trials (semi residue decline studies) in Spain, 1998 Rohm and Haas, RCC Ltd, Report No. 688915, April 14, 1999, ER R67.4 GLP Not published	N	Y	NA	GW	--
KCA 6.3.2	Wais, A.	1999	Determination of residues of RH-117281 and mancozeb in/on table grapes (RAC grapes) following treatment with dithane/RH-117281 75 DG blend (8:1) from two field trials (semi residue decline studies) in Spain, 1998 Rohm and Haas, RCC Ltd, Report No. 693674, April 12, 1999, ER R66.1 GLP Not published	N	Y	NA	GW	--
KCA 6.3.2	Wais, A.	1999	Determination of residues of RH-117281 and mancozeb in/on table grapes (RAC grapes) following treatment with dithane/RH-117281 75 DG blend (8:1) from two field trials (semi residue decline studies) in Portugal, 1998 Rohm and Haas, RCC Ltd, Report No. 688948, April 14, 1999, ER R69.1 GLP Not published	N	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.3.2	Wais, A.	2000	Determination of residues of RH-117,281 and mancozeb in/on grapes (RAC grapes) following treatment with RH-7281/mancozeb 75WG from a field trial in Germany, 1999 Rohm and Haas, RCC Ltd, Report No. 734578, February 2, 2000, ER R72.8 GLP Not published	N	Y	NA	GWI	--
KCA 6.3.2	Grolleau, G.	2000	Magnitude of the residue of RH-2781/mancozeb 76.25 WG in grapes raw agricultural commodity. Northern France 1999 Rohm and Haas, European Agricultural Services, Report No. EA990175, March 28, 2000, ER R73.3 C.I.T., Report No. 19239 ADR GLP Not published	R	Y	NA	GWI	--
KCA 6.3.2	Grolleau, G.	2000	Magnitude of the residue of RH-2781/mancozeb 76.25 WG in grapes raw agricultural commodity. Southern France 1999 Rohm and Haas, European Agricultural Services, Report No. EA990176, March 28, 2000, ER R73.4 C.I.T., Report No. 19240 ADR GLP Not published	N	Y	NA	GWI	--
KCA 6.3.2	Luciani, G.P.	2010	Determination of Zoxamide residues after five application of ELECTIS MZ and ZOXIUM 240 SC on Wine grape and Table grape – Italian trial, year 2010. Res Agraria s.r.l., AgriParadigma s.r.l., Report no. AGRI 010/10 GLP DEC, October 29, 2010 GLP Not published	N	Y	Data not available for first Annex I inclusion and bridge to support use of new formulation and modified GAP	GWI	--
KCA 6.5.1	Mamouni, A.	1998	14C-RH-117281: Vinification Study Rohm and Haas, RCC Ltd, Report No. 34-98-151, ER R30.17 GLP Not published	N	Y	NA	GWI	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 6.5.3	Graves, D.D.	1998	RH-117281 80W and 2F residue studies in grapes and grape process fractions 1996 and 1997 trials Rohm and Haas, Agri Business Group, Inc., Enviro-Test Laboratories, McKenzie Laboratories, California State University at Fresno, Report No. 34-98-154, November 24, 1998, ER R62.1 GLP Not published	N	Y	NA	GW	--
KCA 6.5.3	Wais, A.	2001	Determination of residues of RH-117,281 and mancozeb in/on vine grapes (RAC grapes and processing products) following treatment with RH-7281/mancozeb 75WG from a field trial (semi residue decline study) in Italy; 1999 Rohm and Haas, RCC Ltd, Report No. 734580, April 10, 2001, ER R77.10 GLP Not published	N	Y	Data not available for first Annex I inclusion	GW	--
KCA 6.6.1	Kim-Kang, H.	1998	14C-RH-117281: Confined Rotational Crop Study Rohm and Haas, Report No. 34-98-144, December 4, 1998, ER R60.2 XenoBiotic Laboratories Inc., Report No. RPT00387 GLP Not published	N	Y	NA	GW	--
KCA 7.1.1.1	Burgener, A	1998	14C-RH-117281: Rate of degradation and metabolism in four soils incubated under aerobic conditions Rohm and Haas, Report No. 34-98-45, September 17 1998, ER ref. no. 18.2 RCC Umweltchemie AG, Report No. 626196 GLP Not published	N	Y	NA	GW	--
KCA 7.1.1.1	Smalley, J, Reynolds, JL	1997	Aerobic soil metabolism of [14C]-RH-117281 Fungicide Rohm and Haas, Report No. 34-96-07, June 26, 1997, ER ref. no. 6.13 XenoBiotic Laboratories Inc., Report No. RPT00256 GLP Not published	N	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 7.1.1.2	Kim-Kang, H	1997	Anaerobic soil metabolism of [14C]-RH-117281 Rohm and Haas, Report No. 34-97-43, April 9 1997, ER ref. no. 8.16 XenoBiotic Laboratories Inc., Report No. RPT00267 GLP Not published	N	Y	NA	GW	--
KCA 7.1.1.2	Volkel, W	1998	14C-RH-117281: degradation in one soil incubated under anaerobic conditions Rohm and Haas, Report No. 34-98-46, September 3, 1998, ER ref. no. 4.5 RCC Umweltchemie AG, Report No. 626207 GLP Not published	N	Y	NA	GW	--
KCA 7.1.1.3	Reynolds, JL	1997	Soil photolysis of [14C]-RH-117281 Rohm and Haas, Report No. 34-96-214, July 31, 1997, ER ref. no. 10.2 XenoBiotic Laboratories Inc., Report No. RPT00261 GLP Not published	N	Y	NA	GW	--
KCA 7.1.2.1.1	Callow, B. and Hilton, H.	2013	Determination of rates of decline for zoxamide and its metabolites in soil according to the guidance within the FOCUS Kinetics Guidance Document Exponent International Ltd, UK, Report No. 0907598.UK0 EWC 0021 No GLP Not published	N	Y	Data required to meet new guidance	GW	--
KCA 7.1.2.1.1	Burgener, A	1998	14C-RH-117281: Rate of degradation and metabolism in four soils incubated under aerobic conditions, Rohm and Haas, Report No. 34-98-45, September 17, 1998, ER ref. no. 18.2 RCC Umweltchemie AG, Report No. 626196 GLP Not published	N	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 7.1.2.1.1	Smalley, J, Reynolds, JL	1997	Aerobic soil metabolism of [14C]-RH-117281 Fungicide Rohm and Haas, Report No. 34-96-07, June 26, 1997, ER ref. no. 6.13 XenoBiotic Laboratories Inc., Report No. RPT00256 GLP Not published	N	Y	NA	GW	--
KCA 7.1.2.1.2	Callow, B. and Hilton, H.	2013	Determination of rates of decline for zoxamide and its metabolites in soil according to the guidance within the FOCUS Kinetics Guidance Document Exponent International Ltd, UK, Report No. 0907598.UK0 EWC 0021 No GLP Not published	N	Y	Data required to meet new guidance	GW	--
KCA 7.1.2.1.2	Van den Bosch, M.M.H.	2013	Determination of the aerobic degradation rate of RH-141,455 in soil WIL Research Europe B.V., The Netherlands, Report No. 500850 GLP Not published	N	Y	Data required to meet new guidance	GW	--
KCA 7.1.2.1.3	Kim-Kang, H	1997	Anaerobic soil metabolism of [14C]-RH-117281 Rohm and Haas, Report No. 34-97-43, April 9, 1997, ER ref. no. 8.16 XenoBiotic Laboratories Inc., Report No. RPT00267 GLP Not published	N	Y	NA	GW	--
KCA 7.1.2.1.3	Volkel, W	1998	14C-RH-117281: degradation in one soil incubated under anaerobic conditions Rohm and Haas, Report No. 34-98-46, September 3, 1998, ER ref. no. 4.5 RCC Umweltchemie AG, Report No. 626207 GLP Not published	N	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 7.1.3.1.1	Shelby, DJ	1996	Adsorption and desorption of RH-117281 to soil Rohm and Haas Report No. 34-96-01, February 9, 1996, ER ref. no. 7.2 Ricerca Inc., Report No. 95-0224 GLP Not published	N	Y	NA	GW	--
KCA 7.1.3.1.2	Van den Bosch, M.M.H.	2013	Adsorption/desorption of RH-141,455 on three soils WIL Research Europe B.V., The Netherlands, Report No. 500851 GLP Not published	N	Y	Data required to meet new guidance	GW	--
KCA 7.1.3.1.2	Reynolds, J.L.	1998	Adsorption and desorption of 14C-RH-24549 in three soils Rohm and Haas, Report No. 34-98-53, October 14, 1998, ER ref. no. 18.1 XenoBiotic Laboratories Inc., Report No. 706050 GLP Not published	N	Y	NA	GW	--
KCA 7.1.3.1.2	Volkel, W.	1998	Adsorption/Desorption of RH-127450 on three soils Rohm and Haas, Report No. 34-98-54, December 15, 1998, ER ref. no. 25.4 RCC Ltd., Report No. 688116 GLP Not published	N	Y	NA	GW	--
KCA 7.1.3.1.2	Volkel, W.	1998	Determination of the adsorption coefficient of 14C-RH-163353 on soil and its octanol/water partition coefficient using high performance liquid chromatography (HPLC) Rohm and Haas, Report No. 34-98-55, November 9, 1998, ER ref. no. 31.4 RCC Ltd., Report No. 689951 GLP Not published	N	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 7.1.3.1.2	Volkel, W.	2000	Adsorption/desorption of RH-163,353 in three soils Rohm and Haas, Report No. 34-00-06, January 31, 2000, ER ref. no. 40.7 RCC Ltd., Report No. 733948 GLP Not published	N	Y	NA	GW	--
KCA 7.1.4.1.2	Volkel, W.	1998	14C-RH-117281: Leaching characteristics of aged residues in one soil Rohm and Haas, Report No. 34-98-48, September 15, 1998, ER ref. no. 4.4 RCC Umweltchemie AG, Report No. 636895 GLP Not published	N	Y	NA	GW	--
KCA 7.2.1.1	Reynolds, J.L.	1998	Hydrolysis of [14C]-RH-117281 in Water at pH 4, 7, and 9 Rohm and Haas, Technical Report Number 34-98-39, September 29, 1998, ER ref. no. 15.2 XenoBiotic Laboratories Inc., Report No. RPT00251 GLP Not published	N	Y	NA	GW	--
KCA 7.2.1.1	Chong, B.P.	1998	RH-117281 Fungicide: Hydrolysis rates of relevant degradation products Rohm and Haas, Technical Report No. 34-98-26, September 30, 1998, ER ref. no. 30.16 GLP not relevant Not published	N	Y	NA	GW	--
KCA 7.2.1.2	Smalley, J. and Reynolds, J.L.	1998	Aqueous photolysis of [14C]-RH-117281 Rohm and Haas, Report No. 34-96-215, May 12, 1998, ER ref. no. 12.5 XenoBiotic Laboratories Inc., Report No. RPT00259 GLP Not published	N	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 7.2.2.1	Barnes, SP, Nave, V	1998	RH-117281 - Assessment of ready biodegradability: modified Sturm test Rohm and Haas, Report No. 98RC-1028, December 14, 1998, ER ref. no. 29.1 Huntingdon Life Sciences Limited, Report No. RAS 080/983376 GLP Not published	N	Y	NA	GW I	--
KCA 7.2.2.2	Van den Bosch, M.M.H.	2014	Aerobic mineralisation of zoxamide in surface water WIL Research Europe B.V., The Netherlands, Report No. 503495 GLP Not published	N	Y	Data required to meet new guidance	GW I	--
KCA 7.2.2.3	Callow, B. and Hilton, H.	2013	Determination of rates of decline for zoxamide and its metabolites, in sediment-water studies according to the guidance within the FOCUS Kinetics Guidance Document Exponent International Ltd, UK, Report No. 0907598.UK0/EWC0020 No GLP Not published	N	Y	Data required to meet new guidance	GW I	--
KCA 7.2.2.3	Morgenroth, U	1998	14C-RH-117281: Degradation and metabolism in aquatic systems Rohm and Haas, Report No. 34-98-47, September 15, 1998, ER ref. no. 4.3 RCC Umweltchemie AG, Report No. 624510 GLP Not published	N	Y	NA	GW I	--
KCA 7.3.2	Burgener, A	1998	Investigation of the volatilization of 14C-RH-117281 from soil and dwarf runner bean Rohm and Haas Technical Report No. 34-98-132, August 24, 1998, ER ref. no. 14.2 RCC Ltd, Report No. 687295 GLP Not published	N	Y	NA	GW I	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 8.1.1.1	xxx	1997	RH-117,281 technical: 14-day acute oral LD50 study in bobwhite quail xxx, Report No. 94RC-0240, April 9 1997, ER Ref No. 2.6 xxx., Report No. RH117BWLD-595 GLP Not published	Y	Y	NA	GW	--
KCA 8.1.1.2	xxx	1997	RH-117,281 technical: 8-day acute dietary LC50 study in bobwhite quail xxx, Report No. 94RC-0242, April 10 1997, ER Ref No. 2.4 xxx., Report No. RH117BWLC-395 GLP Not published	Y	Y	NA	GW	--
KCA 8.1.1.2	xxx	1997	RH-117,281 technical: 8-day acute dietary LC50 study in mallard ducklings xxx, Report No. 94RC-0241, April 10 1997 ER Ref No. 2.5 xxx, Report No. RH117MDLC-395 GLP Not published	Y	Y	NA	GW	--
KCA 8.1.1.3	xxx	1998	Avian reproduction study of RH-117,281 technical with northern bobwhite xxx, Report No. 97RC-0081, December 9 1998, ER Ref No. 28.2 xxx, Report No. RH7281BW-97-2 GLP Not published	Y	Y	NA	GW	--
KCA 8.1.1.3	xxx	1999	RH-117,281 technical: A reproduction study with the mallard (Anas platyrhynchos) xxx, Report No. 98RC-0166, April 5 1999, ER Ref No. 33.13 xxx, Ltd., Report No. 129-164 GLP Not published	Y	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 8.2.1	xxx	1995	Acute flow-through toxicity of RH-117,281 technical to rainbow trout (<i>Oncorhynchus mykiss</i>) xxx, Report No. 94RC-0078, July 25 1995, ER Ref No: 2.1 xxx, Report No. 41681 GLP Not published	Y	Y	NA	GW	--
KCA 8.2.1	xxx	1995	Acute flow-through toxicity of RH-117,281 technical to bluegill (<i>Lepomis macrochirus</i>) xxx, Report No. 94RC-0080, July 25 1995, ER Ref No. 4.10 xxx., Report No. 41682 GLP Not published	Y	Y	NA	GW	--
KCA 8.2.1	xxx	1998	RH-117,281 Technical: A flow-through life-cycle toxicity test with the fathead minnow (<i>Pimephales promelas</i>) xxx, Report No. 97RC-0079, September 29 1998, ER Ref No. 17.4 xxx, Report No. 129A-141 GLP Not published	Y	Y	NA	GW	--
KCA 8.2.1	xxx	1998	RH-117,281 Technical: A 96-hour flow-through acute toxicity test with the zebra fish (<i>Brachydanio rerio</i>) xxx, Report No. 97RC-0134, May 15 1998, ER Ref No. 12.11 xxx., Report No. 129A-150 GLP Not published	Y	Y	NA	GW	--
KCA 8.2.1	xxx	1997	RH-117,281 Technical: a 96-hour flow-through acute toxicity test with the sheepshead minnow (<i>Cyprinodon variegatus</i>) xxx, Report No. 95RC-0274, May 15 1997, ER Ref No. 8.1 xxx, Report No. 129A-135 GLP Not published	Y	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 8.2.1	xxx	1998	Acute toxicity of RH-127,450 to the rainbow trout (<i>Oncorhynchus mykiss</i>) in a range-finding test under static conditions xxx, Report No. 98RC-0095, September 11 1998, ER Ref No. 17.5 xxx, Report No. 44667 GLP Not published	Y	Y	NA	GWI	--
KCA 8.2.1	xxx	2002	Zoxamide Metabolite RH-139,432 - acute toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) under static conditions xxx, Report No. 021296, September 27 2002, ER Ref. 47.4 xxx, Report No. 12550.6290 GLP Not published	Y	Y	NA	GWI	--
KCA 8.2.1	xxx	2010	GOW 008: Acute toxicity to zebra fish (<i>Danio rerio</i>) in a 96-hour study under static exposure xxx, Report No. CH-E-081/2010, BT104/10, January 10, 2011 GLP Not published	Y	Y	NA	GWI	--
KCA 8.2.2	xxx	1996	Early life-stage toxicity of RH-117,281 technical to rainbow trout (<i>Oncorhynchus mykiss</i>) under flow-through conditions xxx, Report No. 94RC-0239, July 31 1996, ER Ref No. 7.1 xxx, Report No. 42400 GLP Not published	Y	Y	NA	GWI	--
KCA 8.2.2	xxx	1998	RH-117,281 Technical: A flow-through life-cycle toxicity test with the fathead minnow (<i>Pimephales promelas</i>) xxx, Report No. 97RC-0079, September 29 1998, ER Ref No. 17.4 xxx, Report No. 129A-141 GLP Not published	Y	Y	NA	GWI	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 8.2.2.1	xxx	2014	Zebrafish (Danio rerio), early life stage toxicity test, flow through conditions, test item: zoxamide xxx, Report No. GOW-001/4-43/A, October 31 2014 GLP Not published	Y	Y	New data not previously used to support approval	GWI	--
KCA 8.2.2.3	xxx	1998	Uptake, depuration, bioconcentration and metabolism of 14C-RH-117,281 in bluegill sunfish (Lepomis macrochirus) under flow through test conditions xxx, Report No. 34-98-145, September 15 1998, ER Ref. No. 15.1 xxx, Report No. RPT00328 GLP Not published	Y	Y	NA	GWI	--
KCA 8.2.3	Tognucci, A.	1998	Determination of the partition coefficient (n-octanol/water) of RH-127450 Rohm and Haas, Report No. 34-98-165, October 12 1998, ER Ref. No. 18.3 RCC Ltd. GLP No Published.	N	Y	NA	GWI	--
KCA 8.2.3	Tognucci, A.	1998	Determination of the partition coefficient (n-octanol/water) of RH-139432 Rohm and Haas, Report No. 34-98-53, ER Ref. No. 31.3 RCC Ltd GLP Not published	N	Y	NA	GWI	--
KCA 8.2.4.1	Sword, M.C., Gardner, C.	1995	Acute flow-through toxicity of RH-117,281 Technical to Daphnia magna Rohm and Haas, Report No. 94RC-0081, July 25 1995, ER Ref No. 5.1 ABC Laboratories, Report No. 41683 GLP Not published	N	Y	NA	GWI	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 8.2.4.1	Rhodes, J.E., Williams, S.	1998	Acute toxicity of RH-127,450 to Daphnia magna in a range-finding test under static conditions Rohm and Haas, Report No. 98RC-0096, September 11 1998, ER Ref No. 16.4 ABC Laboratories, Report No. 44666 GLP Not published	N	Y	NA	GW	--
KCA 8.2.4.1	Mantilacci S.	2010	Acute toxicity of product GOW008 on Daphnia magna in a 48-hour immobilization test under static exposure Biotechnologie BT srl, Report No. BT103/10, November 18 2010 GLP Not published	N	Y	NA	GW	--
KCA 8.2.4.1	Caferella, M. A	2002	Zoxamide metabolite RH-139,432 - acute toxicity to daphnids (Daphnia magna) under static conditions Dow AgroSciences LLC, Report No. 021297, September 27 2002, ER Ref. No. 47.3 Springborn Smithers Laboratories, Report No. 1t2550.6289 GLP Not published	N	Y	NA	GW	--
KCA 8.2.4.2	Roberts, C.A., Swigert, J.P	1997	RH-117,281 Technical: A 96-hour flow-through acute toxicity test with the saltwater mysid (Mysidopsis bahia) Rohm and Haas, Report No. 95RC-0275, May 5 1999 Wildlife International Ltd., Report No. 129A-136 GLP Not published	N	Y	Data were generated to support registration in the US and were not available or required for first Annex I inclusion	GW	--
KCA 8.2.5.1	Murrell, H., Rhodes, J.E., Stewart, S.	1997	Chronic toxicity of RH-117,281 technical to Daphnia magna under flow-through test conditions Rohm and Haas, Report No. 95RC-0273, June 12 1997, ER Ref No. 6.11 ABC Laboratories, Report No. 43209 GLP Not published	N	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 8.2.5.2	Drottar, K.R., Krueger, H.O.	1998	RH-117,281 Technical: A flow-through life-cycle toxicity test with the saltwater mysid (<i>Mysidopsis bahia</i>) Rohm and Haas, Report No. 97RC-0077, June 17 1998 Wildlife International Ltd., Report No. 129A-142 GLP Not published	N	Y	Data were generated to support registration in the US and were not available or required for first Annex I inclusion	GW	--
KCA 8.2.5.3	van der Kolk, J.	1998	RH-117,281: Chronic effects on midge larvae (<i>Chironomus riparius</i>) in a water/sediment system. Rohm and Haas, Report No. 97RC-0083, May 26 1998, ER Ref No. 13.3 Springborn Laboratories (Europe)AG, Report No. 97-063-1007 GLP Not published	N	Y	NA	GW	--
KCA 8.2.6.1	Ziegler, T.A., Stewart, S.	1996	Acute toxicity of RH-117,281 Technical to <i>Selenastrum capricornutum</i> Printz. Rohm and Haas, Report No. 94RC-0238, June 20 1996, ER Ref No. 1.1 ABC Laboratories, Report No. 42399 GLP Not published	N	Y	NA	GW	--
KCA 8.2.6.1	Kuhl, R., Härtel, Ch.	2015	Toxicity of (R)-Zoxamide to <i>Desmodesmus subspicatus</i> in an algal growth inhibition test. Ibacon GmbH, Report No. 93441210 GLP Not published	N	Y	New data required to support approval renewal	GW	--
KCA 8.2.6.1	Kuhl, R., Härtel, Ch.	2015	Toxicity of (S)-Zoxamide to <i>Desmodesmus subspicatus</i> in an algal growth inhibition test. Ibacon GmbH, Report No. 93431210 GLP Not published	N	Y	New data required to support approval renewal	GW	--
KCA 8.2.6.1	Hengsberger, A., Härtel, Ch.	2015	RH-141455: Toxicity to <i>Pseudorichneriella subcapitata</i> in an algal growth inhibition test Ibacon GmbH, Report No. 98661210, July 01, 2015 GLP Not published	N	Y	New data required to support approval renewal	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 8.2.6.1	Drottar, K.R., Sutherland, C.A., Krueger, H.O.	1998	RH-117,281 Technical: A 96-hour toxicity test with the freshwater alga (<i>Anabaena flos-aquae</i>) Rohm and Haas, Report No. 97RC-0130, August 7, 1998, ER Ref No. 13.2 Wildlife International, Ltd., Report No. 129A-154 GLP Not published	N	Y	NA	GW	--
KCA 8.2.6.1	Drottar, K.R., Sutherland, C.A., Krueger, H.O.	1998	RH-117,281 Technical: A 96-hour toxicity test with the freshwater diatom (<i>Navicula pelliculosa</i>) Rohm and Haas, Report No. 97RC-0131, ER Ref No. 13.5 Wildlife International, Ltd., Report No. 129A-153 GLP Not published	N	Y	NA	GW	--
KCA 8.2.6.1	Drottar, K.R., Sutherland, C.A., Krueger, H.O.	1998	RH-117,281 Technical: A 96-hour toxicity test with the freshwater alga (<i>Scenedesmus subspicatus</i>) Rohm and Haas, Report No. 97RC-0133, August 7, 1998, ER Ref No. 13.4 Wildlife International, Ltd., Report No. 129A-151 GLP Not published	N	Y	NA	GW	--
KCA 8.2.6.1	Drottar, K.R., Krueger, H.O.	1998	RH-117,281 Technical: A 96-hour toxicity test with the marine diatom (<i>Skeletonema costatum</i>) Rohm and Haas, Report No. 97RC-0132, July 21, 1998, ER Ref No. 12.10 Wildlife International, Ltd., Report No. 129A-152 GLP Not published	N	Y	NA	GW	--
KCA 8.2.6.1	Ward, S.C., Murdock, C.W.	1998	Toxicity of RH-117,281 2F (240 SC) to <i>Selenastrum capricornutum</i> Printz Rohm and Haas, Report No. 97RC-0094, September 23, 1998, ER Ref No. 14.6 ABC Laboratories, USA, Report No. 44196 GLP Not published	N	Y	NA	GW	--

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KCA 8.2.6.1	Rhodes, J.E., Williams, S.	1998	Acute toxicity of RH-127,450 to the green alga, <i>Selenastrum capricornutum</i> Printz Rohm and Haas, Report No. 98RC-0097, October 30, 1998, ER Ref No. 28.3 ABC Laboratories Inc., Report No. 44665 GLP Not published	N	Y	NA	GW	--
KCA 8.2.6.1	Rhodes, J.E., Williams, S.	1999	Acute toxicity of RH-163,353 to <i>Selenastrum capricornutum</i> Printz in a range-finding test under static conditions Rohm and Haas, Report No. 99RC-0023, May 3, 1999, ER Ref No. 36.1 ABC Laboratories Inc., Report No. 45164 GLP Not published	N	Y	NA	GW	--
KCA 8.2.6.1	Hoberg, J.R	2002	Zoxamide Metabolite RH-139,432 - toxicity to freshwater green algae, <i>Scenedesmus subspicatus</i> Dow AgroSciences LLC, Report No. 021298, September 25, 2002, ER Ref. 47.5 Springborn Smithers Laboratories, Report No. 12550.6288 GLP Not published	N	Y	NA	GW	--
KCA 8.2.6.1	Juckeland, D.	2015	Effects of RH-24549 on <i>Desmodesmus subspicatus</i> in an algal growth inhibition test BioChem agrar, Report No. 15 10 48 026 W, June 25 2015 GLP Not published	N	Y	NA	GW	--
KCA 8.2.7	Drott, K.R., Krueger, H.O.	1998	RH-117,281 Technical: A 14-day static-renewal toxicity test with duckweed (<i>Lemna gibba</i> G3) Rohm and Haas, Report No. 97RC-0080, June 24 1998, ER Ref No. 12.7 Wildlife International, Ltd., Report No. 129A-147 GLP Not published	N	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 8.3.1.1.1	Kirkland, R.L.	1993	Acute contact toxicity of RH-117,281 technical to honey bees Rohm and Haas, Report No. 92RC-0235, August 9 1993, ER Ref No. 12.6 Bio Research, Report No. 109-93 GLP Not published	N	Y	NA	GW	--
KCA 8.3.1.1.2	Engelhard, E.K.	1998	RH-117,281 2R (240 SC): Laboratory oral and contact test with the honeybee, Apis mellifera Rohm and Haas, Report No. 97RC-0095, April 25 1998, ER Ref No. 11.6, Springborn Laboratories (Europe) AG, Report No. 97-066-1007 GLP Not published	N	Y	NA	GW	--
KCA 8.3.1.2	Schmitzer, S., Ehmke, A.	2014	Chronic oral toxicity test of Zoxium 240 SC on the honey bee (Apis mellifera L.) in the laboratory IBACON GmbH, Report No. 80052136, February 3 2014 GLP Not published	N	Y	New data requirement	GW	--
KCA 8.3.1.3	Schmitzer, S.	2014	Study on the effects of Zoxium 240 SC on honey bee brood (Apis mellifera L.) – brood feeding test BioChem agrar, Report No. 80051031, March 27 2014 GLP Not published	N	Y	New data requirement	GW	--
KCA 8.3.1.4	Schmitzer, S.	2014	Study on the effects of Zoxium 240 SC on honey bee brood (Apis mellifera L.) – brood feeding test BioChem agrar, Report No. 80051031, March 27 2014 GLP Not published	N	Y	New data requirement	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 8.3.2.1	Engelhard, E.K.	1998	RH-117,281 2R (240 SC): Laboratory acute toxicity test with the parasitic wasp, <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae) Rohm and Haas, Report No.: 97RC-0106, March 3 1998, ER Ref No. 11.8 Springborn Laboratories (Europe) AG, Report No. 97-062-1007 GLP Not published	N	Y	NA	GW I	--
KCA 8.3.2.2	Engelhard, E.K.	1998	RH-117,281 2R (240 SC): Laboratory toxicity test with the predacious mite, <i>Typhlodromus pyri</i> Scheuten (Acari: Phytoseiidae) Rohm and Haas, Report No. 97RC-0105, March 3 1998, ER Ref No. 11.3 Springborn Laboratories (Europe) AG, Report No. 97-070-1007 GLP Not published	N	Y	NA	GW I	--
KCA 8.3.2.2	Engelhard, E.K.	1998	RH-117,281 2R (240 SC): Laboratory toxicity test with the predacious mite, <i>Amblyseius andersoni</i> Chant (Acari: Phytoseiidae) Rohm and Haas, Report No. 97RC-0111, March 3 1998, ER Ref No. 11.7 Springborn Laboratories (Europe) AG, Report No. 97-075-1007 GLP Not published	N	Y	NA	GW I	--
KCA 8.3.2.2	Engelhard, E.K.	1998	RH-117,281 2R (240 SC): Laboratory toxicity test with the spiders, <i>Pardosa</i> sp. (Araneae: Lycosidae) Rohm and Haas, Report No. 97RC-0107, March 3, 1998, ER Ref No. 11.9 Springborn Laboratories (Europe) AG, Report No. 97-059-1007 GLP Not published	N	Y	NA	GW I	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 8.3.2.2	Engelhard, E.K.	1998	RH-117,281 2R (240 SC): Laboratory toxicity test with the green lacewing <i>Chrysoperla carnea</i> Steph. (Neuroptera: Chrysopidae) Rohm and Haas, Report No. 97RC-0109, March 3 1998, ER Ref No. 11.11 Springborn Laboratories (Europe) AG, Report No. 97-068-1007 GLP Not published	N	Y	NA	GW	--
KCA 8.3.2.2	Engelhard, E.K.	1998	RH-117,281 2R (240 SC): Laboratory contact toxicity test with the predator, <i>Orius insidiosus</i> (Heteroptera: Anthrenidae) Rohm and Haas, Report No. 97RC-0110, March 3 1998, ER Ref No. 11.10 Springborn Laboratories (Europe) AG, Report No. 97-077-1007 GLP Not published	N	Y	NA	GW	--
KCA 8.3.2.2	Engelhard, E.K.	1998	RH-117,281 2R (240 SC): Laboratory acute toxicity test with the ground beetle, <i>Poecilus cupreus</i> L. (Coleoptera: Carabidae) Rohm and Haas, Report No. 97RC-0108, March 3 1998, ER Ref No. 11.2 Springborn Laboratories (Europe) AG, Report No. 97-064-1007 GLP Not published	N	Y	NA	GW	--
KCA 8.4.1	Ganssmann, M.	2015	RH-141455: Effects on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil IBACON GmbH, Report No. 98661022, June 1 2005 GLP Not published	N	Y	New data required to support approval renewal	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 8.4.1	Downing, J.	1995	RH-117,281 technical: toxicity to earthworm (<i>Eisenia fetida</i>) Rohm and Haas, Report No. 94RC-0237, July 19 1995, ER Ref No. 5.2 ABC Laboratories Inc., Report No. 42398 GLP Not published	N	Y	NA	GWI	--
KCA 8.4.1	Bryan, R.L., Porch, J.R., Krueger, H.O.	2000	RH-127,450 technical: an acute toxicity study with the earthworm in an artificial soil substrate. Rohm and Haas, Report No. 99RC-0282, March 7 2000, ER Ref No. 41.5 Wildlife International, Ltd., Easton, MD, USA, Report No. 129-173 GLP Not published	N	Y	NA	GWI	--
KCA 8.4.1	Nienstedt, K.	1999	A chronic toxicity and reproduction test exposing the earthworm <i>Eisenia fetida</i> to RH-117,281 Technical material in OECD artificial soil, based on the BBA-guideline VI, 2-2 (1994) and the ISO-draft (ISO/DIS 11268-2) Rohm and Haas, Report No. 98RC-0181, April 14 1999, ER Ref No. 34.1 Springborn Laboratories (Europe) AG, Report No. 99-092-1007 GLP Not published	N	Y	NA	GWI	--
KCA 8.4.1	Nienstedt, K.	2001	Effects of RH-7281 technical applied on natural soil on the cocoon and juvenile production of the earthworm <i>Eisenia fetida</i> Rohm and Haas, Report No. 00RC-0209, February 22 2001, ER Ref No. 45.2 Springborn Laboratories (Europe) AG, Report No. 1007.070.631 GLP Not published	N	Y	NA	GWI	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 8.4.2	Young, D.H.	2000	Evaluation of the biological activity of the RH-117281 metabolites RH-24549, 127450 and 163353 Rohm and Haas, Report No. DIS-00-281, ER Ref No. 44.1 GLP Not published	N	Y	NA	GW	--
KCA 8.5	Hammesfahr, U.	2015	RH-141455: Effects on the activity of soil microflora in the laboratory (nitrogen transformation) IBACON GmbH, Report No. 98661080, May 1, 2015 GLP Not published	N	Y	New data required to support approval renewal	GW	--
KCA 8.5	van der Kolk, J.	1998	RH-117,281 Technical: Determination of the effects on soil microflora activity Rohm and Haas, Report No. 97RC-0084, September 7 1998, ER Ref No. 14.1 Springborn Laboratories (Europe) AG, Report No. 97-060-1007 GLP Not published	N	Y	NA	GW	--
KCA 8.5	van der Kolk, J.	2000	RH-117,281 Technical: Determination of the effects on nitrogen transformation by microflora in soil Rohm and Haas, Report No. 00RC-0085, ER Ref No. 44.12 Springborn Laboratories (Europe) AG, Report No. 1007.070.747 GLP Not published	N	Y	NA	GW	--
KCA 8.6	Nunez, M.V.	1998	Greenhouse phytotoxicity tests with RH-7281 2F Rohm and Haas, Report No. 98R-1092, August 31 1998, ER Ref No. 28.4, GLP Not published	N	Y	NA	GW	--
KCA 8.6	Nunez, M.V.	1998	Greenhouse crop phytotoxicity tests with RH-117281 2F Rohm and Haas, Report No. 98R-1114, November 23 1998, ER Ref No. 28.5 GLP Not published	N	Y	NA	GW	--

Data point²	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not BVL Doc. ID	Vertebrate study (Y/N)	Data protection claimed (Y/N)	Justification if data protection is claimed	Owner	Documents already submitted on/to
KCA 8.6	Sames, B.A.	1998	Insecticidal screening report - pre-screen insecticidal activity with RH-117,281; Primary screening activity per RH-117281 Rohm and Haas, Report No. 98R-1113, November 5 1998, ER Ref No. 28.6 GLP Not published	N	Y	NA	GW	--
KCA 8.8	Heim, D., Heim, L.	2002	Activated sludge, respiration inhibition test of Zoxamide Dow AgroSciences, Report No. GH-C 5421, February 7 2002, CA 3, ER Ref. No. 47.2 GLP Not published	N	Y	NA	GW	--

Under Article 59 of Regulation 1107/2009/EC, the Sponsor Company claims data protection for all Gowan studies for which data protection claimed is reported as YES.

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte- brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner