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): **Lieto 66 WG**

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: Sipcam Oxon S.p.A.

Submission date: 30/12/2020

MS Finalisation date: September 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

The summaries and evaluations contained in this review report may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this review report unless they have received the data on which the summaries and evaluation are based, either –

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Version history

When	What
30th December 2020	Submission of initial Version 0 by the applicant.
September2021	Version evaluated by PL zRMS highlited in blue
December 2021	Revised version by the applicant, addressing the comments of MSs.
December 2021	Corrected by zRMS

Table of Contents

This document summarises the physical/chemical data and the further information on 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 authorisation 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 al 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: Sipcam Oxon S.p.A.
Address: Via Sempione 195
20016 Pero (MI)
Italy

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]

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).

A Letter of Access of the company Gowan Crop Protection Ltd grants the rights to Sipcam Oxon on the active substance data for Zoxamide.

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

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 Step1 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).

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

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

* Same product, but authorised on behalf of Gowan.

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

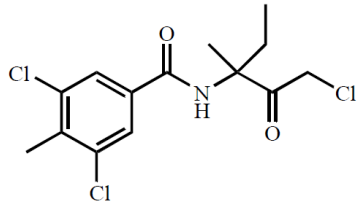
There are no safener or synergists in the formulated product.

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 card-board 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

Not classified
~~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).

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			
			After 2 years at ambient temperature: 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 apperance			
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 UK CRD (zRMS for authorisation): *Not explosive*

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 UK CRD (zRMS for authorisation): *Not oxidising*
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 UK CRD (zRMS for authorisation): *Not highly flammable*
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 UK CRD (zRMS for authorisation): *Noted*
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,	Fresh test item: pH 6.84 (room temp.) After 14 days at 54 °C: pH 6.73 (room temp.)	Y	KCP 2.4.2/01 Lucini, L (2006) Study no. 021/2006 => **filed under KCP 2.1/01**	Accepted UK CRD (zRMS for authorisation): *Noted* *No significant change on storage*

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 UK CRD (zRMS for authorisation): *Noted*
			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 UK CRD (zRMS for authorisation): *Sample stored in 500 ml screw capped bottle*

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)	Under the conditions of the test, 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). No modification of the appearance or significant pack weight change. No noticeable odour before opening of the package. No observable sign of test item contamination of the outer surface. No leak during shaking of turning No deformation and no observable alteration of package material by the test item. **Cymoxanil content:** Before storage: 32.75 ± 0.15% w/w After 14 days at 54°C: 32.89 ± 0.25% w/w Difference of + 0.4 % **Zoxamide content:** Before storage: 32.91 ± 0.17% w/w After 14 days at 54°C: 32.93 ± 0.15% w/w Difference of + 0.1 % **Ratio of enantiomers of zoxamide:** *R*-isomer before storage: 50.65 ± 0.10% After 14 days at 54°C: 50.71 ± 0.28% *S*-isomer before storage: 49.35%± 0.10%	Y	KCP 2.7.1/02 De Ryckel (2019) Study no. 24718	Accepted The active substances have been determined with a HPLC-UV method DAS–AM–02–051 using benzophenone as internal standard. This method has been validated according to US EPA OPPTS Test Guideline 830.1800 by Diogo, 2003 (see dRR Part B.5). It meets SANCO/3030/99 rev.4 requirements.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			After 14 days at 54°C: 49.29 ± 0.28% Zoxamide is a racemate. The chiral center of zoxamide is stable. See further individual table entries for specific test results.			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	Not applciable; 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)	After 14 d at 54°C : 32.07% ± 0.04% Cymoxanil 32.63% ± 0.05% Zoxamide Determined by validated HPLC method no. DAS-M-02-051 (See Section on Analytical Methods)	Y	KCP 2.7.3/01 Lucini, L (2006) Study no. 021/2006 => **filed under KCP 2.1/01**	Accepted UK CRD (zRMS for authorisation): -0.9% Cymoxanil -0.7% Zoxamide Active ingredients within tolerance limits.
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)	After 2 years at ambient temperature : 32.46 ± 0.15 % cymoxanil 33.49 ± 0.13 % zoxamide Determined by validated HPLC method no. DAS-M-02-051 (See Section on Analytical Methods) No weight loss.	Y	KCP 2.7.5/01 Mori, V. (2008) Study no. 022/2006	Accepted UK CRD (zRMS for authorisation): *Packaging described as "commercial aluminium package" which was clarified by the applicant to mean: 1 kg bags made in (from outer to inner layer)*

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						Polyester (12 µm) / Aluminium (7 µm) / Polyethylene (75 µm) (please refer to dRR Section 1, point 4.1.1) containing 0.5 kg of product. *The container was described as "regular" without corrosion, deformation and alteration.* *+0.3% Cymoxanil* *+1.9% Zoxamide* *Active ingredients within tolerance limits* *Product stable for at least 24 months in ambient storage, in the packaging described above.*
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Not applicable.					
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 After 14 days at 54 °C: Static 5 sec Dynamic 2 sec After 2 years at ambient temperature: Static 3 sec	Y	KCP 2.8.1/01 Lucini, L (2006) Study no. 021/2006 **=> filed under KCP 2.1/01** KCP 2.8.1/02 Mori, V. (2008)	Accepted UK CRD (zRMS for authorisation): *Wettable within acceptable limits for fresh and stores product (complete wetting within 1 minute without swirling).*

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Dynamic 2 sec		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´ After 14 days at 54 °C: 70 mL of foam (average) after 1´ After 2 years at ambient temperature: 49 mL of foam (average) after 1´	Y	KCP 2.8.2/01 Lucini, L (2006) Study no. 021/2006 **=> filed under KCP 2.1/01** KCP 2.8.2/02 Mori, V. (2008) Study no. 022/2006 **=> filed under KCP 2.7.5/01**	Accepted UK CRD (zRMS for authorisation): *Standard Water D was used as opposed to C as stated in CIPAC MT 47.2. This is acceptable.* *The maximum in use concentration determined from the GAP in Appendix 2 is 0.45 kg/200 L = 0.225% dispersion), these experiments were conducted with a 0.25% dispersion. This therefore covers the maximum in use concentration.* *The foaming of the fresh product is just at the acceptable limit of 60 ml foam after 1 minute. Although not necessary, the applicant conducted persistent foaming tests after both accelerated and ambient storage. The foaming after 2 years (and 1 year) at ambient temperature was within the acceptable range; however,*

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								the foaming after the accelerated storage exceeded the acceptable limit by 10 ml. Given the results of the tests most representative of the real world use of the product (i.e. on the fresh sample and the ambiently stored sample), the persistent foaming results are unlikely to be an issue. *The applicant has confirmed that there are no foaming issues when the product is used as per the label.*
	CIPAC MT 47.3	Cymoxanil 33% + Zoxamide 33% WG Batch: GSOL7019 (Cymoxanil 32.75 ±0.15% w/w, Zoxamide 32.91 ±0.17% w/w)		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 **=> filed under KCP 2.7.1/02**	Accepted
			After 10 seconds	16 mL	50 mL			
			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	In standard water D		Cymoxanil	Zoxamide	Y	KCP 2.8.3.1/01 Lucini, L (2006) Study no. 021/2006	Accepted UK CRD (zRMS for authorisation):
				0.02 %	103%	98%			

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
		(Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	Fresh test item	0.25 %	101%	89%		=> **filed under KCP 2.1/01**	*In use concentrations: Max: 0.45 kg in 200 L (0.225%) Min 0.35 kg in 1000 L (0.035%) Therefore 0.02% and 0.25% are reasonable representations of the minimum and maximum in-use concentrations.*
			After 14 days at 54 °C	0.02 %	102 %	83 %			
				0.25 %	100 %	85 %			
			After 2 years at ambient temperature	0.02 %	102 %	92 %		KCP 2.8.3.1/02 Mori, V. (2008) Study no. 022/2006	
				0.25 %	101 %	89 %		=> **filed under KCP 2.7.5/01**	*Suspensibility within acceptable range for fresh and stored product.*
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 UK CRD (zRMS for authorisation): *Dispersion within acceptable limits for fresh and stored product.*
			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) 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	CIPAC MT 170	SIP 40936	Fresh test item	Size	1 - 2 mm		Y	KCP 2.8.5.1.1/01 Lucini, L (2006)	Accepted UK CRD (zRMS for

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
size range of granules (KCP 2.8.5.1.1)	OECD 110	Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	After 2 years at ambient tempera-ture	Size	1 – 2 mm		Study no. 021/2006 => **filed under KCP 2.1/01**	authorisation): *Noted.*
			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 UK CRD (zRMS for au-thorisation): *Within acceptable limits for fresh and stored product.* *(Less than 2% retained on a 75 µm sieve)*
			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 => **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 UK CRD (zRMS for au-thorisation): *Nearly Dust Free when fresh and after storage.* *(<<1% dust by weight)*
			After 14 days at 54 °C: Nearly dust free.					
			After 2 years at ambient temperature: Nearly dust free.				KCP 2.8.5.2.1/02 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	
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. After 14 days at 54 °C: Nearly dust free. After 2 years at ambient temperature: Nearly dust free.	Y	KCP 2.8.5.2.2/01 Lucini, L (2006) Study no. 021/2006 **=> filed under KCP 2.1/01** KCP 2.8.5.2.2/02 Mori, V. (2008) Study no. 022/2006 **=> filed under KCP 2.7.5/01**	Accepted UK CRD (zRMS for authorisation): *Nearly Dust Free when fresh and after storage. (<<1% dust by weight)*
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	SIP 40936 Batch No. BPL 212 (Cymoxanil 32.37 ±0.09% w/w, Zoxamide 32.86 ±0.09% w/w)	Fresh test item: 99.95 % After 14 days at 54 °C: 99.94 % After 2 years at ambient temperature: 99.97 %	Y	KCP 2.8.5.3/01 Lucini, L (2006) Study no. 021/2006 **=> filed under KCP 2.1/01** KCP 2.8.5.3/02 Mori, V. (2008) Study no. 022/2006 **=> filed under KCP 2.7.5/01**	Accepted UK CRD (zRMS for authorisation): *Within acceptable limits for fresh and stored product (>98% attrition resistance).*
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.					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
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 UK CRD (zRMS for authorisation): *Flows spontaneously after 14 days under pressure at 54 °C*
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)						UK CRD (zRMS for authorisation): *A suitable Compatibility Assurance Statement has been provided.*
	The physical/chemical compatability has been determined under practical field conditions.	Cymoxanil 33% + Zoxamide 33% WG Batch No. FTZ30AL1001 Aliette WG (Fosetyl aluminium salt 800 g/kg) Batch No. DE 05537184 K	After the application, no residues in the tank, the tubing, filters or the nozzles were observed. The mixture of the test item Cymoxanil 33% + Zoxamide 33% WG and Aliette WG is threfore found compatible under field conditions.	Y	KCP 2.9.1/01 Harant, H. (2014) Study no. 13 10 47 044	Accepted
Chemical	See data point 2.9.1.					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
compatibility of tank mixes (KCP 2.9.2)						
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 gm2 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	Verte-brate 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	GWI 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. Gowan

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			GLP Not Published => Filed under KCP 2.1/01		
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. Gowan

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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	GWI Sipcam Oxon S.p.A.
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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
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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 S.p.A.

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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 S.p.A.

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
			Sipcam S.p.A , Report No. 021/2006 GLP No Published => Filed under KCP 2.1/01		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	GWI Sipcam Oxon 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 No GLP Not published	N	GWI

SIPCAM Oxon S.p.A. is the legal successor of Oxon Italia S.p.A.; Gowan Crop Protection (GWI) is the legal eternity 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	Verte-brate study Y/N	Owner
KCA 2.1.1	Ardern, D.	1998	RH-117281 physicochemical properties Rohm and Haas Co., ER ref. no. 19.15	N	GWI

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
			Huntingdon Life Sciences, Report No. RAS 056/982496, March 19 1998 GLP Not published		
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	GWI
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	GWI
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	GWI
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	GWI
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	GWI
KCA 2.3.2	Ardern, D.	1998	RH-117281 physicochemical properties	N	GWI

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
			Rohm and Haas Co., ER ref. no. 19.15 Huntingdon Life Sciences, Report No. RAS 056/982496, March 19 1998 GLP Not published		
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	GWI
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	GWI
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	GWI
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	GWI
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	GWI
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	N	GWI

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
			Rohm and Haas Co., Report No. 13-96-085TR, August 20 1996, ER ref. no. 30.13 GLP Not published		
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	GWI
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	GWI
KCA 2.7.1	Reynolds, J.L.	1996	n-octanol/water partition coefficient of [14C] RH-117281 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	N	GWI
KCA 2.7.2	Volkel, W.	1998	Determination of the adsorption coefficient of 14C-RH-163353 on soil and its octanol/water partition co-efficient 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	GWI
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	GWI

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
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	GWI
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	GWI
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	GWI
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	GWI
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	GWI
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	GWI

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
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	GWI
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	GWI
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	GWI
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	GWI

GWI – 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.