

REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: Cymoxanil 33% + Zoxamide 33% WG

Product name(s): e. g. **Reboot**

Chemical active substance(s):

Cymoxanil, 330 g/kg

Zoxamide, 330 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(product re-registration)

Applicant: Gowan Crop Protection Ltd.
and its affiliates as detailed in Part A

Submission date: 30/12/2020

MS Finalisation date: August 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 will be confirmed in the respective PART A.

STATEMENT FOR OWNERSHIP

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Version history

When	What
30 th December 2020	Submission of initial Version 0 by the applicant.
August 2021	Version evaluated by PL zRMS highlighted in blue
December 2021	Revised version, Corrected by zRMS.

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This document summarises the physical/chemical data and the further information on the plant protection product Cymoxanil 33% + Zoxamide 33 % WG (trade name e.g. Reboot), a WG formulation containing 330 g/kg zoxamide and 330 g/kg cymoxanil, for re-registration in EU countries. 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 on behalf of Gowan Crop Protection Ltd., UK. 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 is for the renewal of the authorisation of the product according to Article 43 of Regulation (EC) No 1107/2009, following the renewal of approval of the active substance zoxamide according to Regulation (EU) 2018/1981 of 13 December 2018.

The aim of this step of the art. 43 process is to update the existing dossier information with regard to and limited to the 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 product meets the requirements set out in the Regulation on the renewal of the approval of the active substance zoxamide to comply with provisions of article 29 of Regulation (EU) No 1107/2009.

This dossier contains the consolidated version of the previous assessment for the parts which do not require a re-evaluation, including all assessments and data on cymoxanil.

The document is based on the Registration Report provided by UK CRD in October 2014 and inhibits the evaluation results of the zRMS UK for product approval in the central EU zone. Unchanged data from the previous version are highlighted in grey.

As a conclusion, sufficient data on the identity, and physical and chemical properties and other information are available for the plant protection product Cymoxanil 33% + Zoxamide 33 % WG and the contained technical active substance(s).

Noticed data gaps are:

None.

zRMS conclusion on part C after renewal of Zoxamide:

From physicochemical point of view all presented data are still considered as sufficient after renewal.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Gowan Crop Protection Ltd.
and its affiliates as detailed in Part A
Address: Highlands House Basingstoke Road
Spencers Wood
Reading, Berkshire
England, RG7 1NT
United Kingdom

Responsible: xxx

Address: xxx

xxx

xxx

xxx

xxx

Phone: xxx

Fax: xxx

E-Mail:

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s) (KCP 1.2)

1.2.3.1 Zoxamide

Zoxamide purity: min. 953 g/kg Source: EFSA (2017)¹

¹ EFSA (2017): Conclusion on the peer review of the pesticide risk assessment of the active substance zoxamide. EFSA Journal 2017, 5 (9): 4980

The zoxamide source data of Gowan Crop Protection Ltd. (legal successor of the company Gowan Comercio Internacional e Servicos Limitada) have recently been evaluated by the Rapporteur Member State (RMS) Latvia during active ingredient renewal (AIR) on EU level (please refer to Volume 4, Annex C (confidential information) of the RAR 2017).

The active substance is a racemic compound containing one chiral centre. Both enantiomers are present in equal quantities.

For information on impurities of zoxamide technical, please refer to the dRR Part C (Confidential information).

1.2.3.2 Cymoxanil

Cymoxanil: min. 97 % w/w (970 g/kg) Source: 2008/125/EC- 19th December 2008

For detailed information on impurities of Cymoxanil, please refer to the documentation presented for Step 1 re-registration of all products containing Cymoxanil in June 2009.

No toxicologically relevant impurities have been defined for Cymoxanil (2008/125/EC- 19th December 2008).

A Letter of Access of the company Sipcam Oxon grants the rights to Gowan Crop Protection Ltd. on the active substance data for cymoxanil. Sipcam Oxon is a member of the Cymoxanil Task Force, a main notifier for active substance renewal on EU level.

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name:	Gowan ownership	Sipcam Oxon ownership *
	Harpon	Lieto
	Reboot	Lieto 66 WG
	Electis Plus	Lieto WG
	Electis CX	
	Reboot 66 WG	
	Pajo	
	Kimoflex	
	Idaho	

* Same product, but authorised on behalf of Sipcam Oxon.

Company code number(s): GWN-9823 (Gowan's ownership)
SIP 40936, SI 4656 (Sipcam Oxon's ownership)

Developmental names: RH-7281 Cymoxanil 66% DG Blend (1:1)
Cymoxanil 33% + Zoxamide 33 % WG
Harpon XF-98083

1.4 Detailed quantitative and qualitative information on the composition of the

preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

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.). Within this application for re-registration of Cymoxanil 33% + Zoxamide 33 % WG (WG formulation containing 330 g/kg zoxamide and 330 g/kg cymoxanil) all relevant formulation data are presented.

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content (% w/w)
Cymoxanil	330 g/kg	313.5-346.5 g/kg**	340 g/kg	34.0
Zoxamide	330 g/kg	313.5-346.5 g/kg**	346 g/kg	34.6

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

** $\pm 5\%$ according to FAO specification

There are no additives and no relevant impurities of toxicological, environmental or ecotoxicological relevance in the active substances as manufactured.

Table 1.4-2: Relevant impurities of zoxamide and cymoxanil

Relevant impurity	Maximum content (g/L or g/kg)
Not applicable.	--

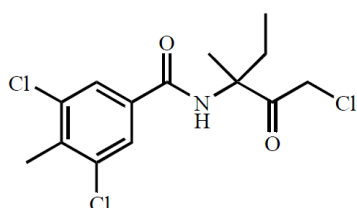
There are no safener or synergists in the formulated product.

For detailed information on the co-formulants in the formulated product Cymoxanil 33% + Zoxamide 33 % WG, please refer to Part C (Confidential information).

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Zoxamide

Zoxamide (previous development codes RH-117,281 and RH-7281) is the ISO common name for (RS)-3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-p-toluamide (IUPAC name).



Zoxamide is a racemate, containing an R- and S-enantiomer at similar ratio.

Table 1.4-3: Information on zoxamide

Type	Name / code number	
ISO common name	Zoxamide	Variant
CAS No.	156052-68-5	--
EC No.	Not assigned.	--
CIPAC No.	640	--

Cymoxanil

Table 1.4-4: Information on Cymoxanil

Data Point	Type	Name/Code Number
1.4.3.1	ISO common name	Cymoxanil
1.4.3.2	CAS No.	57966-95-7
1.4.3.2	EINECS No.	261-043-0
1.4.3.2	CIPAC No.	419
1.4.3.2	ELINCS	-
1.4.3.3	Salt, ester anion or cation present	-

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

There are no safener or synergists that need to be taken into account.

For details on the composition of the formulated product, please refer to confidential information (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Water dispersible granules

[Code: WG]

1.6 Function (KCP 1.6)

Fungicide.

2 Section 2: Physical, chemical and technical properties of the plant protection product

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.

Tank mixtures are not intended for authorisation.

Justified proposals for classification and labelling (KCP 12) - for physical chemical part only

Experimental results for classification and labelling of Cymoxanil 33% + Zoxamide 33% :

Study	Method	Finding	Classification acc. to Reg. (EC) no. 1272/2008
Explosive properties	EEC A.14	Not explosive	None
Oxidising properties	EEC A.17	Not oxidizing	None
Flammability	EEC A.10, A.16	Not highly flammable.	--
Flash point	--	Not required.	--
Auto-flammability	EEC A.16	Self-ignition temperature = 425°C.	None
pH of a 1% dilution	CIPAC MT 75.3	pH = 6.84	None
Viscosity	--	Not applicable / not required.	None
Surface tension	--	Not applicable / not required.	None
Pour and tap density	CIPAC MT 186	Pour: 0.624 g/mL Tap: 0.650 g/mL	None
Dust content	CIPAC MT 171	Nearly dust free.	None

Notifier proposal for risk and safety phrases (KCP 12)

No precautionary statements according to CLP Regulation (EC) No. 1272/2008 are needed with regard to the physical/chemical data of the product.

For all other precautionary and safety measures relevant for the product handling, use, storage and transport, and to protect humans, animals and the environment (KCP 4.1 and KCP 4.2), as well as the recommended measures and precautions in case of an accident or fire (KCP 4.3), please refer to the Material Safety Data Sheet (ref. KCP 12/01) and the draft label for the product Cymoxanil 33% + Zoxamide 33% (in Part A).

Effectiveness of the cleaning procedures

The effectiveness of the cleaning procedure of the field spraying equipment and clothes after use of Cymoxanil 33% + Zoxamide 33% WG has been evaluated during product authorisation. In the following, the related information from the RR issued in October 2014 by UK CRD (zRMS for product authorisation in the central zone) has been copied (highlighted in grey and green).

The expected effectiveness of the cleaning procedure of contaminated equipment and clothing is very high.

Report:	KHIA 4.2.2/01, Lucini L., 2007a
Title:	Cymoxanil 33 % + Zoxamide 33 % WG; Sprayability test and cleaning of the field sprayer equipment
Document No:	034/2006
GLP	Yes

A knack sprayer was used in order to evaluate the sprayability during the application of the product SIP40936 (Cymoxanil 33% + Zoxamide 33% WG) and the effectiveness of the cleaning procedure was assessed after spraying.

To assess the cleaning efficiency, the apparatus was rinsed after use three times with water and one time with a mixture of 3% acetone in water after spraying (EC simulation). The effectiveness of the cleaning procedure was determined by measuring the residues of Zoxamide in the rinsing water and in the mixture by using HPLC method DAS-M-02-051 which has been evaluated in the Registration Report Part B Section 2 (Analytical Methods), IIIA 5.2.2. Linearity over an appropriate range was suitably demonstrated prior to the use of the method. The analysis showed that after the first rinsing the average of the efficacy was 99.27%; after the second and third rinsing the average of the efficacy was 100.00%.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

Name of authority: Chemicals Regulation Directorate, UK

Reviewer's comments:

Residues of Cymoxanil in the washings were not determined, despite the method used being capable of doing so. From the chromatogram produced from the 3% acetone in water EC simulation, it would appear that there is a small peak around the expected retention time of Cymoxanil. The applicant has referred to two other tank cleaning studies conducted on other Cymoxanil-based products which have indicated that the common practice of rinsing the container thoroughly and washing three times is sufficient to remove residual Cymoxanil from the tank. These additional studies (reported below) have not been evaluated in detail, but given the small size of the possible Cymoxanil peak in study 034/2006 (i.e. indicating the presence of only a very small amount), they have been accepted to support the effectiveness of the tank cleaning procedures. Additionally, Cymoxanil is a fungicide and not a herbicide and so is much less likely to cause issues when the sprayer is used on subsequent crops.

Additional data on efficiency of cleaning procedures of tank from Cymoxanil are also reported in the below mentioned studies.

Report:	KHIA 4.2.2/03, Lucini L., 2005
Title:	CYMOXANIL 4% + MANCOZEB 40% WP Sprayability test and cleaning of the field sprayer equipment
Document No:	023/2005
GLP	Yes

In this study a hand-held sprayer was filled with the plant protection product. After spraying, the apparatus was rinsed three times with water and in a mixture of 3% acetone in water (simulation of an EC formulation). Each rinse was analysed for residues of Cymoxanil. The analyses show that common agricultural practice (cleaning of application equipment with triple water rinsing) assures removal of almost all remainders of both active substances from the spraying equipment (>99 % rinse efficacy).

After the first rinsing the average of the cleaning efficiency was 90.54%, after the second was 99.65%, after the third was 99.95%. After the EC simulations test, the average of the active ingredient reduction was 100.00%.

Report:	KIII A 4.2.2/04, Freschi G., 2003
Title:	CYMOXANIL 50% WP Sprayability test and cleaning of the field sprayer equipment
Document No:	006/2003
GLP	Yes

In the present study, a knapsack sprayer was used to assess the Cymoxanil cleaning procedures of spray equipment after applications of Cymoxanil 50% WP.

Cymoxanil content was determined by HPLC in three rinsing water and in a mixture of 3 % acetone in water (in order to simulate EC applications performed immediately after the cleaning).

After the first rinsing the average of the cleaning efficiency was 99.54%, after the second was 100.00%, after the third was 100.00%. After the EC simulations test, the average of the active ingredient reduction was 100.00%.

These data confirm that following the common practices (with triple water rinsings) all Cymoxanil residues are removed from spraying equipment.

Compliance with FAO specifications

The product Cymoxanil 33% + Zoxamide 33% complies with FAO specifications.

Formulation used for tests

Cymoxanil 33% + Zoxamide 33% used in the tests has the same composition as the one cited in Part C.

The following physical/chemical data were evaluated according to FAO/WHO manual (2016) and the CRD final draft Guidance Document for the Generation and Evaluation of Data on the Physical, Chemical and Technical Properties of Plant Protection Products under Reg. (EC) No. 1107/2009 (2018).

The intended concentration of use of the product Cymoxanil 33% + Zoxamide 33% is 0.04 % to 0.225 % (v/v), corresponding to application rates of 0.4 kg product/ha in 1000 L water and 0.45 kg product/ha in 200 L water. This converts to 0.1320 kg a.s./1000 L water and 0.0132 kg a.s./hL up to 0.1485 kg a.s./200 L water and 0.0742 kg a.s./hL.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual and smelling	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	Fresh test item: Free flowing beige cylindrical granules odour: characteristic	Y	KCP 2.1/01 Lucini, L (2006) Study no. 021/2006	Accepted
			After 14 days at 54 °C: Free flowing beige cylindrical granules odour: characteristic		KCP 2.1/02 Mori, V. (2008) Study no. 022/2006 => filed under KCP 2.7.5/01	
	PA-U10-METDESCR Visual method	Cymoxanil 33% + Zoxamide 33% WG Batch: GSOL7019 (Cymoxanil 32.75 ±0.15% w/w, Zoxamide 32.91 ±0.17% w/w)	Fresh test item: Dry granules, free from visible extraneous matter and hard lumps, free-flowing, nearly dust free Colour: clear beige Odour: chemical	Y	KCP 2.1/03 De Ryckel (2019) Study no. 24718 => filed under KCP 2.7.1/02	Accepted
			After 14 days at 54 °C: Dry granules, free from visible extraneous matter and hard lumps, free-flowing, nearly dust free Colour: clear beige Odour: chemical No modification of appearance			
Explosive properties (KCP 2.2.1)	EEC A.14	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	not explosive	Y	KCP 2.2.1/01 Lucini, L (2006) Study no. 021/2006 => filed under KCP 2.1/01	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Oxidizing properties (KCP 2.2.2)	EEC A.17	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	not oxidizing	Y	KCP 2.2.2/01 Lucini, L (2006) Study no. 021/2006 => filed under KCP 2.1/01	Accepted
Flash point (KCP 2.3.1)	Not required, Cymoxanil 33% + Zoxamide 40% WG is not a liquid.					
Flammability (KCP 2.3.2)	EEC A.10, A.16	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	Not highly flammable		KCP 2.3.2/01 Lucini, L (2006) Study no. 021/2006 => filed under KCP 2.1/01	Accepted
Self-heating (KCP 2.3.3)	EEC A.16	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	Self-ignition temperature: 425°C	Y	KCP 2.3.3/01 Lucini, L (2006) Study no. 021/2006 => filed under KCP 2.1/01	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)	Not required, pH of Cymoxanil 33% + Zoxamide 33% WG > 4 and < 10.					
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	Fresh test item: pH 6.84 (room temp.)	Y	KCP 2.4.2/01 Lucini, L (2006) Study no. 021/2006 => filed under KCP 2.1/01	Accepted
			After 14 days at 54 °C: pH 6.73 (room temp.)			

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
		Zoxamide 32.86 ±0.09% w/w)	After 2 years at ambient temperature: pH 6.72 (room temp.)			KCP 2.4.2/02 Mori, V. (2008) Study no. 022/2006 => filed under KCP 2.7.5/01	
Viscosity (KCP 2.5.1)	Not required since not a liquid.						
Surface tension (KCP 2.5.2)	Not required since not a liquid.						
Relative density (KCP 2.6.1)	Not required since not a liquid.						
Bulk density (KCP 2.6.2)	CIPAC MT 186	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	Pour	0.624 g/ml	Y	KCP 2.6.2/01 Lucini, L (2006) Study no. 021/2006 => filed under KCP 2.1/01	Accepted
			Tap	0.650 g/l			
		CIPAC MT 186	Cymoxanil 33% + Zoxamide 33% WG Batch: GSOL7019 (Cymoxanil 32.75 ±0.15% w/w, Zoxamide 32.91 ±0.17% w/w)	Pour and tap density: 0.65 g/mL		Y	KCP 2.6.2/02 De Ryckel (2019) Study no. 24718 => filed under KCP 2.7.1/02
Storage stability after 14 days at 54° C (KCP 2.7.1)		SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w,	Stable, physical-chemical properties comparable with those of fresh sample. No weight loss.		Y	KCP 2.7.1/01 Lucini, L (2006) Study no. 021/2006	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Zoxamide 32.86 ±0.09% w/w)	See individual table entries for specific test results.		=> filed under KCP 2.1/01	
	CIPAC MT 46.3.1	Cymoxanil 33% + Zoxamide 33% WG Batch: GSOL7019 (Cymoxanil 32.75 ±0.15% w/w, Zoxamide 32.91 ±0.17% w/w)	<p>Under the conditions of the test, the formulation was The formulated product is physically and chemically stable in the commercial packaging (white opaque cardboard box of 1 kg, containing an heated sealed with opaque aluminised bag; sealing of cardboard box with points of glue; not reclosable).</p> <p>No modification of the appearance or significant pack weight change.</p> <p>No noticeable odour before opening of the package.</p> <p>No observable sign of test item contamination of the outer surface.</p> <p>No leak during shaking of turning</p> <p>No deformation and no observable alteration of package material by the test item.</p> <p><u>Cymoxanil content:</u></p> <p><u>Before storage:</u> 32.75 ± 0.15% w/w <u>After 14 days at 54°C:</u> 32.89 ± 0.25% w/w Difference of + 0.4 %</p> <p><u>Zoxamide content:</u></p> <p><u>Before storage:</u> 32.91 ± 0.17% w/w <u>After 14 days at 54°C:</u> 32.93 ± 0.15% w/w Difference of + 0.1 %</p> <p><u>Ratio of enantiomers of zoxamide:</u></p> <p><u>R-isomer before storage:</u> 50.65 ± 0.10% <u>After 14 days at 54°C:</u> 50.71 ± 0.28%</p>	Y	KCP 2.7.1/02 De Ryckel (2019) Study no. 24718	Accepted Validation is addressed in the Part B section 5 of the registration report

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p><u>S-isomer before storage:</u> 49.35%± 0.10% <u>After 14 days at 54°C:</u> 49.29 ± 0.28%</p> <p>Zoxamide is a racemate. The chiral center of zoxamide is stable.</p> <p>See further individual table entries for specific test results.</p>			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	Not applicable; see point 2.7.1.					
Minimum content after heat stability testing (KCP 2.7.3)	Validated HPLC Method	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	<p>After 14 d at 54°C : 32.07% ± 0.04% Cymoxanil 32.63% ± 0.05% Zoxamide</p> <p>Determined by validated HPLC method no. DAS-M-02-051 (See Section on Analytical Methods)</p>	Y	KCP 2.7.3/01 Lucini, L (2006) Study no. 021/2006 => filed under KCP 2.1/01	Accepted
Effect of low temperatures on stability (KCP 2.7.4)	Not required, since not a liquid					
Ambient temperature shelf life (KCP 2.7.5)		SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	<p>After 2 years at ambient temperature : 32.46 ± 0.15 % cymoxanil 33.49 ± 0.13 % zoxamide</p> <p>Determined by validated HPLC method no. DAS-M-02-051 (See Section on Analytical Methods)</p> <p>No weight loss.</p>	Y	KCP 2.7.5/01 Mori, V. (2008) Study no. 022/2006	Accepted
Shelf life in months	Not applicable.					

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
(if less than 2 years) (KCP 2.7.6)								
Wettability (KCP 2.8.1)	CIPAC MT 53.3.1, MT 53.3.2	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	Fresh test item: Static 5 sec Dynamic 2 sec			Y	KCP 2.8.1/01 Lucini, L (2006) Study no. 021/2006	Accepted
			After 14 days at 54 °C: Static 5 sec Dynamic 2 sec				=> filed under KCP 2.1/01	
			After 2 years at ambient temperature: Static 3 sec Dynamic 2 sec				KCP 2.8.1/02 Mori, V. (2008) Study no. 022/2006 => filed under KCP 2.7.5/01	
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	Fresh test item: 60 mL of foam (average) after 1´			Y	KCP 2.8.2/01 Lucini, L (2006) Study no. 021/2006	Accepted
			After 14 days at 54 °C: 70 mL of foam (average) after 1´				=> filed under KCP 2.1/01	
			After 2 years at ambient temperature: 49 mL of foam (average) after 1´				KCP 2.8.2/02 Mori, V. (2008) Study no. 022/2006 => filed under KCP 2.7.5/01	
	CIPAC MT 47.3	Cymoxanil 33% + Zoxamide 33% WG Batch: GSOL7019		CIPAC water D Temperature 25°C ± 5°C Concentration: 0.04 % v/v	CIPAC water D Temperature 25°C ± 5°C Concentration: 0.225 % v/v	Y	KCP 2.8.2/03 De Ryckel (2019) Study no. 24718	Accepted

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
		(Cymoxanil 32.75 ±0.15% w/w, Zoxamide 32.91 ±0.17% w/w)	After 10 seconds	16 mL	50 mL		=> filed under KCP 2.7.1/02	
			After 1 minute	9 mL	47 mL			
			After 3 minutes	7 mL	46 mL			
			After 12 minutes	0 mL	44 mL			
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	In standard water D	Cymoxanil	Zoxamide	Y	KCP 2.8.3.1/01 Lucini, L (2006) Study no. 021/2006 => filed under KCP 2.1/01	Accepted
			Fresh test item	0.02 %	103%			
				0.25 %	101%			
			After 14 days at 54 °C	0.02 %	102 %			
				0.25 %	100 %			
			After 2 years at ambient temperature	0.02 %	102 %		KCP 2.8.3.1/02 Mori, V. (2008) Study no. 022/2006 => filed under KCP 2.7.5/01	
				0.25 %	101 %			
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 174	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	Fresh test item: 91% (1%, CIPAC Standard Water D)			Y	KCP 2.8.3.2/01 Lucini, L (2006) Study no. 021/2006 => filed under KCP 2.1/01	Accepted
			After 14 days at 54 °C: 87 % (1%, CIPAC Standard Water D)					
			After 2 years at ambient temperature: 92 % (1%, CIPAC Standard Water D)				KCP 2.8.3.2/02 Mori, V. (2008)	

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments	
							Study no. 022/2006 => filed under KCP 2.7.5/01		
Dispersion stability (KCP 2.8.3.3)	Not required since it is not a liquid.								
Degree of dissolution and dilution stability (KCP 2.8.4)	Not required since not a liquid.								
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 170	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	Fresh test item	Size	1 - 2 mm	Y	KCP 2.8.5.1.1/01 Lucini, L (2006) Study no. 021/2006 => filed under KCP 2.1/01	Accepted	
			After 2 years at ambient temperature	Size	1 – 2 mm				
	OECD 110		Fresh test item	D (v, 0.1)	0.59 µm				
				D (v,0.5)	2.80 µm				
				D (v,0.9)	10.81 µm				
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	Fresh test item: 0.40 %			Y	KCP 2.8.5.1.2/01 Lucini, L (2006) Study no. 021/2006 => filed under KCP 2.1/01	Accepted	
			After 14 days at 54 °C: 0.90 %						
			After 2 years at ambient temperature: 0.10 %				KCP 2.8.5.1.2/02 Mori, V. (2008) Study no. 022/2006		

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					=> filed under KCP 2.7.5/01	
Dust content (KCP 2.8.5.2.1)	CIPAC MT 171	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	Fresh test item: Nearly dust free.	Y	KCP 2.8.5.2.1/01 Lucini, L (2006) Study no. 021/2006 => filed under KCP 2.1/01	Accepted
			After 14 days at 54 °C: Nearly dust free.		KCP 2.8.5.2.1/02 Mori, V. (2008) Study no. 022/2006 => filed under KCP 2.7.5/01	
			After 2 years at ambient temperature: Nearly dust free.			
Particle size of dust (KCP 2.8.5.2.2)	CIPAC MT 171	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	Fresh test item: Nearly dust free.	Y	KCP 2.8.5.2.2/01 Lucini, L (2006) Study no. 021/2006 => filed under KCP 2.1/01	Accepted
			After 14 days at 54 °C: Nearly dust free.		KCP 2.8.5.2.2/02 Mori, V. (2008) Study no. 022/2006 => filed under KCP 2.7.5/01	
			After 2 years at ambient temperature: Nearly dust free.			
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w,	Fresh test item: 99.95 %	Y	KCP 2.8.5.3/01 Lucini, L (2006) Study no. 021/2006 => filed under KCP 2.1/01	Accepted
			After 14 days at 54 °C: 99.94 %			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Zoxamide 32.86 ±0.09% w/w)	After 2 years at ambient temperature: 99.97 %		KCP 2.8.5.3/02 Mori, V. (2008) Study no. 022/2006 => filed under KCP 2.7.5/01	
Hardness and integrity (KCP 2.8.5.4)	Not applicable. The formulated product is not a tablet.					
Emulsifiability (KCP 2.8.6.1)	Not required since not an emulsion.					
Emulsion stability (KCP 2.8.6.2)	Not required since is not an emulsion.					
Re-emulsifiability (KCP 2.8.6.3)	Not required since is not an emulsion.					
Flowability (KCP 2.8.7.1)	CIPAC MT 172	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	After 14 days at 54 °C: Product flows spontaneously.	Y	KCP 2.8.7.1/01 Lucini, L (2006) Study no. 021/2006 => filed under KCP 2.1/01	Accepted
Pourability (KCP 2.8.7.2)	Not required, since the formulated product is a granular.					
Dustability following accelerated storage (KCP 2.8.7.3)	Nearly dust-free.					
Physical compatibility of tank mixes (KCP 2.9.1)						
	The physical/chemical compatability has	Cymoxanil 33% + Zoxamide 33% WG	After the application, no residues in the tank, the tubing, filters or the nozzles were observed. The mixture of the test item Cymoxanil 33% +	Y	KCP 2.9.1/01 Harant, H. (2014)	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	been determined under practical field conditions.	Batch No. FTZ30AL1001 Aliette WG (Fosetyl aluminium salt 800 g/kg) Batch No. DE 05537184 K	Zoxamide 33% WG and Aliette WG is therefore found compatible under field conditions.		Study no. 13 10 47 044	
Chemical compatibility of tank mixes (KCP 2.9.2)	See data point 2.9.1.					
Adhesion to seeds (KCP 2.10.1)	Not used for seed treatment.					
Distribution to seed (KCP 2.10.2)	Not used for seed treatment.					
Other/special studies (KCP 2.11)	No other data available.					

3 Section 3 is presented as a separate document

Please refer to the separate Part B3 “Efficacy Data and Information” for the product Cymoxanil 33% + Zoxamide 33 % WG.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

The packaging has been designed in accordance with the criteria and guidelines specified in the FAO “Guideline for the Packaging of Pesticides” and has been approved according to criteria of ADR, IATA, IMDG (IMO) regulations.

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 aluminised bag (sealing of cardboard box with points of glue, not reclosable), and will be distributed in cartons (outer packaging) at 50x 0.2 kg, 10x 0.5 kg, 10x 1 kg, 4x 2.5 kg or 4x 5 kg. The boxes are not returnable.

The accelerated and two years storage stability studies have been performed with the intended commercial packaging material (i.e. 1 kg cardboard box). Tightness of the packaging material and its compatibility with the preparation have been demonstrated in these studies.

4.1-1: Packaging information for Sachet of 0.2 KG

Type	Description
Material:	PA bx 15µ/ALU 9µ/PE90µ
Shape/size:	310 x 220 mm
Opening:	Cut open
Closure:	Roll down
Seal:	Heat Seal
Manner of construction	Form-Fill-Seal
UN/ADR	Limited quantities exemption applies

Table 4.1-2: Packaging information for Fiberboard Carton 50 x 0.2 KG

Type	Description
Material:	KBSKSK/36365/BC
Shape/size:	477 mm (L) x 292 mm (W) x 282 mm (H)
Opening:	cut tape and fold open
Closure:	By self-adhesive tape
Seal:	self-adhesive tape
Manner of construction	Regular case FEFCO 0201
UN/ADR	Limited quantities exemption applies

Table 4.1-3: Packaging information for Box + Liner Bag of 0.5 KG

Type	Description
Material:	PA bx 15 µm / ALU 9 µm / PE 90 µm
Shape/size:	210 x 110 mm
Opening:	cut open

Type	Description
Closure:	roll down
Seal:	Heat Sealed and glued into carton
Manner of construction	Form-Fill-Seal
UN/ADR	Covered by UN 4G certificate below
Material:	500 gm ² carton board
Shape/size:	150 mm (L) x 70 mm (W) x 180 mm (H)
Opening:	fold open
Closure:	fold closed
Seal:	Glued flaps
Manner of construction	Die cut and folded with glued joint
UN/ADR	Covered by UN 4G certificate below

Table 4.1-4: Packaging information for Fiberboard Carton of 10 x 0.5 KG

Type	Description
Material:	KBSFSK/36265/BC
Shape/size:	367 mm (L) x 317 mm (W) x 198 mm (H)
Opening:	cut tape and fold open
Closure:	fold closed and tape
Seal:	self-adhesive tape
Manner of construction	Regular case FEFCO 0201
UN/ADR	UN 4G/Y9/S**F/BVT 31794/STI

Table 4.1-5: Packaging information for Liner Bag of 1 KG

Type	Description
Material:	PA bx 15 µm /0 ALU 9 µm / PE 90 µm
Shape/size:	220 x 180 mm
Opening:	cut open
Closure:	roll down
Seal:	Heat Sealed and glued into carton
Manner of construction	Form-Fill-Seal
UN/ADR	Covered by UN 4G certificate below
Material:	500 gm ² carton board
Shape/size:	140 mm (L) x 80 mm (W) x 200 mm (H)
Opening:	fold open
Closure:	fold closed
Seal:	Glued flaps
Manner of construction	Die cut and folded with glued joint

Type	Description
UN/ADR	Covered by UN 4G certificate below

Table 4.1-6: Packaging information for Fiberboard Carton of 10 x 1 KG

Type	Description
Material:	KBSFSK/36265/BC
Shape/size:	425 mm (L) x 297 mm (W) x 222 mm (H)
Opening:	cut tape and fold open
Closure:	fold closed and tape
Seal:	self-adhesive tape
Manner of construction	Regular case FEFCO 0201
UN/ADR	UN 4G/Y12/**F/BVT 317960/STI

Table 4.1-7: Packaging information for Liner Bag of 2.5 KG

Type	Description
Material:	PA bx 15 µm /0 ALU 9 µm / PE 90 µm
Shape/size:	190 + 130 + 130 x 420h
Opening:	cut open
Closure:	roll down
Seal:	Heat Sealed and glued into carton
Manner of construction	Form-Fill-Seal
UN/ADR	Covered by UN 4G certificate below
Material:	Clay coated cartonboard 230g KB SVFSVK32222EF
Shape/size:	235mm long x 148mm wide x 210mm high
Opening:	rip pre-perforated tab
Closure:	fold closed
Seal:	Glued flaps
Manner of construction	Die cut and folded with glued joint
UN/ADR	Covered by UN 4G certificate below

Table 4.1-8: Packaging information for Fiberboard Carton of 4 x 2.5 KG

Type	Description
Material:	KBSFSK/36265/BC
Shape/size:	497mm long x 317mm wide x 234mm high
Opening:	cut tape and fold open
Closure:	fold closed and tape
Seal:	self-adhesive tape
Manner of construction	Regular case FEFCO 0201
UN/ADR	UN 4G/Y13/**F/BVT 317969/STI

Table 4.1-9: Packaging information for Bag of 5 KG

Type	Description
Material:	PET 12 µm / ALU 9 µm / PE 90 µm
Shape/size:	250 mm (L) x 50 + 50 mm (W) x 600 mm (H)
Opening:	cut
Closure:	roll down
Seal:	Heat Seal; glued to 5 kg carton
Manner of construction	preformed, gusseted bag
UN/ADR	Covered by UN 4G certificate below
Material:	KBSVFSVK/32222/EF
Shape/size:	235 mm (L) x 148 mm (W) x 282 mm (H)
Opening:	rip pre-perforated tab
Closure:	fold closed
Seal:	Glued flaps
Manner of construction	Die cut carton, folded and glued
UN/ADR	Covered by UN 4G certificate below

Table 4.1-10: Packaging information for Fiberboard Carton of 4 x 5 KG

Type	Description
Material:	KBSFSK/36265/BC
Shape/size:	497 mm (L) x 317 mm (W) x 302 mm (H)
Opening:	cut tape and fold open
Closure:	fold closed
Seal:	self-adhesive tape
Manner of construction	Regular case FEFCO 0201
UN/ADR	UN 4G/23/S/**F/BVT 317961/STI

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1/01	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Oxon Italia, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published	N	Oxon Italia S.p.A. Gowan
KCP 2.1/02	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Oxon Italia, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006 GLP Not Published => Filed under KCP 2.7.5/01	N	Oxon Italia S.p.A. Gowan
KCP 2.1/03	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 2.7.1/02	N	GW Sipcam Oxon S.p.A.
KCP 2.2.1/01	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Oxon Italia, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006	N	Oxon Italia S.p.A.

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			GLP Not Published => Filed under KCP 2.1/01		Gowan
KCP 2.2.2/01	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Oxon Italia, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1/01	N	Oxon Italia S.p.A. Gowan
KCP 2.3.2/01	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Oxon Italia, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1/01	N	Oxon Italia S.p.A. Gowan
KCP 2.3.3/01	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Oxon Italia, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1/01	N	Oxon Italia S.p.A. Gowan
KCP 2.4.2/01	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Oxon Italia, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1/01	N	Oxon Italia S.p.A. Gowan
KCP 2.4.2/02	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Oxon Italia, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006	N	Oxon Italia S.p.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
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KCP 2.6.2/01	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Oxon Italia, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1/01	N	Oxon Italia S.p.A. Gowan
KCP 2.6.2/02	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 2.7.1/02	N	GW Sipcam Oxon S.p.A.
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KCP 2.7.3/01	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Oxon Italia, S.p.A, Italy	N	Oxon Italia

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			Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1/01		S.p.A. Gowan
KCP 2.7.5/01	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Oxon Italia, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006 GLP Not Published	N	Oxon Italia S.p.A. Gowan
KCP 2.8.1/01	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Oxon Italia, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1/01	N	Oxon Italia S.p.A. Gowan
KCP 2.8.1/02	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Oxon Italia, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006 GLP Not Published => Filed under KCP 2.7.5/01	N	Oxon Italia S.p.A. Gowan
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KCP 2.8.2/02	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Oxon Italia, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006	N	Oxon Italia S.p.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
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KCP 2.8.2/03	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 2.7.1/02	N	GW Sipcam Oxon S.p.A.
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KCP 2.8.3.2/01	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Oxon Italia, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1/01	N	Oxon Italia S.p.A. Gowan
KCP 2.8.3.2/02	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Oxon Italia, S.p.A., Italy	N	Oxon Italia

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			Sipcam S.p.A , Report No. 022/2006 GLP Not Published => Filed under KCP 2.7.5/01		S.p.A. Gowan
KCP 2.8.5.1.1/01	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Oxon Italia, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1/01	N	Oxon Italia S.p.A. Gowan
KCP 2.8.5.1.2/01	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Oxon Italia, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1/01	N	Oxon Italia S.p.A. Gowan
KCP 2.8.5.1.2/02	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Oxon Italia, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006 GLP Not Published => Filed under KCP 2.7.5/01	N	Oxon Italia S.p.A. Gowan
KCP 2.8.5.2.1/01	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Oxon Italia, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1/01	N	Oxon Italia S.p.A. Gowan
KCP 2.8.5.2.1/02	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Oxon Italia, S.p.A., Italy	N	Oxon Italia

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Sipcam S.p.A , Report No. 022/2006 GLP Not Published => Filed under KCP 2.7.5/01		S.p.A. Gowan
KCP 2.8.5.2.2/01	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Oxon Italia, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP Not Published => Filed under KCP 2.1/01	N	Oxon Italia S.p.A. Gowan
KCP 2.8.5.2.2/02	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Oxon Italia, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006 GLP Not Published => Filed under KCP 2.7.5/01	N	Oxon Italia S.p.A. Gowan
KCP 2.8.5.3/01	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Oxon Italia, S.p.A, Italy Sipcam S.p.A , Report No. 021/2006 GLP No Published => Filed under KCP 2.1/01	N	Oxon Italia S.p.A. Gowan
KCP 2.8.5.3/02	Mori, V.	2008	Cymoxanil 33 %+ Zoxamide 33 % WG Shelf life at room temperature. Oxon Italia, S.p.A., Italy Sipcam S.p.A , Report No. 022/2006 GLP Not Published => Filed under KCP 2.7.5/01	N	Oxon Italia S.p.A. Gowan
KCP 2.8.7.1/01	Lucini, L.	2006	Cymoxanil 33 %+ Zoxamide 33 % WG; physical, chemical and technical properties Oxon Italia, S.p.A, Italy	N	Oxon Italia

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Sipcam S.p.A , Report No. 021/2006 GLP No Published => Filed under KCP 2.1/01		S.p.A. Gowan
KCP 2.9.1/01	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/Oxon Italia S.p.A., Italy BioChem agrar, Germany, Report No. 13 10 47 044 GLP Not published	N	GW Sipcam Oxon S.p.A.
KCP 4.2/01	Lucini L.	2007a	Cymoxanil 33 %+ Zoxamide 33 % WG; Sprayability test and cleaning of the field sprayer equipment Sipcam S.p.A, Report No. 034/2006 GLP Unpublished.	N	Oxon Italia S.p.A. Gowan
KCP 4.2/01	Lucini L.	2007b	Cymoxanil 33 %+ Zoxamide 33 % WG; Evaluation of Zoxamide cleaning efficiency on clothes Sipcam S.p.A Report No. 030/2006 GLP, Unpublished.	N	Oxon Italia S.p.A. Gowan
KCP 4.2/01	Lucini, L.	2005	CYMOXANIL 4% + MANCOZEB 40% WP Sprayability test and cleaning of the field sprayer equipment Sipcam S.p.A Report No. 023/2005 GLP, Unpublished.	N	Oxon Italia S.p.A.
KCP 4.2/01	Freschi, G.	2003	CYMOXANIL 50% WP Sprayability test and cleaning of the field sprayer equipment Sipcam S.p.A Report No. 006/2003 GLP, Unpublished.	N	Oxon Italia S.p.A.
KCP 12/01	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	N	GW

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			No GLP Not published		

SIPCAM Oxon S.p.A. is the legal successor of Oxon Italia S.p.A.; Gowan Crop Protection (GWI) is the legal entity of the company Gowan in Europe

Grey shaded = data / reference already provided during product authorisation

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 2.1.1	Ardern, D.	1998	RH-117281 physicochemical properties Rohm and Haas Co., ER ref. no. 19.15 Huntingdon Life Sciences, Report No. RAS 056/982496, March 19 1998 GLP Not published	N	GW
KCA 2.1.1	Betteley, J.	1998	RH-117,281 melting temperature Rohm and Haas Co., ER ref. no. 19.14 Huntingdon Life Sciences, Report No. RAS 092/983391, June 23 1998 GLP Not published	N	GW
KCA 2.2.1	Kogovsek, L.M.	1996	RH-117,281 vapor pressure Rohm and Haas Co., Report No. 34-96-58, September 23 1996, ER ref. no. 6.6 Ricerca, Inc., Report No. 1960-95-0151-AS-001 GLP Not published	N	GW

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 2.2.2	Betteley, J.	1998	RH-117,281 Henry's Law Constant Rohm and Haas Co., ER ref. no. 19.16 Huntingdon Life Sciences, Report No. RAS 082/983272, June 26 1998 GLP Not published	N	GW I
KCA 2.3.1	Ardern, D.	1998	RH-117281 physicochemical properties Rohm and Haas Co., ER ref. no. 19.15 Huntingdon Life Sciences, Report No. RAS 56/982496, March 19 1998 GLP Not published	N	GW I
KCA 2.3.1	Betteley, J.	1998	RH-117,281 - appearance Rohm and Haas Co., ER ref. no. 19.13 Huntingdon Life Sciences, Report No. RAS 085/983389, July 23 1998 GLP Not published	N	GW I
KCA 2.3.2	Ardern, D.	1998	RH-117281 physicochemical properties Rohm and Haas Co., ER ref. no. 19.15 Huntingdon Life Sciences, Report No. RAS 056/982496, March 19 1998 GLP Not published	N	GW I
KCA 2.3.2	Betteley, J.	1998	RH-117,281 appearance Rohm and Haas Co., ER ref. no. 19.13 Huntingdon Life Sciences, Report No. RAS 085/983389, July 23 1998 GLP Not published	N	GW I
KCA 2.4.1	Betteley, J.	1998	RH-117,281 spectral data (IR and NMR) Rohm and Haas Co., ER ref. no. 30.12 Huntingdon Life Sciences, Report No. RAS 100/983371, August 7 1998 GLP Not published	N	GW I

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 2.4.1	Hafer, J.H.	1996	UV-visible spectrum of RH-117281 Rohm and Haas Co., Report No. 13-96-013TR, February 26 1996, ER ref. no. 30.15 GLP Not published	N	GW
KCA 2.4.1	Quinn, C.J.	1993	Qualitative analysis of RH-117281 standard by mass spectrometry Rohm and Haas Co., Report No. 13-93-130, November 3 1993, ER ref. no. 30.11 GLP Not published	N	GW
KCA 2.4.2	Betteley, J.	1998	RH-131,889 spectral data Rohm and Haas Co., ER ref. no. 19.6 Huntingdon Life Sciences, Report No.: RAS 105/983943, September 24 1998 GLP Not published	N	GW
KCA 2.4.2	Quinn, C.J.	1996	Qualitative analysis of RH-016,971 and RH-131,889 by desorption chemical ionization (DCI) Mass Spectrometry Rohm and Haas Co., Report No. 13-96-085TR, August 20 1996, ER ref. no. 30.13 GLP Not published	N	GW
KCA 2.5	Reynolds, J.L.	1996	Water solubility of 14C-RH-117281, Rohm and Haas Co., Report No. 34-95-163, March 22 1996. ER ref. no. 1.8 XenoBiotic Laboratories, Inc., Report No. RPT00237 GLP Not published	N	GW
KCA 2.6	Betteley, J.	1998	RH-117,281 solubility in a range of organic solvents Rohm and Haas Co., ER ref. no. 19.12 Huntingdon Life Sciences, Report No.: RAS 084/983622, September 25 1998 GLP Not published	N	GW
KCA 2.7.1	Reynolds, J.L.	1996	n-octanol/water partition coefficient of [14C] RH-117281	N	GW

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Rohm and Haas Co., Report No. 34-95-162, February 14 1996, ER ref. no. 1.7 XenoBiotic Laboratories, Inc., Report No. RPT00240 GLP Not published		
KCA 2.7.2	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 Co., Report No. 34-98-55, November 9 1998, ER ref. no. 31.4 RCC Ltd., Report No. 689951 GLP Not published	N	GW I
KCA 2.7.2	Tognucci, A.	1998	Determination of the partition coefficient (n-octanol/water) of RH-127450 Rohm and Haas Co., Report No. 34-98-165, ER Ref. No. 18.3, October 12 1998 RCC Ltd, Report No. 702630 GLP Not published	N	GW I
KCA 2.7.2	Tognucci, A.	1998	Determination of the partition coefficient (n-octanol/ water) of RH-139432 Rohm and Haas Co., Report No. 34-98-53, ER Ref. No. 31.3, October 22 1998 RCC Ltd, Report No. 706050 GLP Not published	N	GW I
KCA 2.7.2	O'Connor, B.J.	2014	Zoxamide metabolite, RH-24549: Determination of partition coefficient Gowan Comercio Internacional e Servicos Limitada, Portugal Harlan Laboratories Ltd, UK, Study No. 41400466, March 18, 2004 GLP Not published	N	GW I
KCA 2.7.2	O'Connor, B.J.	2014	Zoxamide metabolite, RH-141452: Determination of partition coefficient Gowan Comercio Internacional e Servicos Limitada, Portugal Harlan Laboratories Ltd., UK, Study No. 41400467, March 18, 2004 GLP Not published	N	GW I

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 2.7.2	O'Connor, B.J.	2014	Zoxamide metabolite, RH-150721: Determination of partition coefficient Gowan Comercio Internacional e Servicos Limitada, Portugal Harlan Laboratories Ltd., UK, Study No. 41400468, March 18 2004 GLP Not published	N	GW I
KCA 2.7.2	Liney, P., Miles, D.	2014	Metabolite of zoxamide (RH-141455) octanol-water partition coefficient Gowan Comercio Internacional e Servicos Limitada, Portugal Exponent International Ltd., UK, Report No. 0907598 – 5495, Project No. 0907598.UK0 Not GLP Not published	N	GW I
KCA 2.8	Betteley, J.	1998	RH-117,281 determination of dissociation constant Rohm and Haas Co., ER ref. no. 19.11 Huntingdon Life Sciences, Report No. RAS 090/983783, August 13 1998 GLP Not published	N	GW I
KCA 2.9.1	Betteley, J.	1998	RH-117281 flammability (solids) Rohm and Haas Co., ER ref. no. 19.9 Huntingdon Life Sciences Report No. RAS 086/983225, June 3 1998 GLP Not published	N	GW I
KCA 2.9.2	Betteley, J.	1998	RH-117,281 relative self-ignition temperature for solids Rohm and Haas Co., ER ref. no. 19.8 Huntingdon Life Sciences, Report No. RAS 088/983290, June 26 1998 GLP Not published	N	GW I
KCA 2.11	Betteley, J.	1998	RH-117,281 explosive properties Rohm and Haas Co., ER ref. no. 19.7 Huntingdon Life Sciences, Report No. RAS 087/983530, August 13 1998 GLP Not published	N	GW I

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 2.13	Betteley, J.	1998	RH-117,281 oxidising properties Rohm and Haas Co., ER ref. no. 19.5 Huntingdon Life Sciences, Report No. RAS 089/983438, July 8 1998 GLP Not published	N	GW I

GW I – Gowan Crop Protection Ltd.

For cymoxanil it is referred to the references in the EU review dossier (DAR 2007) and the EFSA Peer Review Conclusion (2008).

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	Verte- brate study Y/N	Owner

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

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	Owner

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Zoxamide

None.

A 2.2 Cymoxanil

None.