

Renewal Assessment Report

under Regulation (EC) 1107/2009



Zoxamide

Volume 2

Rapporteur Member State: Latvia
Co-Rapporteur Member State: France

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TABLE OF CONTENTS

A.	LIST OF THE TESTS, STUDIES AND INFORMATION SUBMITTED	4
A.1	Identity of the active substance	4
A.2	Physical and chemical properties of the active substance	6
A.3	Data on application and efficacy	12
A.4	Further information	13
A.5	Methods of analysis	14
A.6	Toxicological and metabolism studies on the active substance.....	21
A.7	Residue data.....	35
A.8	Environmental fate and behaviour.....	51
A.9	Ecotoxicology.....	57

A. LIST OF THE TESTS, STUDIES AND INFORMATION SUBMITTED**A.1 IDENTITY OF THE ACTIVE SUBSTANCE****Zoxamide:****New studies**

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA,1.8/01	O'Brien, J. and Holmes, T	2014	Comparative QSAR analysis of Zoxamide against the impurities RH-24,549, RH-127,450, RH-150,721, RH-141,288, RH-119231, RH-123,917 in OECD QSAR Toolbox version 3.2.0.103. Exponent International Ltd, Harrogate, HG2 8E, UK Report No. 0907598.UK0 EWC 7062 Not GLP, Not published.	N	Y	New Information generated to meet current requirements.	Gowan
KCA, 1.11/01 KCA, 4.1.1/01	Deierling, T. & Herrmann, S,	2015	Analytical Profile of Five Production Batches of Zoxamide, IBACON, Germany, Project No. 79161102 GLP, not published	N	Y	Confidential business information	Gowan

Studies relied on for the first inclusion of zoxamide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) 1107/2009

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
KCA, 1.11/01	IIA 1.2 – 1.11/03	Kemmerer, S.C	2001	Product Chemistry Series 830 Group A, Supplement 2 to EPA MRID 44731802. Guideline Numbers OPPTS: 830.1700, 830.1750, 830.1800: Product Identity, Composition, and Analysis for RH-117,281 Technical, APR-01-103. ER ref. No. 46.2	N	N		Gowan
KCA 4.1.1/01 KCA 4.2.1/01 4.2.1/02 4.2.1/03 4.2.1/04	IIA 1.2 – 1.11/01 IIA 4.1	Kemmerer, S.C	1998	Product Chemistry Series 830 Group A, Guideline Numbers OPPTS: 830.1550, 830.1600, 830.1620, 830.1670, 830.1700, 830.1750, 830.1800: Product Identity, Composition, and Analysis for RH-117,281 Technical, APR-98-282, ER Ref. No. 32.7	N	N		Gowan

Zoxium 240 SC:

None

A.2 PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

Zoxamide:

New studies

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA, 2.7.2 /04	O'Connor, B.J.	2014	Zoxamide metabolite, RH-24549: Determination of partition coefficient Harlan Laboratories Ltd Shardlow Business Park Derbyshire, DE72 2GD, UK Study No. 41400466 GLP, not published	N	Y	New data requirement.	Gowan
KCA, 2.7.2 /05	O'Connor, B.J.	2014	Zoxamide metabolite, RH-141452: Determination of partition coefficient Harlan Laboratories Ltd Shardlow Business Park Derbyshire, DE72 2GD, UK Study No. 41400467 GLP, not published	N	Y	New data requirement.	Gowan
KCA, 2.7.2 /06	O'Connor, B.J.	2014	Zoxamide metabolite, RH-150721: Determination of partition coefficient Harlan Laboratories Ltd Shardlow Business Park Derbyshire, DE72 2GD, UK Study No. 41400468 GLP, not published	N	Y	New data requirement.	Gowan

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA, 2.7.2 /07	Liney, P. and Miles, D	2014	Metabolite of Zoxamide (RH-141455) Octanol-Water Partition Coefficient Exponent International Ltd. Hornbeam Business Park Harrogate, Yorkshire, HG2 8RE, UK Project Number: 0907598.UK0 Report Number: 0907598 – 5495 Not GLP, not published	N	Y	New data requirement.	Gowan

Studies relied on for the first inclusion of zoxamide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) 1107/2009

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 2.1.1/01	IIA, 2.1/01	Arden, D.	1998	RH-117281 Physicochemical Properties Huntingdon Life Sciences, Report No. RAS 056/982496, March 19, 1998, ER ref. no. 19.15 GLP, unpublished	N	N	NA	Gowan
CA, 2.1.1/02	IIA, 2.1/02	Betteley, J	1998a	RH-117,281 Melting Temperature Huntingdon Life Sciences, Report No.: RAS 092/98331, ER ref. no. 19.14 GLP, Unpublished	N	N	NA	Gowan
CA, 2.2.1/01	IIA, 2.3.1	Kogovsek, LM	1996	RH-117,281 Vapor Pressure, Ricerca, Inc., Rohm and Haas Technical Report No. 34-96-58, September 23, 1996, ER ref. no. 6.6 GLP, unpublished.	N	N	NA	Gowan
CA, 2.2.2/01	IIA, 2.3.2/01	Betteley, J.	1998b	RH-117,281 Henry's Law Constant, Huntingdon Life Sciences Report No. RAS 082/983272, June 26, 1998, ER ref. no. 19.16 GLP, unpublished	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 2.3.1/01	IIA, 2.4.1/01	Arder, D.	1998	RH-117281 Physicochemical Properties Huntingdon Life Sciences, Report No. RAS 056/982496, March 19, 1998, ER ref. no. 19.15 GLP, unpublished	N	N	NA	Gowan
CA, 2.3.1/02	IIA, 2.4.1/02	Betteley, J.	1998c	RH-117,281 Appearance Huntingdon Life Sciences, Report No.: RAS 085/983389, ER ref. no. 19.13 GLP, Unpublished	N	N	NA	Gowan
CA, 2.3.2/01	IIA, 2.4.2/01	Arder, D.	1998	RH-117281 Physicochemical Properties Huntingdon Life Sciences, Report No. RAS 056/982496, March 19, 1998. ER ref. no. 19.15 GLP, unpublished	N	N	NA	Gowan
CA, 2.3.2/02	IIA, 2.4.2/02	Betteley, J.	1998c	RH-117,281 Appearance Huntingdon Life Sciences, Report No.: RAS 085/983389. ER ref. no. 19.13 GLP, Unpublished	N	N	NA	Gowan
CA, 2.4.1/01	IIA, 2.5.1/01	Betteley, J.	1998d	RH-117,281 Spectral Data (IR and NMR) Huntingdon Life Sciences, Report No.: RAS 100/983371. ER ref. no. 30.12 GLP, Unpublished	N	N	NA	Gowan
CA, 2.4.1/02	IIA, 2.5.1/02	Hafer, JH.	1996	UV-Visible Spectrum of RH-117281, Rohm and Haas Technical Report No. 13-96-013TR, February 26, 1996, ER ref. no. 30.15 GLP, unpublished	N	N	NA	Gowan
CA, 2.4.1/03	IIA, 2.5.1/03	Quinn, CJ	1993	Qualitative Analysis of RH-117281 Standard by Mass Spectrometry, Rohm and Haas Technical Report No. 13-93-130, November 3, 1993, ER ref. no. 30.11 GLP, unpublished	N	N	NA	Gowan
CA, 2.4.2/01	IIA, 2.5.2/01	Betteley, J.	1998e	RH-131,889 Spectral Data Huntingdon Life Sciences, Report No.: RAS 105/983943, ER ref. no. 19.6 GLP, Unpublished	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 2.4.2/02	IIA, 2.5.2/02	Quinn, CJ	1996	Qualitative Analysis of RH-016,971 and RH-131,889 by Desorption Chemical Ionization (DCI) Mass Spectrometry, Rohm and Haas Technical Report No. 13-96-085TR, August 20, 1996, ER ref. no. 30.13 GLP, unpublished	N	N	NA	Gowan
CA, 2.5/01	IIA, 2.6	Reynolds, JL	1996a	Water solubility of 14C-RH-117281, XenoBiotic Laboratories, Inc., Rohm and Haas Technical Report No. 34-95-163, March 22, 1996. ER ref. no. 1.8 GLP, unpublished.	N	N	NA	Gowan
CA, 2.6/01	IIA, 2.7/01	Betteley, J.	1998f	RH-117,281 Solubility in a Range of Organic Solvents Huntingdon Life Sciences, Report No.: RAS 084/983622. ER ref. no. 19.12 GLP, Unpublished	N	N	NA	Gowan
CA, 2.7.1/01	IIA, 2.8	Reynolds, JL	1996b	n-Octanol/water partition coefficient of [14C]RH-117281, XenoBiotic Laboratories, Inc., Rohm and Haas Technical Report No. 34-95-162, February 14, 1996, ER ref. no. 1.7 GLP, unpublished.	N	N	NA	Gowan
CA, 2.7.2/01	IIA, 7.1.2.2/03	Volkel, W.	1998c	Determination of the Adsorption Coefficient of 14C-RH-163353 on Soil and its Octanol/Water Partition Coefficient Using High Performance Liquid Chromatography (HPLC), RCC Ltd., Rohm and Haas Technical Report No. 34-98-55, November 9, 1998, GLP, unpublished. ER ref. no. 31.4	N	N	NA	Gowan
CA, 2.7.2/02	IIA, 8.2.3/03	Tognucci, A	1998a	Determination of the partition coefficient (n-octanol/water) of RH-127450, RCC Ltd, Rohm and Haas Technical Report No. 34-98-165, ER Ref. No. 18.3, October 12, 1998, GLP, unpublished.	Y	N	NA	Gowan
CA, 2.7.2/03	IIA, 8.2.3/04	Tognucci, A	1998b	Determination of the partition coefficient (n-octanol/water) of RH-139432, RCC Ltd, Rohm and Haas Technical Report No. 34-98-53, ER Ref. No. 31.3, October 22, 1998, GLP, unpublished.	Y	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 2.8/01	IIA, 2.9.4	Betteley, J.	1998g	RH-117,281 Determination of Dissociation Constant, Huntingdon Life Sciences, Report No.: RAS 090/983783, August 13, 1998, ER ref. no. 19.11 GLP, unpublished	N	N	NA	Gowan
CA, 2.9.1/01	IIA, 2.11.1/01	Betteley, J.	1998i	RH-117281 Flammability (Solids) Huntingdon Life Sciences Report No.: RAS 086/983225, ER ref. no. 19.9 GLP, Unpublished	N	N	NA	Gowan
CA, 2.9.2/01	IIA, 2.11.2/01	Betteley, J.	1998j	RH-117,281 Relative Self Ignition Temperature for Solids Huntingdon Life Sciences, Report No.: RAS 088/983290, ER ref. no. 19.8 GLP, Unpublished	N	N	NA	Gowan
CA, 2.11/01	IIA, 2.13/01	Betteley, J.	1998k	RH-117,281 Explosive Properties Huntingdon Life Sciences, Report No.: RAS 087/983530, ER ref. no. 19.7 GLP, Unpublished	N	N	NA	Gowan
IIA, 2.13/01	IIA, 2.15/01	Betteley, J.	1998l	RH-117,281 Oxidising Properties Huntingdon Life Sciences, Report No.: RAS 089/983438, ER ref. no. 19.5 GLP, Unpublished	N	N	NA	Gowan

Zoxium 240 SC:**New studies**

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCP 2, 2.1.1, 2.1.2, 2.4, 2.5.1, 2.5.2, 2.6, 2.7, 2.8.2, 2.8.3.1, 2.8.3.2, 2.8.3.3, 2.8.7	Fifi A.P.	2013	Chemical-physical characterization of product ZOXIUM 240 SC after 2 years shelf life BioTecnologie BT SrL c/o Parco Tecnologico Agroalimentare dell'Umbria Report No. BT119/10 (Final Report) GLP, Not published	N	Y	Data to support new representative formulation	Gowan
KCP 2.9	Borgo F.	2011	Prove miscibilità Zoxium 240 SC Sipcam SPA Via Semplone, 195, 20016 Pero (MI), Italy. Not GLP, Not published	N	Y	Data to support new representative formulation	Gowan

Studies relied on for the first inclusion of zoxamide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) 1107/2009

None (Zoxium 240 SC was not the representative formulation for the inclusion of zoxamide in Annex I to Directive 91/414/EEC).

A.3 DATA ON APPLICATION AND EFFICACY**Zoxamide:**

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
CA 1.9/01	Edmonds, J	2002	Information requested to clarify which of the enantiomers is the active molecule	N	Y	Data to support new representative formulation	Gowan
CA 1.9/02	Harrison, C	1996	Field evaluation of the efficacy of RH-6949 SC and RH-7281 WP applied alone, RH-7281 SC alone and in tank mixtures with Dithane M45, and WP and DG formulations of RH-7281 + Mancozeb for the control of late blight in potatoes under irrigated conditions. Agrisearch UK Ltd, Derbyshire, UK Report No. AK/2793/RH Not GLP, Not published	N	Y	Data to support new representative formulation	Gowan

Zoxium 240 SC:

None.

A.4 FURTHER INFORMATION

Zoxamide:

None

Zoxium 240 SC:

None

A.5 METHODS OF ANALYSIS

Zoxamide:

New studies

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA 4.1.2/01	Weber, H.	2012	Validation of an enforcement method ("QuEChERS") for the determination of residues of zoxamide in grapes and potatoes and their processed products using LC-MS/MS. Eurofins Agrosience Services Chem GmbH Grossmoorbehogen 25, D-21079 Hamburg. Report: S12-03949 GLP, Not published.	N	Y	To ensure that the validation data comply with current requirements.	Gowan
KCA 4.1.2/02	Weber, H., and Giesau, A.	2013a	Validation of analytical method for the determination of residues of the zoxamide metabolite RH-150721 in grapes and processing fractions using LC-MS/MS. Eurofins Agrosience Services Chem GmbH Grossmoorbehogen 25, D-21079 Hamburg. Report: S12-03950 GLP, Not published.	N	Y	To ensure that the validation data comply with current requirements.	Gowan

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA 4.1.2/03	Weber, H., and Giesau, A.	2013b	Validation of analytical method for the determination of residues of the zoxamide metabolites RH-1452 and RH-1455 in potatoes and processing fractions using LC-MS/MS. Eurofins Agrosience Services Chem GmbH Grossmoorbehogen 25, D-21079 Hamburg. Report: S12-03951 GLP, Not published.	N	Y	To ensure that the validation data comply with current requirements.	Gowan
KCA 4.1.2/04	Luciani, G.P.	2010	Determination of zoxamide residues after five applications of ELECTIS MZ and ZOXIUM 240 SC on potato under field conditions – Italian trial AgriParadigma S r.l., Via Faentina, 224-48100 Ravenna, Italy Report Number AGRI 012/10 GLP DEC GLP, Not published	N	Y	To ensure that the validation data comply with current requirements.	Gowan
KCA, 4.1.2/05	Nixon, W.B. and Sulairman, M.W.	1997	The analysis of RH-117,281 technical in filtered saltwater in support of Wildlife International Ltd Project No.: 129A-136 Appendix III to RH-117,281 Technical: A 96-Hour-Flow Through Acute Toxicity Test with the Saltwater Mysid (Mysidopsis bahia) Wildlife International Ltd 898 Commerce Drive, Eastern Maryland 21601, USA. Report Number: 95RC-0275 GLP, Not published	N	Y	To ensure that the validation data comply with current requirements.	Gowan

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA, 4.1.2/06	Kendall, T. Z.	1998	The analysis of RH-117,281 technical in filtered saltwater in support of Wildlife International Ltd Project No.: 129A-142 Appendix III to RH-117,281 Technical: A flow-through life-cycle toxicity test with the saltwater mysid (<i>Mysidopsis bahia</i>) Wildlife International Ltd 898 Commerce Drive, Eastern Maryland 21601, USA. Report Number: 97RC-0077 GLP, Not published	N	Y	To ensure that the validation data comply with current requirements.	Gowan
KCA, 4.1.2/07	Aversa, S	2010	Validation of an analytical method for the determination of zoxamide in solutions of aquatic toxicity test with GOW 008 Biotechnologie BT Srl c/o Parco Tecnologico Agroalimentare dell'Umbria Frazione Pantalla, 06050 Todi (PG), Italy. Study BT102/10 GLP, Not published	N	Y	To ensure that the validation data comply with current requirements.	Gowan
KCA, 6.1/04	Weber, H. and Kissmann, H.	2014	Storage Stability of residues of Zoxamide, RH-150721, RH-1452 and RH-1455 in Grape and Processed Products and Potato Eurofins Agroscience Services Chem GmbH (EAS Chem), Großmoorbogen 25, D-21079 Hamburg, Germany Report Number: S12-03952 Interim Report GLP, Not Published	N	Y	Data required to supplement existing storage stability data	Gowan

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA, 6.3.2/21	Luciani, G.P.	2010b	Determination of Zoxamide residues after five application of ELECTIS MZ and ZOXIUM 240 SC on Wine grape and Table grape – Italian trial, year 2010. Research Centre “Agriparadigma Srl” Via Facentina, 224 Ravenna, Italy Study Identification Code: AGRI 010/10 GLP DEC GLP, Not published	N	Y	Data not available for first Annex I inclusion and bridge to support use of new formulation and modified GAP	Gowan
KCA, 6.5.3/02	Wais, A.	2001	Determination of residues of RH-117,281 and mancozeb in/on vine grapes (RAC grapes and processing products) following treatment with RH-7281/mancozeb 75WG from a field trial (semi residue decline study) in Italy; 1999 RCCLtd., CH-4452 Intigen, Switzerland Report Number: 734580, ER ref R 77.10 GLP, Not published	N	Y	Data not available for first Annex I inclusion	Gowan
KCA, 6.2.1/09	Hein, W.	2014b	Extraction Efficiency of [phenyl-UL-14C] Zoxamide from Plant Metabolism Samples (Pea) RLP AgroScience GmbH, Breitenweg 71 67435 Neustadt / Germany. Report Number: AS362 GLP, Not published	N	Y	Data not available for first Annex I inclusion	Gowan

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA, 4.2/01	Weber, H.	2012	Validation of an enforcement method ("QuEChERS") for the determination of residues of zoxamide in grapes and potatoes and their processed products using LC-MS/MS. Eurofins Agrosience Services Chem GmbH Grossmoorbehogen 25, D-21079 Hamburg. Report: S12-03949 GLP, Not published.	N	Y	To ensure that the validation data comply with current requirements.	Gowan
KCA, 4.2/02	Richter, S.	2014	Validation of the QuEChERS Multi-Residue Method for the Determination of Zoxamide in Various Crop Types PTRL Europe, Helmholtzstr. 22, Science Park I D-89081 Ulm, Germany Report ID: P 3114G GLP, Not published.	N	Y	To ensure that the validation data comply with current requirements.	Gowan
KCA, 4.2/03	Schlewitz, P.	2014	Independent Laboratory Validation of the Analytical Method for the Determination of Zoxamide Residues in Lettuce Aandag, 16, rue Ampère, 67500 Haguenau, France Report ID: R B4023 GLP, Not published	N	Y	To ensure that the validation data comply with current requirements.	Gowan
KCA, 4.2/04	Jooß, S.	2013a	Development and validation of a residue method for the determination of zoxamide in soil PTRL Europe, Helmholtzstr. 22, Science Park I D-89081 Ulm, Germany Report ID: P 3051 G GLP, Not published	N	Y	To ensure that the validation data comply with current requirements.	Gowan

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA, 4.2/05	Jooß, S.	2013b	Development and Validation of a Residue Method for the Determination of Zoxamide in Drinking and in Surface Water. PTRL Europe, Helmholtzstr. 22, Science Park I D-89081 Ulm, Germany Report ID: P 3050 G GLP, Not published	N	Y	To ensure that the validation data comply with current requirements.	Gowan
KCA, 4.2/06	Schlewitz, P.	2014	Independent Laboratory Validation of a Residue Method for the Determination of Zoxamide in Drinking Water Anadiag 16, rue Ampère, 67500 Haguenau, France Report No. R B4049 GLP, Not published.	N	Y	To ensure that the validation data comply with current requirements.	Gowan
KCA, 4.2/07	Miller, C.	2014	Zoxamide: Validation of Methodology for the Determination of Residues in Air Huntingdon Life Sciences Eye Research Centre, Suffolk, IP23 7PX, UK Report ID: FRK0048 GLP, Not published	N	Y	To ensure that the validation data comply with current requirements.	Gowan

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None

Zoxium 240 SC:**New studies**

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCP 5.1.1	Fifi A.P.	2011	Accelerated storage stability of product Zoxium 240 SC after 2 weeks at 54°C BioTecnologie BT SrL c/o Parco Tecnologico Agroalimentare dell'Umbria Report No. BT118/10 GLP, Not published	N	Y	Data to support new representative formulation	Gowan

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None (Zoxium 240 SC was not the representative formulation for the inclusion of zoxamide in Annex I to Directive 91/414/EEC).

A.6 TOXICOLOGICAL AND METABOLISM STUDIES ON THE ACTIVE SUBSTANCE

Zoxamide:

New studies

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA, 5.1.1/04	Scullion, P.	2013	A study to compare the metabolite profile of 14C-zoxamide in cryopressed human, dog, rat and mouse hepatocytes. CXR Biosciences James Lindsay Place, Dundee Technopole, Dundee DD1 5JJ, UK Report Number: CXR1237 Not GLP, Not published	N	Y	New data requirement.	Gowan
KCA, 5.1.1/05	Powrie, R.H.	2014	A study to investigate the presence of a specific metabolite of zoxamide, RH-150721, in Analytical Data From Previous Study CXR1237 CXR Biosciences James Lindsay Place, Dundee Technopole, Dundee DD1 5JJ, UK Report Number: CXR1416 Not GLP, Not published	N	Y	New data requirement.	Gowan
KCA, 5.2.7/01	Heppenheimer, A.	2014	Zoxamide: Cytotoxicity assay <i>in vitro</i> with Balb/c 3T3 cells: Natural red test at simultaneous irradiation with artificial sunlight. Harlan Cytotest Cell Research GmbH In den Leppsteinswiesen 19, 64380 Rossdorf, Germany GLP, Not Published	N	Y	New data requirement.	Gowan

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA, 5.8.1/07	Woods, I	2014	RH-141455: <i>In vitro</i> mutation test using mouse lymphoma L5178Y Huntingdon Life Sciences Eye Research Centre, Suffolk, IP23 7PX, UK Study No. FRK0049 GLP, Not published	N	Y	To demonstrate that the metabolite is not of toxicological relevance.	Gowan
CA, 5.8.1/08	Woods, I	2014	RH-141455: <i>In Vitro</i> Micronucleus Test in Human Lymphocytes Huntingdon Life Sciences Eye Research Centre, Suffolk, IP23 7PX, UK Study No. FRK0050 GLP, Not published	N	Y	To demonstrate that the metabolite is not of toxicological relevance.	Gowan
KCA, 5.8.1/09	Sokolowski, A.	2013	RH-150,721: Salmonella typhimurium reverse mutation assay Harlan CCR, In den Leppsteinswiesen 19, 64380 Rossdorf, Germany Report Number 1549300 GLP, Not Published	N	Y	To address potential toxicity of metabolite found in wine.	Gowan
KCA, 5.8.1/10	Thandi, K	2013	DEREK evaluation of the toxicities of zoxamide and metabolite RH-150,721. LSR Associates Ltd , Woolley Road, Alconbury, Cambridgeshire, PE28 4HS, UK Study No: FRK0046 Not GLP, Not Published	N	Y	To address potential toxicity of metabolite found in wine.	Gowan

Studies relied on for the first inclusion of zoxamide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) 1107/2009

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 5.1.1/01	IIA, 5.1/01	[REDACTED]	1998a	14C-RH-117,281: Pharmacokinetic and metabolism study in rats. [REDACTED] Report No: 94R-235 ER Ref No: 24.1 US Ref No: 94R-235, GLP, Unpublished	Y	N	NA	Gowan
CA, 5.1.1/02 (5.4.2/03)	IIA, 5.1/02 (5.4.2/03)	[REDACTED]	1998b	Distribution of 14C-RH-117,281 to the bone marrow of mice. [REDACTED] Report No: 97R-173 ER Ref No: 24.2 US Ref No: 97R-173, GLP, Unpublished	Y	N	NA	Gowan
CA, 5.1.1/03 Add. study	IIA, 5.1/03 Add. study	Reibach P.H., Detweiler B.S.	2001	Identification of RH-139432 from zoxamide (RH-117281) Rat Pharmacokinetic Study Samples Rohm and Haas Co. Report No: 34-00-105 ER Ref No: 45.3, GLP, Unpublished	N	N	NA	Gowan
CA, 5.2.1/01	IIA, 5.2.1/01	[REDACTED]	1996a	RH-117,281 Technical: acute oral toxicity study in male and female rats. [REDACTED] Report No: 95R-268 ER Ref No: 1.3, US Ref No: 95R-268 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.2.1/02	IIA, 5.2.1/02	[REDACTED]	1998a	RH-117,281 Technical: Acute oral toxicity study in male and female mice. [REDACTED] Report No. 98R-165 ER Ref No: 24.3, US Ref No: 98R-165 GLP, Unpublished	Y	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 5.2.2/01	IIA, 5.2.2/01	██████████ ██████████ ██████████	1996b	RH-117,281 Technical: acute dermal toxicity study in male and female rats. ██████████ Report No: 95R-269 ER Ref No: 1.4, US Ref No: 95R-269 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.2.3/01	IIA, 5.2.3/01	██████████ ██████████ ██████████ ██████████	1996	RH-117,281 Technical: acute inhalation toxicity study in rats. ██████████ Report No: 95R-266 ER Ref No: 2.2, US Ref No: 95R-266 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.2.4/01	IIA, 5.2.4/01	██████████ ██████████ ██████████	1996c	RH-117,281 Technical: skin irritation study in rabbits. ██████████ Report No: 95R-270 ER Ref No: 1.5, US Ref No: 95R-270 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.2.5/01	IIA, 5.2.5/01	██████████ ██████████ ██████████	1996d	RH-117,281 Technical: eye irritation study in rabbits. ██████████ Report No: 95R-271 ER Ref No: 1.6 US Ref No: 95R-271 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.2.6/01	IIA, 5.2.6/01	██████████	1997	Dermal sensitization study of RH-117,281 Technical in guinea pigs - maximization test. ██████████ Project No. 6228-112 ██████████ Report No: 95RC-170 ER Ref No: 4.2 US Ref No: 95RC-170 GLP, Unpublished	Y	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 5.2.6/02	IIA, 5.2.6/02	[REDACTED]	1998a	RH-117,281 Technical: Delayed contact hypersensitivity study in guinea pigs. [REDACTED] Report No: 97R-074 ER Ref No: 23.2 US Ref No: 97R-074 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.2.6/03	IIA, 5.2.6/03	[REDACTED]	1998b	RH-117,281 Technical: Delayed contact hypersensitivity (dilution) study in guinea pigs. [REDACTED] Report No: 98R-154 ER Ref No: 24.4 US Ref No: 98R-154 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.3.1/01	IIA, 5.3.1/01	[REDACTED]	1996	RH-117,281 Technical: four-week range-finding toxicity study in dogs. [REDACTED] Report No: 94R-234 ER Ref No: 2.3 US Ref No: 94R-234 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.3.2/01	IIA, 5.3.2/01	[REDACTED]	1996	RH-117,281: three-month dietary toxicity study in mice. [REDACTED] Report No: 94R-075 ER Ref No: 5.3 US Ref No: 94R-075 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.3.2/02 (5.8.2.1/02)	IIA, 5.3.2/02 (5.8.2.1/02)	[REDACTED]	1996a	RH-117,281: three-month dietary toxicity/neurotoxicity study in rats. [REDACTED] Report No: 94R-233 ER Ref No: 3.1 US Ref No: 94R-233 GLP, Unpublished	Y	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 5.3.2/03	IIA, 5.3.2/03	[REDACTED]	1997	RH-117,281 Technical: three-month dietary toxicity study in dogs. [REDACTED] Report No: 96R-030 ER Ref No: 9.1 US Ref No: 96R-030 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.3.2/04	IIA, 5.3.2/04	[REDACTED]	1998c	RH-117,281 Technical: one-year chronic dietary toxicity study in dogs. [REDACTED] Report No: 95R-277 ER Ref No: 25.1 US Ref No: 95R-277 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.3.3/01	IIA, 5.3.3/01	[REDACTED]	1998d	RH-117,281 Technical: twenty-eight day dermal toxicity study in rats. [REDACTED] Report No: 97R-075 ER Ref No: 23.3 US Ref No: 97R-075 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.4.1/01	IIA, 5.4.1/01	Sames, J.S., Ciaccio, P.C.	1996a	RH-117,281 Technical: Salmonella Typhimurium gene mutation assay (Ames test). Rohm and Haas Co. Report No: 95R-262 ER Ref No: 2.7 US Ref No: 95R-262 GLP, Unpublished	N	N	NA	Gowan
CA, 5.4.1/02	IIA, 5.4.1/02	Riley, S.	1998	RH-117,281: Test for chemical induction of chromosome aberrations in cultured Chinese hamster ovary (CHO) cells. Covance Laboratories, UK Project No. 616/20-D5140 ER Ref No: 23.6 US Ref No: 96RC-125 GLP, Unpublished	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 5.4.1/03	IIA, 5.4.1/03	Pant, K.	1994	RH-117,281: Test for chemical induction of gene mutation at the HGPT locus in cultured Chinese hamster ovary cells with and without metabolic activation. Sitek Study No: 0282-2510 ER Ref No: 23.4 US Ref No: 94RC-077 GLP, Unpublished	N	N	NA	Gowan
CA, 5.4.2/01	IIA, 5.4.2/01	Sames, J.S., Vandenberghe, Y.L.	1996b	RH-117,281 Technical: micronucleus assay in CD-1 mouse bone marrow cells. Rohm and Haas Co. Report No: 95R-264 ER Ref No: 1.9 US Ref No: 95R-264 GLP, Unpublished	N	N	NA	Gowan
CA, 5.4.2/02 (5.1/02)	IIA, 5.4.2/03 (5.1/02)	██████████ ██████ ██████████ ██████	1998b	Distribution of 14C-RH-117,281 to the bone marrow of mice. ██████████ Report No: 97R-173 ER Ref No: 24.2 US Ref No: 97R-173 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.4.2/02 (5.8.2.2/01)	IIA, 5.4.2/02 (5.8.2.2/01)	Young, D.H.	1998	Mechanism of action of the oomycete fungicides RH-54032 and RH-117281 on <i>Phytophthora capsici</i> , tobacco, mouse lymphoma cells and isolated bovine tubulin. Rohm and Haas Co. Report No: 98R-1098 ER Ref No: 23.5 US Ref No: 98R-1098 GLP, Unpublished	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 5.5/01	IIA, 5.5/01	██████	1998a	RH-117,281 Technical: 24-month dietary chronic/oncogenicity study in rats. Covance project No. 417-505 ██████ Report No: 94RC-236 ER Ref No: 21.1 US Ref No: 94RC-236 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.5/02	IIA, 5.5/03	██████ ██████ ██████ ██████	1998c	RH-117,281 Technical: Eighteen-month dietary oncogenicity study in mice. ██████ Report No: 96R-094 ER Ref No: 20.1 US Ref No: 96R-094 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.6.1/01	IIA, 5.6.1/01	██████ ██████ ██████ ██████	1998	RH-117,281 Technical: Two-generation reproductive toxicity study in rats. ██████ Report No: 95R-272 ER Ref No: 26.1 US Ref No: 95R-272 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.6.2/01	IIA, 5.6.2/01	██████ ██████	1995b	RH-7281 Technical: oral (gavage) developmental toxicity study in rats. ██████ Report No: 94R-079 ER Ref No: 6.1 US Ref No: 94R-079 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.6.2/02	IIA, 5.6.2/02	██████	1997	RH-117,281 Technical: oral (gavage) developmental study in rabbits. ██████ Report No: 95R-267 ER Ref No: 8.2 US Ref No: 95R-267 GLP, Unpublished	Y	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 5.7.1/01	IIA, 5.8.2.1/01	██████████ ██████████ ██████████	1997	RH-117,281 Technical: acute oral (gavage) neurotoxicity study in rats. ██████████ Report No: 95R-182 ER Ref No: 10.1 US Ref No: 95R-182 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.7.1/02 (5.3.2/02)	IIA, 5.8.2.1/02 (5.3.2/02)	██████████ ██████████ ██████████ ██████████	1996a	RH-117,281: three-month dietary toxicity/neurotoxicity study in rats. ██████████ Report No: 94R-233 ER Ref No: 3.1 US Ref No: 94R-233 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.7.1/03	IIA, 5.8.2.1/03	██████████ ██████████ ██████████ ██████████	1995	Carbaryl and DDT: Neurotoxicity Evaluation of Positive Control Substances in Rats. ██████████ Report No: 94R-224 ER Ref No: 27.5 US Ref No: 94R-224 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.7.1/04	IIA, 5.8.2.1/04	██████████ ██████████ ██████████ ██████████	1995a	d-Amphetamine and Chlorpromazine: Motor Activity Assessment of Positive Control Substances in Rats. ██████████ Report No: 94R-225 ER Ref No: 27.6 US Ref No: 94R-225 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.7.1/04	IIA, 5.8.2.1/05	██████████ ██████████ ██████████ ██████████	1995	Triethyltin and Acrylamide: Neurotoxicity Evaluation of Positive Control Substances in Rats. ██████████ Report No: 94R-211 ER Ref No: 28.1 US Ref No: 94R-211 GLP, Unpublished	Y	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 5.8.1/01	IIA, 5.8.1.1/01	██████ ██████	1998a	14C-RH-141,452: Rat metabolism study, Tier I testing ██████ Report No. RPT00410 ER Ref No: 27.1 US Ref No: 97RC-154 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.8.1/02	IIA, 5.8.1.1/02	██████ ██████ ██████ ██████ ██████	1998d	RH-141,452: Acute oral toxicity study in male and female mice. ██████. Report No: 98R-049 ER Ref No: 25.2 US Ref No: 98R-049 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.8.1/03	IIA, 5.8.1.1/03	██████ ██████	1998a	RH-141,452: <i>Salmonella typhimurium</i> gene mutation assay (Ames test). ██████ Report No: 98R-050 ER Ref No: 25.3 US Ref No: 98R-050 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.8.1/04	IIA, 5.8.1.2/01	██████ ██████	1998b	14C-RH-141,455: Rat metabolism study, Tier I testing ██████ Report No. RPT00411 ER Ref No: 27.2 US Ref No: 98RC-017 GLP, Unpublished	Y	N	NA	Gowan
CA, 5.8.1/05	IIA, 5.8.1.2/02	██████ ██████ ██████ ██████ ██████	1998b	RH-141,455: Acute oral toxicity study in male and female mice. ██████ Report No: 98R-047 ER Ref No: 27.3 US Ref No: 98R-047 GLP, Unpublished	Y	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 5.8.1/06	IIA, 5.8.1.2/03	Sames, J.L., Ciaccio, P.J.	1998b	RH-141,455: Salmonella typhimurium gene mutation assay (Ames test). Rohm and Haas Co. Report No: 98R-048 ER Ref No: 27.4 US Ref No: 98R-048 GLP, Unpublished	N	N	NA	Gowan

Zoxium 240 SC:**New studies**

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCP 7.1.1/01	██████ ██████ ██████	1999	RH-117,281 2F (240 SC): Acute oral toxicity study in male and female rats ████████████████████ ████████████████████ ████████████████████ ████████████████████ Report N:° 98R-026 GLP, Unpublished	Y	Y	Data to support new representative formulation	Gowan
KCP 7.1.1/02	██████████ ██████	1999	RH-117,281 2F (240 SC): Acute oral toxicity study in male and female mice ████████████████████ ████████████████████ ████████████████████ ████████████████████ Report N:° 98R-031 GLP, Unpublished	Y	Y	Data to support new representative formulation	Gowan

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCP 7.1.2/01	██████ ██████ ██████	1999	RH-117,281 2F (240SC): Acute dermal toxicity study in male and female rats ████████████████████ ████████████████████ ████████████████████ ████████████████████ Report N:° 98R-027 GLP, Unpublished	Y	Y	Data to support new representative formulation	Gowan
KCP 7.1.3/01	██████████ ██████████ ██████	1999	Acute Inhalation Toxicity Study in Rats Report N:° 98R-025 ████████████████████ ████████████████████ ████████████████████ ████████████████████ GLP, Unpublished	Y	Y	Data to support new representative formulation	Gowan
KCP 7.1.4/01	██████ ██████ ██████	1999	RH-117,281 2F (240SC): Skin irritation study in rabbits ████████████████████ ████████████████████ ████████████████████ ████████████████████ Report N:° 98R-028 GLP, Unpublished	Y	Y	Data to support new representative formulation	Gowan

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCP 7.1.5/01	[REDACTED]	1999	RH-117,281 2F (240SC): Eye irritation study in rabbits [REDACTED] [REDACTED] [REDACTED] [REDACTED] Report N:° 98R-029 GLP, Unpublished	Y	Y	Data to support new representative formulation	Gowan
KCP, 7.1.6/01	[REDACTED]	1999	RH-117,281 2F (240SC): Delayed contact hypersensitivity study in guinea pigs [REDACTED] [REDACTED] [REDACTED] [REDACTED] Report N:° 98R-030 GLP, Unpublished	Y	Y	Data to support new representative formulation	Gowan
KCP, 7.3	Craig, S.	2014	Zoxamide: The In Vitro Percutaneous Absorption of Radiolabelled Zoxamide in the Concentrate and Two In Use Spray Dilutions Through Human Skin. Charles River, Tranent, Edinburgh, UK Study No. 794002, Report No. 35303 GLP, Unpublished	N	Y	Data to support new representative formulation	Gowan

Studies relied on for the first inclusion of zoxamide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) 1107/2009

None.

A.7 RESIDUE DATA

Zoxamide:

New studies

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA, 6.1/04	Weber, H. and Kissmann, H.	2014	Storage Stability of residues of Zoxamide, RH-150721, RH-1452 and RH-1455 in Grape and Processed Products and Potato Eurofins Agroscience Services Chem GmbH (EAS Chem), Großmoorbogen 25, D-21079 Hamburg, Germany Report Number: S12-03952 Interim Report GLP, Not Published	N	Y	Data required to supplement existing storage stability data	Gowan
KCA, 6.2.1/05	Staffa, C. and Möndel, M.	2014	¹⁴ C-phenyl UL zoxamide: Plant metabolism in grape. RLP AgroScience GmbH, Breitenweg 71, 67435 Neustadt, Germany Report Number: AS209 Amendment No. 1 GLP, Not published	N	Y	Data required to replace existing study that was not performed in full accordance with intended GAP.	Gowan
KCA, 6.2.1/06	Sharma, A. K.	1999a	RH-117,281 : Nature of Residue in Fruiting Tomato Plants Rohm and Haas Company Research Laboratories 727 Norristown Road, Springhouse, PA 19477. Report Number 34-99-159, ER Ref R80.1 GLP, Not Published	N	Y	Data not available for first Annex I inclusion	Gowan

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA, 6.2.1/07	Sharma, A. K.	1999b	RH-117,281: Nature of Residue in cucurbits (Cucumber) Rohm and Haas Company Research Laboratories 727 Norristown Road, Springhouse, PA 19477 Report Number 34-99-57 GLP, Not Published	N	Y	Data not available for first Annex I inclusion	Gowan
KCA, 6.2.1/08	Hein, W.	2014a	[Phenyl-UL- ¹⁴ C] Zoxamide: Plant Metabolism in Pea RLP AgroScience GmbH, Breitenweg 71 67435 Neustadt / Germany. Report Number: AS290 GLP, Not published	N	Y	Data not available for first Annex I inclusion	Gowan
KCA, 6.2.1/09	Hein, W.	2014b	Extraction Efficiency of [phenyl-UL- ¹⁴ C] Zoxamide from Plant Metabolism Samples (Pea) RLP AgroScience GmbH, Breitenweg 71 67435 Neustadt / Germany. Report Number: AS362 GLP, Not published	N	Y	Data not available for first Annex I inclusion	Gowan
KCA, 6.3.1/18	Luciani, G.P.	2010a	Determination of Zoxamide residues after five application of ELECTIS MZ and ZOXIUM 240 SC on Potato– Italian trial, year 2010. Research Centre “Agriparadigma Srl” Via Facentina, 224 Ravenna, Italy Study Identification Code: AGRI 012/10 GLP DEC GLP, Not published	N	Y	Data not available for first Annex I inclusion and bridge to support use of new formulation and modified GAP	Gowan

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA, 6.3.2/21	Luciani, G.P.	2010b	Determination of Zoxamide residues after five application of ELECTIS MZ and ZOXIUM 240 SC on Wine grape and Table grape – Italian trial, year 2010. Research Centre “Agriparadigma Srl” Via Facentina, 224 Ravenna, Italy Study Identification Code: AGRI 010/10 GLP DEC GLP, Not published	N	Y	Data not available for first Annex I inclusion and bridge to support use of new formulation and modified GAP	Gowan
KCA, 6.5.3/02	Wais, A.	2001	Determination of residues of RH-117,281 and mancozeb in/on vine grapes (RAC grapes and processing products) following treatment with RH-7281/mancozeb 75WG from a field trial (semi residue decline study) in Italy; 1999 RCCLtd., CH-4452 Itingen, Switzerland Report Number: 734580, ER ref R 77.10 GLP, Not published	N	Y	Data not available for first Annex I inclusion	Gowan

Studies relied on FOR the first inclusion of zoxamide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) 1107/2009

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 6.1/01	IIA, 6.	Ross, JR	1998a	Ross, J.R., Storage Stability of RH-117281 Residues in Grapes, Grape Juice, Raisins and Potatoes under Conditions of Frozen Storage, Rohm and Haas Technical Report No. 34-98-161, December 15, 1998, GLP, unpublished. ER ref. no. R 61.1	N	N	NA	Gowan
CA, 6.1/02	IIA, 6.	Ross, JR	1998b	Ross, J.R., Stability of RH-141455 and RH-141452 Residues in Potatoes, Potato Chips, and Potato Flakes under Conditions of Frozen Storage, Rohm and Haas Technical Report No. 34-98-162, December 15, 1998, GLP, unpublished. ER ref. no. R 61.2	N	N	NA	Gowan
CA, 6.1/03	IIA, 6 See add. vol August 2000	Reibach, P.H.	2000	Storage Stability of RH-117,281 Residue in Potato Samples under Conditions of Frozen Storage: Supplement to TR34-98-161 (ER 61.1) Rohm and Haas unpublished Technical Report No. 34-00-80 September 2, 2000 ER ref. no. R 77.11 (submitted with 44.7)	N	N	NA	Gowan
CA, 6.2.1/01	IIA, 6.1/01	Reibach, PH, Spencer, WO	1998a	Reibach, PH and Spencer, WO, 14C-RH-117,281: Nature of the Residue in Fruiting Grape Plants, Rohm and Haas Technical Report No. 34-98-49, October 1, 1998, GLP, unpublished. ER ref. no. 14.5	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 6.2.1/02	IIA, 6.1/02	Reibach, PH, Spencer, WO	1998b	Reibach, PH and Spencer, WO, 14C-RH-117,281: Nature of the Residue in Potato, Rohm and Haas Technical Report No. 34-98-50, September 17, 1998, GLP, unpublished. ER ref. no. 14.3	N	N	NA	Gowan
CA, 6.2.1/03	IIA, 6.1/03 Add study	Graves D.D., Reibach P.	2000	Consideration of the Difference in the Magnitude of the Residues of RH-7281 in Grapes from Supervised Field Residue Trials Compared to the 14C Grape Metabolism Study ER 14.5 Rohm and Haas unpublished Technical Report No. 34-00-83 September 11, 2000 ER ref. no. R 76.6	N	N	NA	Gowan
CA, 6.2.1/04	IIA, 6.1/04 Add study	Wolf S	2001	Determination of RH-0721 Residues in/on Grape (RAC Grape) from Field Trials in Europe (1997/1999) - to support ER 14.5 Rohm and Haas unpublished Technical Report No. 799773 February 13, 2001 ER ref. no. R 79.1	N	N	NA	Gowan
CA, 6.2.3/01	IIA, 6.2.1	██████████ ██████	1998	Robert A. Robinson, Metabolism of 14C-RH-117,281 in lactating goats, ██████████ ██ Technical Report No. 34-97-166, September 10, 1998, GLP, unpublished. ER ref. no. 16.1	Y	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 6.3.1/01	IIA, 6.3.1/01	Wais, A.	1999a	Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane /RH-117,281 75 DG Blend from field trials in Germany; 1996 Report no. 553002/649776, April 12, 1999 GLP, unpublished ER ref. no. R 66.4/R 66.5	N	N	NA	Gowan
CA, 6.3.1/02	IIA, 6.3.1/02	Wais, A.	1999b	Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane /RH-117,281 75 DG Blend from field trials in the United Kingdom; 1996 Report no. 553300/649811, April 16, 1999 GLP, unpublished ER ref. no. R 70.3/R 70.4	N	N	NA	Gowan
CA, 6.3.1/03	IIA, 6.3.1/03	Grolleau, G.	1999a	Magnitude of the residue of RH-7281 and its metabolites RH-1452 and RH-1455 in Potato Raw Agricultural Commodity. Northern and Southern France, 1996 Report no. EA960112, April 6, 1999 GLP, unpublished ER ref. no. R 63.3	N	N	NA	Gowan
CA, 6.3.1/04	IIA, 6.3.1/04	Wais, A.	1999c	Determination of residues of RH-117281 and mancozeb in/on potato (RAC tubers) following treatment with RH-7281 2F and Dithane /RH-117,281 75 DG Blend from field trials in Italy; 1996 Report no. 553103/649800, April 13, 1999 GLP, unpublished ER ref. no. R 67.5/R 67.6	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 6.3.1/05	IIA, 6.3.1/05	Wais, A.	1999d	Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane /RH-117,281 75 DG Blend from field trials in Germany; 1997 Report no. 652252, March 18, 1999 GLP, unpublished ER ref. no. R 64.4/R 64.5	N	N	NA	Gowan
CA, 6.3.1/06	IIA, 6.3.1/06	Wais, A.	1999e	Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane /RH-117,281 75 DG Blend from field trials in UK; 1997 Report no. 652263, March 23, 1999 GLP, unpublished ER ref. no. R 65.5/R 65.6	N	N	NA	Gowan
CA, 6.3.1/07	IIA, 6.3.1/07	Wais, A.	1999f	Magnitude of the residue of RH-7281 and its metabolites RH-1452 and RH-1455 in Potato Raw Agricultural Commodity. Northern and Southern France, 1997 Report no. EA970131, April 6, 1999 GLP, unpublished ER ref. no. R 64.1	N	N	NA	Gowan
CA, 6.3.1/08	IIA, 6.3.1/08	Wais, A.	1999g	Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane /RH-117,281 75 DG Blend from field trials in Italy; 1997 Report no. 652285, March 25, 1999 GLP, unpublished ER ref. no. R 65.3/R 65.4	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 6.3.1/09	IIA, 6.3.1/09	Wais, A.	1999h	Determination of residues of RH-117281 and mancozeb in/on potatoes (RAC tubers) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Greece; 1997 Report no. 652307, March 17, 1999 GLP, unpublished ER ref. no. R 64.2/R 64.3	N	N	NA	Gowan
CA, 6.3.1/10	IIA, 6.3.1/10	Wais, A.	1999i	Determination of residues of RH-117,281 and mancozeb in/on potato (RAC tubers) following treatment with Dithane/RH-117,281 75 DG Blend (8:1) and Dithane/RH-117,281 75 WP Blend (8:1) from two field trials in Germany; 1998 Report no. 688904, April 13, 1999 GLP, unpublished,ER ref. no. R 68.1/R 68.2	N	N	NA	Gowan
CA, 6.3.1/11	IIA, 6.3.1/11	Wais, A.	1999j	Determination of residues of RH-117,281 and mancozeb in/on potato (RAC tubers) following treatment with Dithane/RH-117,281 75 DG Blend (8:1) and Dithane/RH-117,281 75 WP Blend (8:1) from two field trials in UK; 1998 Report no. 688937, April 13, 1999 GLP, unpublished,ER ref. no. R 68.3/R 68.4	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 6.3.1/12	IIA, 6.3.1/12	Wais, A.	1999k	Determination of residues of RH-117,281 and mancozeb in/on potato (RAC tubers) following treatment with Dithane/RH-117,281 75 DG Blend (8:1) and Dithane/RH-117,281 75 WP Blend (8:1) from four field trials in Spain; 1998 Report no. 688926, April 13, 1999 GLP, unpublished ER ref. no. R 66.6/R 66.7	N	N	NA	Gowan
CA, 6.3.1/14	IIA, 6.3.1/14 See add. vol. April 2000	Wais, A.	2000	Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH-141,455 in/on potatoes (RAC tubers) following treatment with RH-7281/mancozeb 75WG from a field trial (semi residue decline study) in the Netherlands; 1999 Report no. 734567, January 2000 GLP, unpublished ER ref. no. R 72.5	N	N	NA	Gowan
CA, 6.3.1/15	IIA, 6.3.1/15 See add. vol. April 2000	Wais, A.	2000	Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH-141,455 in/on potatoes (RAC tubers and processing products) following treatment with RH-7281/mancozeb 75WG from a field trial (semi residue decline study) in Northern France; 1999 Report no. 734556, February 2000 GLP, unpublished ER ref. no. R 72.9	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 6.3.1/16	IIA, 6.3.1/16 See add. vol. April 2000	Wais, A.	2000	Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH-141,455 in/on potatoes (RAC tubers) following treatment with RH-7281/mancozeb 75WP from a field trial (semi residue decline study) in Northern France; 1999 Report no. 739001, March 2000 GLP, unpublished ER ref. no. R 72.4	N	N	NA	Gowan
CA, 6.3.1/17	IIA, 6.3.1/17 See add. vol. April 2000	Wais, A.	2000	Determination of residues of RH-117,281 and its metabolites RH-141,452 and RH-141,455 in/on potatoes (RAC tubers and processing products) following treatment with RH-7281/mancozeb 75WG from a field trial (semi residue decline study) in Italy; 1999 Report no. 734545, March 2000 GLP, unpublished, ER ref. no. R 73.2	N	N	NA	Gowan
CA, 6.3.2/01	IIA, 6.3.2/01	Wais, A.	1999	Determination of residues of RH-117281 and mancozeb in/on vine (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Germany, 1996 Report no. 553001/649765, April 16, 1999 GLP, unpublished ER ref. no. R 69.4/R 69.5	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 6.3.2/02	IIA, 6.3.2/02	Grolleau, G.	1999b	Magnitude of the Residue of RH-7281 and Mancozeb in Grape Raw Agricultural Commodity and of RH-7281 in Wine and Processed Fractions - Northern and Southern France - 1996 Report no. EA960110, March 15, 1999 GLP, unpublished ER ref. no. R 60.1	N	N	NA	Gowan
CA, 6.3.2/03	IIA, 6.3.2/03	Wais, A.	1999m	Determination of residues of RH-117281 and mancozeb in/on vine (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Italy, 1996 Report no. 553101/649787, April 16, 1999 GLP, unpublished ER ref. no. R 70.1/R 70.2	N	N	NA	Gowan
CA, 6.3.2/04	IIA, 6.3.2/04	Wais, A.	1999n	Determination of residues of RH-117281 and mancozeb in/on table grapes (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Italy, 1996 Report no. 553102/649798, April 16, 1999 GLP, unpublished ER ref. no. R 71.3/R 71.4	N	N	NA	Gowan
CA, 6.3.2/05	IIA, 6.3.2/05	Wais, A.	1999o	Determination of residues of RH-117281 and mancozeb in/on table grapes (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Spain, 1996 Report no. 553200/620875, April 16, 1999 GLP, unpublished ER ref. no. R 70.5/R 70.6	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 6.3.2/06	IIA, 6.3.2/06	Wais, A.	1999p	Determination of residues of RH-117281 and mancozeb in/on vine (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117281 75 DG Blend from field trials in Germany, 1997 Report no. 652241, April 16, 1999 GLP, unpublished ER ref. no. R 71.1/R 71.2	N	N	NA	Gowan
CA, 6.3.2/07	IIA, 6.3.2/07	Grolleau, G.	1999c	Magnitude of the Residue of RH-7281 and Mancozeb in Grape Raw Agricultural Commodity and of RH-7281 in Wine - Northern and Southern France - 1997 Report no. EA 970130, March 15, 1999 GLP, unpublished ER ref. no. R 62.3	N	N	NA	Gowan
CA, 6.3.2/08	IIA, 6.3.2/08	Wais, A.	1999q	Determination of residues of RH-117281 and mancozeb in/on vine (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Italy, 1997 Report no. 652274, April 14, 1999 GLP, unpublished ER ref. no. R 68.5/R 68.6	N	N	NA	Gowan
CA, 6.3.2/09	IIA, 6.3.2/09	Wais, A.	1999r	Determination of residues of RH-117281 and mancozeb in/on vine (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117281 75 DG Blend from field trials in Greece, 1997 Report no. 652296, April 14, 1999 GLP, unpublished ER ref. no. R 69.2/R 69.3	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 6.3.2/10	IIA, 6.3.2/10	Wais, A.	1999s	Determination of residues of RH-117281 and mancozeb in/on table grapes (RAC grapes) following treatment with RH-7281 2F and Dithane/RH-117,281 75 DG Blend from field trials in Italy, 1997 Report no. 660688, March 19, 1999 GLP, unpublished ER ref. no. R 65.1/R 65.2	N	N	NA	Gowan
CA, 6.3.2/11	IIA, 6.3.2/11	Wais, A.	1999t	Determination of residues of RH-117,281 and mancozeb in/on vine grapes (RAC grapes) following treatment with Dithane/RH-117,281 75 DG Blend (8:1), Dithane/RH-117,281 75 WP Blend (8:1) and RH-7281 2F Experimental fungicide from four field trials in Germany, 1998 Report no. 688893, April 13, 1999 GLP, unpublished ER ref. no. R67.2/R 67.3	N	N	NA	Gowan
CA, 6.3.2/12	IIA, 6.3.2/12	Grolleau, G.	1999d	Magnitude of the Residue of RH-7281 and Mancozeb in Grape Raw Agricultural Commodity and of RH-7281 in Wine - Northern and Southern France - 1998 Report no. EA 980117, March 15, 1999 GLP, unpublished ER ref. no. R 63.1	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 6.3.2/13	IIA, 6.3.2/13	Wais, A.	1999u	Determination of residues of RH-117,281 and mancozeb in/on vine grapes (RAC grapes) following treatment with Dithane/RH-117,281 75 DG Blend (8:1) and Dithane/RH-117,281 75 WP Blend (8:1) from two field trials in Italy, 1998 Report no. 688961, April 12, 1999 GLP, unpublished ER ref. no. R 66.2/R 66.3	N	N	NA	Gowan
CA, 6.3.2/14	IIA, 6.3.2/14	Wais, A.	1999v	Determination of residues of RH-117,281 and mancozeb in/on vine grapes (RAC grapes) following treatment with Dithane/RH-117,281 75 DG Blend (8:1) from two field trials in Spain, 1998 Report no. 688915, April 14, 1999 GLP, unpublished ER ref. no. R 67.4	N	N	NA	Gowan
CA, 6.3.2/15	IIA, 6.3.2/15	Wais, A.	1999w	Determination of residues of RH-117,281 and mancozeb in/on table grapes (RAC grapes) following treatment with Dithane/RH-117,281 75 DG Blend (8:1) from two field trials in Spain, 1998 Report no. 693674, April 12, 1999 GLP, unpublished ER ref. no. R 66.1	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 6.3.2/16	IIA, 6.3.2/16	Wais, A.	1999x	Determination of residues of RH-117,281 and mancozeb in/on table grapes (RAC grapes) following treatment with Dithane/RH-117,281 75 DG Blend (8:1) from two field trials in Portugal, 1998 Report no. 688948, April 14, 1999 GLP, unpublished ER ref. no. R 69.1	N	N	NA	Gowan
CA, 6.3.2/18	IIA, 6.3.2/18 See add. vol. April 2000	Wais, A.	2000	Determination of residues of RH-117,281 and mancozeb in/on grapes (RAC grapes) following treatment with RH-7281/mancozeb 75WG from a field trial in Germany, 1999 Report no. 734578, February 2000 GLP, unpublished ER ref. no. R 72.8	N	N	NA	Gowan
CA, 6.3.2/19	IIA, 6.3.2/19 See add. vol. April 2000	Grolleau, G.	2000	Magnitude of the Residue of RH-7281/mancozeb 76.25WG in grapes raw agricultural commodity - Northern France - 1999 Report no. EA990175, March 2000 GLP, unpublished ER ref. no. R 73.3	N	N	NA	Gowan
CA, 6.3.2/20	IIA, 6.3.2/20 See add. vol. April 2000	Grolleau, G.	2000	Magnitude of the Residue of RH-7281/mancozeb 76.25WG in grapes raw agricultural commodity - Southern France - 1999 Report no. EA990176, March 2000 GLP, unpublished ER ref. no. R 73.4	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 6.5.1/01	IIA, 6.5.1	Mamouni, A	1998	Mamouni, A, 14C-RH-117281: Vinification Study, RCC Ltd., Rohm and Haas Technical Report No. 34-98-151, December 3, 1998, GLP, unpublished. ER ref. no. 30.17	N	N	NA	Gowan
IIA, 6.5.3/01	IIA, 6.5.2.2	Graves, DD	1998	Graves, D.D., RH-117281 80W and 2F Residue Studies in Grapes and Grape Process Fractions 1996 and 1997 Trials, Agri Business Group, Inc., Enviro-Test Laboratories, McKenzie Laboratories, California State University at Fresno, Rohm and Haas Technical Report No. 34-98-154, November 24, 1998, GLP, unpublished. ER ref. no. R 62.1	N	N	NA	Gowan
IIA, 6.6.1/01	IIA, 6.6/01	Kim-Kang, H	1998	Kim-Kang, H., 14C-RH-117,281: Confined Rotational Crop Study, XenoBiotic Laboratories, Inc., Rohm and Haas Technical Report No. 34-98-144, December 4, 1998, GLP, unpublished. ER ref. no. R 60.2	N	N	NA	Gowan

A.8 ENVIRONMENTAL FATE AND BEHAVIOUR

Zoxamide:

New studies

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA, 7.1.2.1.1	Callow, B. and Hilton, H.	2013a	Determination of rates of decline for zoxamide and its metabolites in soil according to the guidance within the FOCUS Kinetics Guidance Document Exponent International Ltd, Harrogate, HG2 8E, UK Report No. 0907598.UK0 EWC 0021 Not GLP, Not published.	N	Y	Data required to meet new guidance	Gowan
KCA, 7.1.2.1.2	Callow, B. and Hilton, H.	2013a	Determination of rates of decline for zoxamide and its metabolites in soil according to the guidance within the FOCUS Kinetics Guidance Document Exponent International Ltd, Harrogate, HG2 8E, UK Report No. 0907598.UK0 EWC 0021 Not GLP, Not published.	N	Y	Data required to meet new guidance	Gowan
KCA, 7.1.2.1.2	Van den Bosch, M.M.H.	2013a	Determination of the aerobic degradation rate of RH-141,455 in soil. WIL Research Europe B.V., Hambakenwetering 7 5231 DD 's-Hertogenbosch, The Netherlands Project 500850 GLP, Not published	N	Y	Data required to meet new guidance	Gowan
KCA, 7.1.3.1.2	Van den Bosch, M.M.H.	2013b	Adsorption / desorption of RH-141,455 on three soils WIL Research Europe B.V., Hambakenwetering 7 5231 DD 's-Hertogenbosch, The Netherlands Project 500851 GLP, not published	N	Y	Data required to meet new guidance	Gowan
KCA,	Van den Bosch,	2014	Aerobic mineralisation of zoamide in surface water	N	Y	Data required to meet	Gowan

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
7.2.2.2	M.M.H.		WIL Research Europe B.V., Hambakenwetering 7 5231 DD 's-Hertogenbosch, The Netherlands Project 503495 (DRAFT Interim Report) GLP, not published			new requirement.	
KCA, 7.2.2.3	Callow, B. and Hilton, H.	2013b	Determination of rates of decline for zoxamide and its metabolites, in sediment-water studies according to the guidance within the FOCUS Kinetics Guidance Document Exponent International Ltd, Harrogate, HG2 8E, UK Report No: 0907598.UK0/EWC0020 Not GLP, Not published.	N	Y	Data required to meet new guidance	Gowan

Studies relied on for the first inclusion of zoxamide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) 1107/2009

Data point	Annex point (old)	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
CA, 7.1.1.1	IIA, 7.1.1.1.1	Burgener, A	1998a	14C-RH-117281: Rate of degradation and metabolism in four soils incubated under aerobic conditions, RCC Umweltchemie Ag, Rohm and Haas Technical Report No. 34-98-45, September 17, 1998, GLP, unpublished. ER ref. no. 18.2	N	N	NA	Gowan
CA, 7.1.1.1	IIA, 7.1.1.1.1	Smalley, J, Reynolds, JL	1997	Aerobic soil metabolism of [14C]-RH-117281 Fungicide, XenoBiotic Laboratories, Inc., Rohm and Haas Technical Report No. 34-96-07, June 26, 1997, GLP, unpublished. ER ref. no. 6.13	N	N	NA	Gowan
CA, 7.1.1.2	IIA, 7.1.1.1.2.1	Kim-Kang, H	1997	Anaerobic soil metabolism of [14C]RH-117281, XenoBiotic Laboratories, Inc., Rohm and Haas	N	N	NA	Gowan

Data point	Annex point (old)	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
				Technical Report No. 34-97-43, April 9, 1997, GLP, unpublished. ER ref. no. 8.16				
CA, 7.1.1.2	IIA, 7.1.1.1.2.1	Volkel, W	1998a	14C-RH-117281: degradation in one soil incubated under anaerobic conditions, RCC Umweltchemie Ag, Rohm and Haas Technical Report No. 34-98-46, September 3, 1998, GLP, unpublished. ER ref. no. 4.5	N	N	NA	Gowan
CA, 7.1.1.3	IIA, 7.1.1.1.2.2	Reynolds, JL	1997	Soil photolysis of [14C]RH-117281, XenoBiotic Laboratories, Inc., Rohm and Haas Technical Report No. 34-96-214, July 31, 1997, GLP, unpublished. ER ref. no. 10.2	N	N	NA	Gowan
CA, 7.1.2.1.1	IIA, 7.1.1.2.1	Burgener, A	1998	14C-RH-117281: Rate of degradation and metabolism in four soils incubated under aerobic conditions, RCC Umweltchemie Ag, Rohm and Haas Technical Report No. 34-98-45, September 17, 1998, GLP, unpublished. ER ref. no. 18.2	N	N	NA	Gowan
CA, 7.1.2.1.1	IIA, 7.1.1.2.1	Smalley, J, Reynolds, JL	1997	Aerobic soil metabolism of [14C]-RH-117281 Fungicide, XenoBiotic Laboratories, Inc., Rohm and Haas Technical Report No. 34-96-07, June 26, 1997, GLP, unpublished. ER ref. no. 6.13	N	N	NA	Gowan
CA, 7.1.2.1.3	IIA, 7.1.1.2.1	Kim-Kang, H	1997	Anaerobic soil metabolism of [14C]RH-117281, XenoBiotic Laboratories, Inc., Rohm and Haas Technical Report No. 34-97-43, April 9, 1997, GLP, unpublished. ER ref. no. 8.16	N	N	NA	Gowan
CA, 7.1.2.1.3	IIA, 7.1.1.2.1	Volkel, W	1998a	14C-RH-117281: degradation in one soil incubated under anaerobic conditions, RCC Umweltchemie Ag, Rohm and Haas Technical Report No. 34-98-46, September 3, 1998, GLP, unpublished. ER ref. no. 4.5	N	N	NA	Gowan
CA, 7.1.3.1.1	IIA, 7.1.2.1	Shelby, DJ	1996	Adsorption and desorption of RH-117281 to soil, Ricerca, Inc., Rohm and Haas Technical Report No.	N	N	NA	Gowan

Data point	Annex point (old)	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
				34-96-01, February 9, 1996, GLP, unpublished. ER ref. no. 7.2				
CA, 7.1.3.1.2	IIA, 7.1.2.2	Reynolds, JL	1998a	Adsorption and desorption of 14C-RH-24549 in three soils, XenoBiotic Laboratories, Inc., Rohm and Haas Technical Report No. 34-98-53, October 14, 1998, GLP, unpublished. ER ref. no. 18.1	N	N	NA	Gowan
CA, 7.1.3.1.2	IIA, 7.1.2.2	Volkel, W.	1998b	Adsorption/Desorption of RH-127450 on Three Soils, RCC Ltd., Rohm and Haas Technical Report No. 34-98-54, December 15, 1998, GLP, unpublished. ER ref. no. 25.4	N	N	NA	Gowan
CA, 7.1.3.1.2	IIA, 7.1.2.2	Volkel, W.	1998c	Determination of the Adsorption Coefficient of 14C-RH-163353 on Soil and its Octanol/Water Partition Coefficient Using High Performance Liquid Chromatography (HPLC), RCC Ltd., Rohm and Haas Technical Report No. 34-98-55, November 9, 1998, GLP, unpublished. ER ref. no. 31.4	N	N	NA	Gowan
CA, 7.1.3.1.2	IIA, 7.1.2.2	Volkel, W.	2000	Adsorption/Desorption of RH-163,353 In Three Soils, RCC Ltd, Rohm and Haas Technical Report No. 34-00-06, January 31, 2000, GLP, unpublished. ER ref. no. 40.7	N	N	NA	Gowan
CA, 7.1.4.1.2	IIA, 7.1.3.2	Volkel, W	1998d	14C-RH-117281: Leaching characteristics of aged residues in one soil, RCC Umweltchemie Ag, Rohm and Haas Technical Report No. 34-98-48, September 15, 1998, GLP, unpublished. ER ref. no. 4.4	N	N	NA	Gowan
CA, 7.2.1.1	IIA, 7.2.1.1	Reynolds, JL	1998b	Hydrolysis of [14C]RH-117281 in Water at pH 4, 7, and 9, XenoBiotic Laboratories, Inc., Rohm and Haas Technical Report Number 34-98-39, September 29, 1998, GLP, unpublished. ER ref. no. 15.2	N	N	NA	Gowan
CA, 7.2.1.1	IIA, 7.2.1.1	Chong, BP	1998	RH-117281 Fungicide: Hydrolysis rates of relevant degradation products, Rohm and Haas Technical	N	N	NA	Gowan

Data point	Annex point (old)	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
				Report No. 34-98-26, September 30, 1998, GLP not relevant, unpublished. ER ref. no. 30.16				
CA, 7.2.1.2	IIA, 7.2.1.2	Smalley, J and Reynolds, JL	1998	Aqueous photolysis of [14C]-RH-117281, XenoBiotic Laboratories, Inc., Rohm and Haas Technical Report No. 34-96-215, May 12, 1998, GLP, unpublished. ER ref. no. 12.5	N	N	NA	Gowan
CA, 7.2.2.1	IIA, 7.2.1.3.1	Barnes, SP, Nave, V	1998	RH-117281 - Assessment of ready biodegradability: modified Sturm test, Huntingdon Life Sciences Limited, Rohm and Haas Report No. 98RC-1028, December 14, 1998, GLP, unpublished. ER ref. no. 29.1	N	N	NA	Gowan
CA, 7.2.2.3	IIA, 7.2.1.3.2	Morgenroth, U	1998	14C-RH-117281: Degradation and metabolism in aquatic systems, RCC Umweltchemie Ag, Rohm and Haas Technical Report No. 34-98-47, September 15, 1998, GLP, unpublished. ER ref. no. 4.3	N	N	NA	Gowan
CA, 7.3.2	IIA, 7.2.2	Burgener, A	1998b	Investigation of the volatilization of 14C-RH-117281 from soil and dwarf runner bean, RCC Ltd, Rohm and Haas Technical Report No. 34-98-132, August 24, 1998, GLP, unpublished. ER ref. no. 14.2	N	N	NA	Gowan

Zoxium 240 SC:**New studies**

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCP 9.2.4.1	Callow B. and Montesano V.	2015a	Predicted environmental concentrations of Zoxamide and its metabolites in groundwater in the EU using the FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models. Exponent International Ltd Harrogate, UK Report No: 0907598.UK0-9393 Not GLP, Not published	N	Y	New modelling required to comply with current guidance.	Gowan
KCP 9.2.5	Callow B. and Montesano V.	2014	Predicted environmental concentrations of zoxamide in surface water in the EU using the FOCUS surface water scenarios. Exponent International Ltd Harrogate, UK Report No: 0907598.UK0-4493 Not GLP, Not published	N	Y	New modelling required to comply with current guidance	Gowan
KCP 9.2.5	Callow B. and Montesano V.	2015b	Predicted environmental concentrations of zoxamide in surface water in the EU using the FOCUS surface water scenarios – Additional simulations. Exponent International Ltd Harrogate, UK Report No: 0907598.UK0-7794 Not GLP, Not published	N	Y	New modelling required to comply with current guidance	Gowan

Studies relied on for the first inclusion of zoxamide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) 1107/2009

None.

A.9 ECOTOXICOLOGY

Zoxamide:

New studies

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA, 8.2.4.2/01	Roberts, C.A. and Swigert, J.P	1997	RH-117,281 Technical: A 96-Hour-Flow Through Acute Toxicity Test with the Saltwater Mysid (<i>Mysidopsis bahia</i>) Wildlife International Ltd 898 Commerce Drive, Eastern Maryland 21601, USA. Report Number: 95RC-0275 GLP, Not published	N	Y	Data were generated to support registration in the US and were not available or required for first Annex I inclusion	Gowan
KCA, 8.2.5.2/01	Drottar, K.R. and Krueger, H.O.	1998	RH-117,281 Technical: A flow-through life-cycle toxicity test with the saltwater mysid (<i>Mysidopsis bahia</i>) Wildlife International Ltd 898 Commerce Drive, Eastern Maryland 21601, USA. Report Number: 97RC-0077 GLP, Not published	N	Y	Data were generated to support registration in the US and were not available or required for first Annex I inclusion	Gowan
KCA, 8.3.1.2/01	Schmitzer, S. and Ehmke, A.	2014	Chronic oral toxicity test of Zoxium 240 SC on the honey bee (<i>Apis mellifera</i>) in the laboratory. Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany Project 80052136 GLP, Not published	N	Y	New data requirement	Gowan

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCA, 8.3.1.3/01	Schmitzer, S.	2014	Effects of Zoxium 240 SC on honey bee brood. Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany Project 80051031 GLP, Not published	N	Y	New data requirement	Gowan
KCA, 8.3.1.4/01	Schmitzer, S.	2014	Effects of Zoxium 240 SC on honey bee brood. Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany Project 80051031 GLP, Not published	N	Y	New data requirement	Gowan

Studies relied on for the first inclusion of zoxamide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) 1107/2009

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 8.1.1.1/01	IIA, 8.1.1/01	██████████ ██████████	1997a	RH-117,281 Technical: 14-day acute oral LD50 study in bobwhite quail. ██ Project No. RH117BWLD-595. ER Ref No: 2.6 US Ref No: 94RC-0240 GLP, Unpublished	Y	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 8.1.1.2/01	IIA, 8.1.2/01	[REDACTED]	1997b	RH-117,281 Technical: 8-day acute dietary LC50 study in bobwhite quail. [REDACTED] Project No. RH117BWLC-395. ER Ref No: 2.4 US Ref No: 94RC-0242 GLP, Unpublished	Y	N	NA	Gowan
CA, 8.1.1.2/02	IIA, 8.1.2/02	[REDACTED]	1997c	RH-117,281 Technical: 8-day acute dietary LC50 study in mallard ducklings. [REDACTED], Project No. RH117MDLC-395. ER Ref No: 2.5 US Ref No: 94RC-0241 GLP, Unpublished	Y	N	NA	Gowan
CA, 8.1.1.3/01	IIA, 8.1.3/01	[REDACTED]	1998	Avian reproduction study of RH-117,281 Technical with northern bobwhite. [REDACTED] Project ID No. RH7281BW-97-2 ER Ref No: 28.2 US Ref No: 97RC-0081 GLP, Unpublished	Y	N	NA	Gowan
CA, 8.1.1.3/02	IIA, 8.1.3/02	[REDACTED]	1999	RH-117,281 technical: A reproduction study with the mallard (<i>Anas platyrhynchos</i>). [REDACTED] Project No. 129-164 ER Ref No: 33.13 US Ref No: 98RC-0166 GLP, Unpublished	Y	N	NA	Gowan
CA, 8.2.1/01	IIA, 8.2.1/01	[REDACTED]	1995a	Acute flow-through toxicity of RH-117,281 Technical to rainbow trout (<i>Oncorhynchus mykiss</i>). [REDACTED] Report No. 41681. ER Ref No: 2.1 US Ref No: 94RC-0078 GLP, Unpublished	Y	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 8.2.1/02	IIA, 8.2.1/02	[REDACTED]	1995b	Acute flow-through toxicity of RH-117,281 Technical to bluegill (<i>Lepomis macrochirus</i>). [REDACTED] Report No. 41682. ER Ref No: 4.10 US Ref No: 94RC-0080 GLP, Unpublished	Y	N	NA	Gowan
CA, 8.2.1/03 (8.2.2.3 /01)	IIA, 8.2.1/03 (8.2.2.3 /01)	[REDACTED]	1998d	RH-117,281 Technical: A flow-through life-cycle toxicity test with the fathead minnow (<i>Pimephales promelas</i>). [REDACTED] Project No. 129A-141 ER Ref No: 17.4 US Ref No: 97RC-0079 GLP, Unpublished	Y	N	NA	Gowan
CA, 8.2.1/04	IIA, 8.2.1/04	[REDACTED]	1998a	RH-117,281 Technical: A 96-hour flow-through acute toxicity test with the zebra fish (<i>Brachydanio rerio</i>). [REDACTED] Project No. 129A-150 ER Ref No: 12.11 US Ref No: 97RC-0134 GLP, Unpublished	Y	N	NA	Gowan
CA, 8.2.1/05	IIA, 8.2.1/05	[REDACTED]	1997	RH-117,281 Technical: a 96-hour flow-through acute toxicity test with the sheepshead minnow (<i>Cyprinodon variegatus</i>). [REDACTED] Project No. 129A-135. ER Ref No: 8.1 US Ref No: 95RC-0274 GLP, Unpublished	Y	N	NA	Gowan
CA, 8.2.1/06	IIA, 8.2.1/06	[REDACTED]	1998a	Acute toxicity of RH-127,450 to the rainbow trout (<i>Oncorhynchus mykiss</i>) in a range-finding test under static conditions. [REDACTED] Report No. 44667 ER Ref No: 17.5 US Ref No: 98RC-0095 GLP, Unpublished	Y	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 8.2.1/07	IIA, 8.2.1/07	[REDACTED]	2002	Zoxamide Metabolite RH-139,432 - Acute Toxicity to Rainbow Trout (<i>Oncorhynchus mykiss</i>) under static conditions [REDACTED] Study Number 12550.6290 CA 1 ER Ref. 47.4 GLP, Not published	Y	N	NA	Gowan
CA, 8.2.2.1/01	IIA, 8.2.2.2/01	[REDACTED]	1996	Early life-stage toxicity of RH-117,281 Technical to rainbow trout (<i>Oncorhynchus mykiss</i>) under flow-through conditions. [REDACTED] Report No. 42400. ER Ref No: 7.1 US Ref No: 94RC-00239 GLP, Unpublished	Y	N	NA	Gowan
CA, 8.2.2.2/01 (8.2.1/03)	IIA, 8.2.2.3/01 (8.2.1/03)	[REDACTED]	1998d	RH-117,281 Technical: A flow-through life-cycle toxicity test with the fathead minnow (<i>Pimephales promelas</i>). [REDACTED] Project No. 129A-141 ER Ref No: 17.4 US Ref No: 97RC-0079 GLP, Unpublished	Y	N	NA	Gowan
CA, 8.2.2.3/01	IIA, 8.2.3/01	[REDACTED]	1998	Uptake, Depuration, Bioconcentration and Metabolism of 14C-RH-117,281 in Bluegill Sunfish Under Flow Through Test Conditions, [REDACTED] [REDACTED] Technical Report No. 34-98-145, ER Ref. No. 15.1, September 15, 1998, GLP, unpublished.	Y	N	NA	Gowan
CA, 8.2.3/03	IIA, 8.2.3./03	Tognucci, A	1998a	Tognucci, A, Determination of the partition coefficient (n-octanol/water) of RH-127450, RCC Ltd, Rohm and Haas Technical Report No. 34-98-165, ER Ref. No. 18.3, October 12, 1998.	N	N	NA	Gowan
CA, 8.2.3/04	IIA, 8.2.3./04	Tognucci, A	1998b	Tognucci, A, Determination of the partition coefficient (n-octanol/water) of RH-139432, RCC Ltd, Rohm and Haas Technical Report No. 34-98-53, ER Ref. No. 31.3, October 22, 1998 .	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 8.2.4.1/01	IIA, 8.2.4/01	Sword, M.C., Gardner, C.	1995c	Acute flow-through toxicity of RH-117,281 Technical to <i>Daphnia magna</i> . ABC Laboratories Report No. 41683. ER Ref No: 5.1 US Ref No: 94RC-0081 GLP, Unpublished	N	N	NA	Gowan
CA, 8.2.4.1/02	IIA, 8.2.4/02	Rhodes, J.E., Williams, S.	1998b	Acute toxicity of RH-127,450 to <i>Daphnia magna</i> in a range-finding test under static conditions. ABC Study No. 44666 ER Ref No: 16.4 US Ref No: 98RC-0096 GLP, Unpublished	N	N	NA	Gowan
CA, 8.2.4.1/03	IIA, 8.2.4/03	Caferella, M.A	2002	Zoxamide Metabolite RH-139,432 - Acute Toxicity to Daphnids (<i>Daphnia magna</i>) under static conditions Springborn Smithers Laboratories, Study Number 12550.6289 ER Ref. 47.3 GLP, Not published	N	N	NA	Gowan
CA, 8.2.5.1/01	IIA, 8.2.5/01	Murrell, H., Rhodes, J.E., Stewart, S.	1997	Chronic toxicity of RH-117,281 Technical to <i>Daphnia magna</i> under flow-through test conditions. ABC Laboratories Report No. 43209. ER Ref No: 6.11 US Ref No: 95RC-0273 GLP, Unpublished	N	N	NA	Gowan
CA, 8.2.5.3/01	IIA, 8.2.7/01	van der Kolk, J.	1998a	RH-117,281: Chronic effects on midge larvae (<i>Chironomus riparius</i>) in a water/sediment system. Springborn Laboratories (Europe)AG Report No. 97-063-1007 ER Ref No: 13.3 US Ref No: 97RC-0083 GLP, Unpublished	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 8.2.6.1/01	IIA, 8.2.6/01	Ziegler, T.A., Stewart, S.	1996	Acute toxicity of RH-117,281 Technical to <i>Selenastrum capricornutum</i> Printz. ABC Laboratories Report No. 42399. ER Ref No: 1.1 US Ref No: 94RC-0238 GLP, Unpublished	N	N	NA	Gowan
CA, 8.2.6.1/02	IIA, 8.2.6/02	Drottar, K.R., Sutherland, C.A., Krueger, H.O.	1998e	RH-117,281 Technical: A 96-hour toxicity test with the freshwater alga (<i>Anabaena flos-aquae</i>). Wildlife International, Ltd. Project No. 129A-154 ER Ref No: 13.2 US Ref No: 97RC-0130 GLP, Unpublished	N	N	NA	Gowan
CA, 8.2.6.1/03	IIA, 8.2.6/03	Drottar, K.R., Sutherland, C.A., Krueger, H.O.	1998f	RH-117,281 Technical: A 96-hour toxicity test with the freshwater alga (<i>Scenedesmus subspicatus</i>). Wildlife International, Ltd. Project No. 129A-151 ER Ref No: 13.4 US Ref No: 97RC-0133 GLP, Unpublished	N	N	NA	Gowan
IIA, 8.2.6.1/04	IIA, 8.2.6/04	Drottar, K.R., Sutherland, C.A., Krueger, H.O.	1998g	RH-117,281 Technical: A 96-hour toxicity test with the freshwater diatom (<i>Navicula pelliculosa</i>). Wildlife International, Ltd. Project No. 129A-153 ER Ref No: 13.5 US Ref No: 97RC-0131 GLP, Unpublished	N	N	NA	Gowan
CA, 8.2.6.1/05	IIA, 8.2.6/05	Drottar, K.R., Krueger, H.O.	1998c	RH-117,281 Technical: A 96-hour toxicity test with the marine diatom (<i>Skeletonema costatum</i>) Wildlife International, Ltd. Project No. 129A-152 ER Ref No: 12.10 US Ref No: 97RC-0132 GLP, Unpublished	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 8.2.6.1/06	IIA, 8.2.6/06	Ward, S.C., Murdock, C.W.	1998	Toxicity of RH-117,281 2F (240SC) to <i>Selenastrum capricornutum</i> Printz ABC Laboratories Report No. 44196 ER Ref No: 14.6 US Ref No: 97RC-0094 GLP, Unpublished	N	N	NA	Gowan
CA, 8.2.6.1/07	IIA, 8.2.6/07	Rhodes, J.E., Williams, S.	1998c	Acute toxicity of RH-127,450 to the green alga, <i>Selenastrum capricornutum</i> Printz ABC Laboratories Report No. 44665 ER Ref No: 28.3 US Ref No: 98RC-0097 GLP, Unpublished	N	N	NA	Gowan
CA, 8.2.6.1/08	IIA, 8.2.6/08	Rhodes, J.E., Williams, S.	1999	Acute toxicity of RH-163,353 to <i>Selenastrum capricornutum</i> Printz in a range-finding test under static conditions. ABC Laboratories Report No. 45164 ER Ref No: 36.1 US Ref No: 99RC-0023 GLP, Unpublished	N	N	NA	Gowan
CA, 8.2.6.1/09		Hoberg, J.R	2002	Zoxamide Metabolite RH-139,432 - Toxicity to Freshwater Green Algae, <i>Scenedesmus subspicatus</i> Springborn Smithers Laboratories Study Number 12550.6288 CA 2 ER Ref. 47.5 GLP, Not published	N	N	NA	Gowan
CA, 8.2.7/01	IIA, 8.2.8/01	Drottar, K.R., Krueger, H.O.	1998b	RH-117,281 Technical: A 14-day static-renewal toxicity test with duckweed (<i>Lemna gibba</i> G3). Wildlife International, Ltd. Report No. 129A-147. ER Ref No: 12.7 US Ref No: 97RC-0080 GLP, Unpublished	N	N	NA	Gowan
CA, 8.3.1.1.1/01	IIA, 8.3.1.1/01	Kirkland, R.L.	1993	Acute contact toxicity of RH-117,281 Technical to honey bees. Bio Research Study No. 109-93. ER Ref No: 12.6 US Ref No: 92RC-0235 GLP, Unpublished	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 8.3.1.1.2/01	IIA, 8.3.1.1/02	Engelhard, E.K.	1998a	RH-117,281 2F (240SC): Laboratory oral and contact test with the honeybee, <i>Apis mellifera</i> . Springborn Laboratories (Europe) AG Report No. 97-066-1007. ER Ref No: 11.6 US Ref No: 97RC-0095 GLP, Unpublished	N	N	NA	Gowan
CA, 8.3.2.1/01	IIA, 8.3.2/01	Engelhard, E.K.	1998b	RH-117,281 2F (240SC): Laboratory acute toxicity test with the parasitic wasp, <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae). Springborn Laboratories (Europe) AG Report No. 97-062-1007. ER Ref No: 11.8 US Ref No: 97RC-0106 GLP, Unpublished	N	N	NA	Gowan
CA, 8.3.2.2/01	IIA, 8.3.2/02	Engelhard, E.K.	1998c	RH-117,281 2F (240SC): Laboratory toxicity test with the predacious mite, <i>Typhlodromus pyri</i> Scheuten (Acari: Phytoseiidae). Springborn Laboratories (Europe) AG Report No. 97-070-1007. ER Ref No: 11.3 US Ref No: 97RC-0105 GLP, Unpublished	N	N	NA	Gowan
CA, 8.3.2.2/02	IIA, 8.3.2/03	Engelhard, E.K.	1998d	RH-117,281 2F (240SC): Laboratory toxicity test with the predacious mite, <i>Amblyseius andersoni</i> Chant (Acari: Phytoseiidae). Springborn Laboratories (Europe) AG Report No. 97-075-1007. ER Ref No: 11.7 US Ref No: 97RC-0111 GLP, Unpublished	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 8.3.2.2/03	IIA, 8.3.2/04	Engelhard, E.K.	1998e	RH-117,281 2F (240SC): Laboratory toxicity test with the spiders, <i>Pardosa sp.</i> (Araneae: Lycosidae). Springborn Laboratories (Europe) AG Report No. 97-059-1007. ER Ref No: 11.9 US Ref No: 97RC-0107 GLP, Unpublished	N	N	NA	Gowan
CA, 8.3.2.2/04	IIA, 8.3.2/05	Engelhard, E.K.	1998f	RH-117,281 2F (240SC): Laboratory acute toxicity test with the ground beetle, <i>Poecilus cupreus L.</i> (Coleoptera: Carabidae). Springborn Laboratories (Europe) AG Report No. 97-064-1007. ER Ref No: 11.2 US Ref No: 97RC-0108 GLP, Unpublished	N	N	NA	Gowan
CA, 8.3.2.2/05	IIA, 8.3.2/06	Engelhard, E.K.	1998g	RH-117,281 2F (240SC): Laboratory toxicity test with the green lacewing, <i>Chrysoperla carnea</i> Steph. (Neuroptera: Chrysopidae). Springborn Laboratories (Europe) AG Report No. 97-068-1007. ER Ref No: 11.11 US Ref No: 97RC-0109 GLP, Unpublished	N	N	NA	Gowan
CA, 8.3.2.2/06	IIA, 8.3.2/07	Engelhard, E.K.	1998h	RH-117,281 2F (240SC): Laboratory contact toxicity test with the predator, <i>Orius insidiosus</i> (Heteroptera: Anthrenidae). Springborn Laboratories (Europe) AG Report No. 97-077-1007. ER Ref No: 11.10 US Ref No: 97RC-0110 GLP, Unpublished	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 8.4.1/01	IIA, 8.4.1/01	Downing, J.	1995	RH-117,281 Technical: toxicity to earthworm (<i>Eisenia fetida</i>). ABC Laboratories Report No. 42398. ER Ref No: 5.2 US Ref No: 94RC-0237 GLP, Unpublished	N	N	NA	Gowan
CA, 8.4.1/02	IIA, 8.4.1/02 See add. vol. April 2000	Bryan, R.L., Porch, J.R., Krueger, H.O.	2000	RH-127,450 Technical: an acute toxicity study with the earthworm in an artificial soil substrate. Wildlife International, Ltd., Easton, MD, USA, Project No. 129-173, March 7, 2000 ER Ref No. 41.5 US Ref No. 99RC-0282 GLP, unpublished	N	N	NA	Gowan
CA, 8.4.1/01	IIA, 8.4.2/01	Nienstedt, K.	1999	A chronic toxicity and reproduction test exposing the earthworm <i>Eisenia fetida</i> to RH-117,281 Technical material in OECD artificial soil, based on the BBA-guideline VI, 2-2 (1994) and the ISO-draft (ISO/DIS 11268-2) Springborn Laboratories (Europe) AG Report No. 99-092-1007 ER Ref No: 34.1 US Ref No: 98RC-0181 GLP, Unpublished	N	N	NA	Gowan
CA, 8.4.1/02	IIA 8.4.2/02 Add. Vol. March 2001	K.M Niesnstedt	2001	Effects of RH-7281 Technical Applied On Natural Soil On The Cocoon And Juvenile Production Of The Earthworm <i>Eisenia fetida</i> Springborn Laboratories (Europe) AG - Switzerland, February 9, 2001. ER Ref No. 45.2 US Ref. No. 00RC-0209, GLP, unpublished	N	N	NA	Gowan
CA 8.4.2/03	IIA 8.4.2/03 Add. study	Young D. H.	2000	Evaluation of the Biological Activity of the RH-117281 Metabolites RH-24549, 127450 and 163353. Rohm and Haas Unpublished report US Ref. DIS-00-281, ER Ref. 44.10	N	N	NA	Gowan

Data point	Annex point (Old)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
CA, 8.5/01	IIA, 8.5/01	van der Kolk, J.	1998b	RH-117,281 Technical: Determination of the effects on soil microflora activity. Springborn Laboratories (Europe) AG # 97-060-1007. ER Ref No: 14.1 US Ref No: 97RC-0084 GLP, Unpublished	N	N	NA	Gowan
CA, 8.5/02	IIA, 8.5/02	Van der Kolk, J	2000	RH-117-281 technical: Determination of the effects on nitrogen transformation by Microflora in soil. Rohm and Haas Rept. 00RC-0085 ER Ref 44.12 GLP, Not published	N	N	NA	Gowan
CA, 8.6/01	IIA, 8.6/01	Nunez, M.V.	1998a	Greenhouse phytotoxicity tests with RH-7281 2F. Rohm and Haas Report No. 98R-1092 ER Ref No: 28.4 US Ref No: 98R-1092 GLP, Unpublished	N	N	NA	Gowan
CA, 8.6/02	IIA, 8.6/02	Nunez, M.V.	1998b	Greenhouse crop phytotoxicity tests with RH-117281 2F. Rohm and Haas Report No. 98R-1114 ER Ref No: 28.5 US Ref No: 98R-1114 GLP, Unpublished	N	N	NA	Gowan
CA, 8.6/03	IIA, 8.6/03	Sames, B.A.	1998	Insecticidal screening report - prescreen insecticidal activity with RH-117,281; Primary screening activity per RH-117281. Rohm and Haas Report No. 98R-1113 ER Ref No: 28.6 US Ref No: 98R-1113 GLP, Unpublished	N	N	NA	Gowan
CA, 8.8/01		Heim, D and Heim, L	2002	Activated Sludge, Respiration Inhibition Test of Zoxamide Dow AgroSciences Report GH-C 5421 CA 3 ER Ref. 47.2 GLP, Not published	N	N	NA	Gowan

Zoxium 240 SC:**New studies**

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCP, 10.2.1.1/01	██████████	2010	GOW 008: Acute toxicity to zebra fish (<i>Danio rerio</i>) in a 96-hour study under static exposure. ████████████████████ GLP Unpublished report.	Y	Y	Data to support new representative formulation	Gowan
KCP, 10.2.1.2/01	Mantilacci S.	2010	Acute toxicity of product GOW008 on <i>Daphnia magna</i> in a 48-hour immobilization test under static exposure. Biotechnologie BT srl GLP Unpublished report.	Y	Y	Data to support new representative formulation	Gowan
KCP, 10.3.1.2/01	Schmitzer, S. and Ehmke, A.	2014	Chronic oral toxicity test of Zoxium 240 SC on the honey bee (<i>Apis mellifera</i>) in the laboratory. Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany Project 80052136 GLP, Not published	N	Y	New data requirement	Gowan
KCP, 10.3.1.3/01	Schmitzer, S.	2014	Effects of Zoxium 240 SC on honey bee brood. Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany Project 80051031 GLP, Not published	N	Y	New data requirement	Gowan

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCP, 10.3.1.4/01	Schmitzer, S.	2014	Effects of Zoxium 240 SC on honey bee brood. Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany Project 80051031 GLP, Not published	N	Y	New data requirement	Gowan

Studies relied on for the first inclusion of zoxamide in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) 1107/2009

Data point	Annex point (Original dossier)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
KCP, 10.2.1.3/01 KCA, 8.2.6.1/06	IIA, 8.2.6/06	Ward, S.C., Murdock, C.W.	1998	Toxicity of RH-117,281 2F (240SC) to <i>Selenastrum capricornutum</i> Printz ABC Laboratories Report No. 44196 ER Ref No: 14.6 US Ref No: 97RC-0094 GLP, Unpublished	N	N	NA	Gowan
KCP, 10.3.1.1.1/01 KCP, 10.3.1.1.2 /01 KCA, 8.3.1.1.2/01	IIA, 8.3.1.1/02	Engelhard, E.K.	1998a	RH-117,281 2F (240SC): Laboratory oral and contact test with the honeybee, <i>Apis mellifera</i> . Springborn Laboratories (Europe) AG Report No. 97-066-1007. ER Ref No: 11.6 US Ref No: 97RC-0095 GLP, Unpublished	N	N	NA	Gowan

Data point	Annex point (Original dossier)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
KCP, 10.3.2.1/01 KCA, 8.3.2.1/01	IIA, 8.3.2/01	Engelhard, E.K.	1998b	RH-117,281 2F (240SC): Laboratory acute toxicity test with the parasitic wasp, <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae). Springborn Laboratories (Europe) AG Report No. 97-062-1007. ER Ref No: 11.8 US Ref No: 97RC-0106 GLP, Unpublished	N	N	NA	Gowan
KCP, 10.3.2.1/02 KCA, 8.3.2.2/01	IIA, 8.3.2/02	Engelhard, E.K.	1998c	RH-117,281 2F (240SC): Laboratory toxicity test with the predacious mite, <i>Typhlodromus pyri</i> Scheuten (Acari: Phytoseiidae). Springborn Laboratories (Europe) AG Report No. 97-070-1007. ER Ref No: 11.3 US Ref No: 97RC-0105 GLP, Unpublished	N	N	NA	Gowan
KCP, 10.3.2.1/03 KCA, 8.3.2.2/02	IIA, 8.3.2/03	Engelhard, E.K.	1998d	RH-117,281 2F (240SC): Laboratory toxicity test with the predacious mite, <i>Amblyseius andersoni</i> Chant (Acari: Phytoseiidae) Springborn Laboratories (Europe) AG Report No. 97-075-1007. ER Ref No: 11.7 US Ref No: 97RC-0111 GLP, Unpublished	N	N	NA	Gowan
KCP, 10.3.2.1/04 KCA, 8.3.2.2/03	IIA, 8.3.2/04	Engelhard, E.K.	1998e	RH-117,281 2F (240SC): Laboratory toxicity test with the spiders, <i>Pardosa sp.</i> (Araneae: Lycosidae). Springborn Laboratories (Europe) AG Report No. 97-059-1007. ER Ref No: 11.9 US Ref No: 97RC-0107 GLP, Unpublished	N	N	NA	Gowan

Data point	Annex point (Original dossier)	Author(s)	Year	Title, Source (where different from company), Company, Report No, GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection claimed	Owner
KCP, 10.3.2.1/05 KCA, 8.3.2.2/04	IIA, 8.3.2/05	Engelhard, E.K.	1998f	RH-117,281 2F (240SC): Laboratory acute toxicity test with the ground beetle, <i>Poecilus cupreus</i> L. (Coleoptera: Carabidae). Springborn Laboratories (Europe) AG Report No. 97-064-1007. ER Ref No: 11.2 US Ref No: 97RC-0108 GLP, Unpublished	N	N	NA	Gowan
KCP, 10.3.2.1/06 KCA, 8.3.2.2/05	IIA, 8.3.2/06	Engelhard, E.K.	1998g	RH-117,281 2F (240SC): Laboratory toxicity test with the green lacewing, <i>Chrysoperla carnea</i> Steph. (Neuroptera: Chrysopidae). Springborn Laboratories (Europe) AG Report No. 97-068-1007. ER Ref No: 11.11 US Ref No: 97RC-0109 GLP, Unpublished	N	N	NA	Gowan
KCP, 10.3.2.1/07 KCA, 8.3.2.2/06	IIA, 8.3.2/07	Engelhard, E.K.	1998h	RH-117,281 2F (240SC): Laboratory contact toxicity test with the predator, <i>Orius insidiosus</i> (Heteroptera: Anthocoridae) Springborn Laboratories (Europe) AG Report No. 97-077-1007. ER Ref No: 11.10 US Ref No: 97RC-0110 GLP, Unpublished	N	N	NA	Gowan
KCP, 10.6.2/01 KCA, 8.6/01	IIA, 8.6/01	Nunez, M.V.	1998a	Greenhouse phytotoxicity tests with RH-7281 2F. Rohm and Haas Report No. 98R-1092 ER Ref No: 28.4 US Ref No: 98R-1092 GLP, Unpublished	N	N	NA	Gowan
KCP, 10..2/02 KCA, 8.6/02	IIA, 8.6/02	Nunez, M.V.	1998b	Greenhouse crop phytotoxicity tests with RH-117281 2F. Rohm and Haas Report No. 98R-1114 ER Ref No: 28.5 US Ref No: 98R-1114 GLP, Unpublished	N	N	NA	Gowan