European Commission

Renewal Assessment Report of the Inclusion of the Active Substance in Annex I of the Regulation (EC) 1107/2009

Oxamyl 10SL

Volume 3 (CP)
ANNEX B.2 Physical and Chemical properties

Rapporteur Member State: Italy
Co-Rapporteur Member State: France

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VERSION HISTORY

Date	Data points containing amendments or additions	Document identifier or version number
July 2017	First RAR of Italy	
January 2018	Revised RAR after comment CoRMS (France)	

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B.2 PHYSICAL AND CHEMICAL PROPERTIES

Unless specifically indicated, all reports in this section are submitted to address mandatory data requirements for the approval of active substance.

B.2.1 Appearance

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Appearance	Visual assessment and olfactory assessment	Oxamyl 10SL (DPX-D1410-424) (Document J)	Oxamyl 10SL is a dark green liquid, sold as a Soluble Concentrate (SL). This product has a faint sulphurous odour.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	N	DuPont-6603, Revision No. 1
		Oxamyl 10SL (DPX-D1410-531) (Document J)	Oxamyl 10SL is a dark green liquid (10GY 5/12), sold as a Soluble Concentrate (SL). This product has a mild sulphurous odour.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-32987

B.2.2 Explosive and oxidising properties

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Explosive properties	EEC A.14	Oxamyl 10SL (DPX-D1410-569) (Document J)	Thermal sensitivity - Oxamyl 10SL was subject to conditions of intense heat and confinement. No explosions were observed. Mechanical Sensitivity of Oxamyl 10SL with respect to shock was negative; no positive results were obtained in 6 drop impact tests conducted from a height of 40 cm with a weight of 10 kg. Mechanical Sensitivity with respect to friction is not required for liquids.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-41655
Oxidising properties	EEC A.21	Oxamyl 10SL (DPX-D1410-569) (Document J)	The sample of Oxamyl 10SL was found to have a mean pressure rise time greater than that observed for the nitric acid reference sample. The test substance is not classified as an oxidizing liquid in accordance with the criteria of EC Test A21.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-41655

B.2.3 Flammability and auto-flammabillity

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Flash point	EEC A.9	Oxamyl 10SL (DPX-D1410-569) (Document J)	The flash point of Oxamyl 10SL is >100°C. The flash point was determined in accordance with the EEC A.9 method. A Pensky-Martens closed cup apparatus was used for the measurement. Oxamyl 10SL did not flash at temperatures up to and including 100°C.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-41655
Flammability	EEC A.10			Not applicable to liquid preparations.		
Auto-flammability	EEC A.15	Oxamyl 10SL (DPX-D1410-569) (Document J)	A known volume of the test substance is injected into a heated open flask containing air, and the contents observed until ignition occurs. The test is repeated with different sample volumes and temperatures. The auto-ignition temperature was determined to be ≥600°C.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-41655

B.2.4 Acidity/alkalinity and pH value

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Free acidity/alkalinity	CIPAC MT 31	Oxamyl 10SL (DPX-D1410-424) (Document J)	A buffer solution was prepared and the pH determined. A 10 gram sample of the product was added to a solution of acetone and water and titrated with a 0.02 N solution of sodium hydroxide to the same pH value as the buffer solution. Total acidity was determined to be 0.827% m/m as H_2SO_4.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-6603, Revision No. 1
		Oxamyl 10SL (DPX-D1410-531) (Document J)	A buffer solution was prepared and the pH determined. A 10 gram sample of the product was added to a solution of acetone and water and titrated with a 0.02 N solution of sodium hydroxide to the same pH value as the buffer solution. Total acidity was determined to be 0.5% m/m as H_2SO_4.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-32987

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
pH of a 1% aqueous dilution	CIPAC MT 75.3 EPA FIFRA Guideline 63-12	Oxamyl 10SL (DPX-D1410-424) (Document J)	The pH of Oxamyl 10SL in a 1% aqueous dilution with distilled water is 3.5.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-6603, Revision No. 1
pH of a 1% aqueous dilution (continued)	CIPAC MT 75.3 EPA FIFRA Guideline 63-12	Oxamyl 10SL (DPX-D1410-531) (Document J)	The pH of Oxamyl 10SL in a 1% aqueous dilution with distilled water is 3.8.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-32987
		Oxamyl 10SL (DPX-D1410-527) (Document J)	The pH of undiluted Oxamyl 10SL was 3.3	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-35139

B.2.5Viscosity and surface tension

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Kinematic viscosity	OECD 114			Viscosity not required, as this preparation was not designed for Ultra Low Volume (ULV) use		
Viscosity	CIPAC MT 192	Oxamyl 10SL (DPX-D1410-424) (Document J)	The viscosity measurement, although not required for a Newtonian liquid, was performed with the test substance maintained at a temperature of 25°C, using a Brookfield Viscometer. The viscosity of Oxamyl 10SL was measured as: 2 cps @ 30 rpm and 1 cps @ 6 rpm.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-6603, Revision No. 1

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Surface tension	EEC A.5 OECD 115	Oxamyl 10SL (DPX-D1410-424) (Document J)	The surface tension of Oxamyl 10SLwas recorded as 48.5 mN/m neat and 71.2 mN/m diluted to 1% with distilled water. The surface tension measurement of Oxamyl 10SL was made using a White Instruments Surface Tension (torsion) Balance, employing the ring method. The instrument was calibrated with distilled water. Following calibration, the surface tension of the neat test substance and a 1% dilution in double distilled water were measured by the ring method. Results are as follows: Neat material: 48.5 mN/m 1% dilution in distilled water: 71.2 mN/m	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-6605

B.2.6 Relative density and bulk density

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Relative density	EEC A.3 OECD 109 (1995)	Oxamyl 10SL (DPX-D1410-424) (Document J)	The density of Oxamyl 10SL was recorded at 1.023g/mL at 20 ºC. The relative density of Oxamyl 10SL was measured using a Paar Mettler Density Meter. The instrument was calibrated with water at a temperature of 20°C and the density of the test substance was recorded at 1.023 g/mL at this same temperature.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-6603, Revision No. 1
Bulk/tap density	CIPAC MT 186			Bulk/tap density measurements do not apply to liquid preparations		

B.2.7Storage stability and shelf-life: effects of temperature on technical characteristics of the plant protection product

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Stability after storage for 14 days at 54°C	CIPAC MT 46.3 (accelerated storage)	Oxamyl 10SL (DPX-D1410-424) (Document J)	Oxamyl 10SL was stored at a temperature of 54°C for a period of 2 weeks. The oven-aged sample was analysed for active substance content and pH was measured. Assay content is reported below in "Minimum content after heat stability testing." pH: Aged: 3.5	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-6603, Revision No. 1
Stability after storage for 14 days at 54°C (continued)	CIPAC MT 46.3 (accelerated storage)	Oxamyl 10SL (DPX-D1410-531) (Document J)	Oxamyl 10SL was stored in an HDPE container at a temperature of 54°C for a period of 2 weeks. The following tests were performed. Colour: dark green (10GY 5/12) Odour: mild sulphurous Physical state liquid No perforations, darkening, leakage or rust in the seam of the packaging. At the conclusion of the storage period the packaging remained intact and unaffected by the storage. Assay content (g/L oxamyl): Aged: 106.2 ± 0.1	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-32987

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
	CIPAC MT 75.3		pH: Aged: 3.7 ± 0.0	Acceptable		
	CIPAC MT 31		Acidity: Aged: 0.5 ± 0.0% m/m	Acceptable		
	CIPAC MT 41.1		Dilution stability: Aged: No separated material after 30 min No sediment volume after 30 min No separated material after 24 hr No sediment volume after 24 hr	Acceptable		
Stability after storage for other periods and/or temperatures	CIPAC MT 46.3 (accelerated storage)		Testing was conducted at a temperature of 54ºC (see above).	Acceptable		
Minimum content after heat stability testing	CIPAC MT 46.3 (accelerated storage)	Oxamyl 10SL (DPX-D1410-424) (Document J)	Assay (as made): 106.3 g/L oxamyl Assay (after accelerated storage at 54°C for a period of 2 weeks): 104.8 g/L oxamyl	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	N	DuPont-6603, Revision No. 1

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
		Oxamyl 10SL (DPX-D1410-531) (Document J)	Assay (as made): 106.7 ± 0.1 g/L oxamyl Assay (after accelerated storage at 54°C for a period of 2 weeks): 106.2 ± 0.1 g/L oxamyl	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-32987
Effect of low temperature on stability	CIPAC MT 39.3	Oxamyl 10SL (DPX-D1410-424) (Document J)	Oxamyl 10SL was stored at a temperature of 0 ± 2°C for a period of seven days. There was no separation nor any indication of crystal growth noted.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	N	DuPont-6603, Revision No. 1

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Shelf life following storage at ambient temperature	GIFAP Monograph No 17	Oxamyl 10SL (DPX-D1410-424) (Document J)	Assay 103.1 g/L oxamyl Colour dark green Odour: sulphurous (very faint) The test substance was evaluated from a sealed container (constructed of the same material as a commercial container) that was aged 2 years in an agricultural products warehouse The container appears intact. No leakage or seepage noted, nor is there any apparent interaction between product and container. pH: 4.1	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	N	DuPont-6604, Revision No. 1

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Shelf life following storage at ambient temperature (continued)	GIFAP Monograph No 17	Oxamyl 10SL (DPX-D1410-531) (Document J)	Oxamyl 10SL, in an HDPE container, was stored under warehouse conditions for 2 years. The product was removed and the following test conducted: Assay: 105.7 ± 0.1 g/L oxamyl Colour: dark green Odour: mild sulphurous Physical state liquid No perforations, darkening, leakage or rust in the seam of the packaging (High Density Polyethylene container). At the conclusion of the storage period the packaging remained intact and unaffected by the storage.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-32988
	CIPAC MT 75.3		pH: 3.7 ± 0.0	Acceptable		
	CIPAC MT 31		Acidity 0.5 ± 0.0% m/m	Acceptable		
	CIPAC MT 41.1		Dilution stability No separated material after 30 min No sediment volume after 30 min No separated material after 24 hr No sediment volume after 24 hr	Acceptable		

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Shelf life in months				Not applicable as test substance has been demonstrated to be stable for a minimum of 2-years.		

B.2.8Technical characteristics of the plant protection product

B.2.8.1 Wettability

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Wettability	CIPAC MT 53.3.1			Not required for liquid preparations.		

B.2.8.2 Persistent foaming

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Persistent foaming	CIPAC MT 47.2	Oxamyl 10SL (DPX-D1410-424) (Document J)	The volume of foam recorded after 1 minute was 0 mL. Oxamyl 10SL (at its highest recommended use rate) was added to CIPAC standard hard water "D" and agitated as directed by the method. After standing, undisturbed for 1 minute, no foam was present.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	N	DuPont-6603, Revision No. 1

B.2.8.3 Suspensibility, spontaneity and dispersion stability

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Suspensibility	CIPAC MT 184			Not applicable to soluble liquid formulations.		
Dispersibility (WG) or Spontaneity of dispersion (SC)	CIPAC MT 174 CIPAC MT 160			Not applicable to soluble liquid formulations.		

B.2.8.4 Degree of dissolution and dilution stability

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Degree of dissolution and dilution stability	CIPAC MT 41	Oxamyl 10SL (DPX-D1410-424) (Document J)	A 5 mL sample of Oxamyl 10SL was diluted to 100 mL with CIPAC Standard Water "D" and allowed to stand undisturbed for a period of 18 hours at a temperature of 20°C. There was no evidence of any separation of material.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	N	DuPont-6603, Revision No. 1
	CIPAC MT 41.1	Oxamyl 10SL (DPX-D1410-531) (Document J)	A 5 mL sample of Oxamyl 10SL was diluted to 100 mL with CIPAC Standard Water "D" and allowed to stand undisturbed for a period of 24 hours at a temperature of 20°C. There was no evidence of any separation of material.	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted." Acceptable	Y	DuPont-32987

B.2.8.5 Particle size distribution, dust content, attrition and mechanical stability

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Dry sieve test	CIPAC MT 59.1			The dry sieve test required in this section is only applicable to dustable powders.		
Wet sieve test	CIPAC MT 185			Not required for soluble liquid formulations.		

B.2.8.5.1 Particle size distribution

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Size distribution of particles	OECD 110 or CIPAC MT 187 (WP)			Only required for powder formulations		

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Nominal size range of granules	CIPAC 170 (WG)			Not applicable to liquid preparations		

B.2.8.5.2 Dust content

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Dust content	CIPAC MT 171			Not applicable to liquid preparations.		
Particle size of dust	OECD 110			Not required since it is not relevant for operator exposure		

B.2.8.5.3 Attrition

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Attrition	CIPAC MT 178			Not applicable to liquid formulations		

B.2.8.5.4 Hardness and integrity

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Hardness and integrity				Not applicable to liquid formulations		

B.2.8.6 Emulsifiability, re-emulsifiability, emulsion stability

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Emulsifiability	CIPAC MT 36.3			Not applicable to soluble liquid formulations.		
Emulsion stability	CIPAC MT 20 (EC)			Not applicable to soluble liquid formulations.		
Re-emulsifiability	CIPAC MT 36.3			Not applicable to soluble liquid formulations.		
Stability of dilute emulsions	CIPAC MT 20 (EO, EW)			Not applicable to soluble liquid formulations.		
Stability of emulsions				Not applicable to soluble liquid formulations.		

B.2.8.7 Flowability, pourability and dustability

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Flowability	CIPAC MT 172			Only applies to Water Dispersible Granule Preparations.		
Pourability	CIPAC MT 148.1			Not applicable to soluble liquid formulations.		
Dustability following accelerated storage	CIPAC MT 34			Test is only applicable to dustable powders.		

B.2.9 Physical compatibility with other products including plant protection products with which its use is to be authorised

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Physical compatibility of tank mixes			No tank mix recommendations are included in the label. For Oxamyl 10SL, no use with other products, including plant protection products, needs to be authorised in the context of which this dossier is submitted.	Acceptable		
Chemical compatibility of tank mixes			See physical compatibility above.	Acceptable		

B.2.10 Adherence and distribution to seeds

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Distribution (seed treatment)				Not required since Oxamyl 10SL is not a seed treatment		

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Adhesion (seed treatment)				Not required since Oxamyl 10SL is not a seed treatment		

B.2.11 Other studies

No studies required.

B.2.12 Overview of the physical and chemical properties of the plant protection product

Oxamyl 10SL is non-flammable, non-explosive, and not an oxidizer. The pH of a 1% concentration of the preparation in water was consistently measured between 3.5 and 4.1 pH units. The pH of undiluted Oxamyl 10SL was 3.3.

The pure active substance content of Oxamyl 10SL, as manufactured was 10.39%. The physical and chemical properties of the preparation were measured using CIPAC Methods. All physical and chemical properties specifications, as defined by "The Manual on the Development and Use of FAO Specifications for Plant Protection Products," were met both prior to and after completion of accelerated storage. The preparation was stored at a temperature of 54°C for a period of 2 weeks and for a period of 2 years at ambient temperature. The storage data have clearly demonstrated that Oxamyl 10SL is stable under normal storage conditions for a minimum of two years in an HDPE container.

Oxamyl 10SL product can be conveniently measured using a calibrated volumetric measuring guide and easily diluted in water. It can be applied by drip irrigation pipelines. Equipment cleanout is easily accomplished using standard wash out procedures.

The plant protection product is a soluble concentrate that can easily be recovered (soaked up with inert absorbent material). If liquid has been spilt in large quantities, it can be cleaned up promptly by scoop or vacuum.

B.2.13 References relied on

List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the approval of the active substance.

Studies marked in yellow are submitted for the first time.

List of studies submitted sorted by Annex Point

Data Requirement No., Reference No.	Author(s)	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Y/N	Justification if data protection is claimed	Owner
B.2.1 B.2.4 B.2.5 B.2.6 B.2.7 B.2.8.2 B.2.8.4	Bloemer, D.S.	2002	Oxamyl 100g/liter soluble concentrate insecticide formulation: Laboratory study of physical, chemical and technical properties DuPont Stine-Haskell Research Center DuPont-6603, Revision No. 1 GLP: Yes Published: No	N	Y	Data protection on a MS by MS basis. The study provides additional data for the regulatory decision, conducted according to GLP and has not previously been protected or submitted in all MS	DuPont
B.2.1 B.2.4 B.2.7 B.2.8.4	Shanthaveerappa, K.S.	2011	Oxamyl 100 g/L soluble concentrate (SL) insecticide formulation: Laboratory study of physical chemical and technical properties with accelerated storage performed in a high density polyethylene (HDPE) container Advinus Therapeutics Limited DuPont-32987 GLP: Yes Published: No	N	Y	Data protection on a MS by MS basis. The study provides additional data for the regulatory decision, conducted according to GLP and has not previously been protected or submitted in all MS	DuPont
B.2.2 B.2.3	Livingston, I.	2015	Oxamyl 100 g/L soluble concentrate (SL) formulation: Laboratory study of flash point, autoflammability, oxidizing and explosive properties of liquids Chilworth Technology Limited DuPont-41655 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont

Data Requirement No., Reference No.	Author(s)	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Y/N	Justification if data protection is claimed	Owner
B.2.4	Robson, D.D.	2012	Oxamyl (DPX-D1410 100 g/L SL) and Methomyl (DPX-X1179 200g/L SL): Laboratory study undiluted pH DuPont Stine-Haskell Research Center DuPont-35139 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont
B.2.5	Bates, M.L.	2001	Oxamyl 100 g/L solubile concentrate (SL) insecticide/nematicide formulation [DPX-D1410-424]: Evaluaton of surface tension Covance Laboratories (UK) DuPont-6605 GLP: Yes Published: No	N	Y	Data protection on a MS by MS basis. The study provides additional data for the regulatory decision, conducted according to GLP and has not previously been protected or submitted in all MS	DuPont
B.2.7	Robson, D.D.	2012	Oxamyl 100g/liter soluble concentrate insecticide formulation: Laboratory study of storage stability DuPont Stine-Haskell Research Center DuPont-6604, Revision No. 1 GLP: No Published: No	N	N		DuPont

Data Requirement No., Reference No.	Author(s)	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Y/N	Justification if data protection is claimed	Owner
B.2.7	Shanthaveerappa, K.S.	2013	Oxamyl 100 g/L soluble concentrate (SL) insecticide formulation: Laboratory study of shelf-life stability in a high density polyethylene (HDPE) container Advinus Therapeutics Limited DuPont-32988 GLP: Yes Published: No	N	Y	Data protection on a MS by MS basis. The study provides additional data for the regulatory decision, conducted according to GLP and has not previously been protected or submitted in all MS	DuPont

List of studies submitted sorted by Author

Data Requirement No., Reference No.	Author(s)	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Y/N	Justification if data protection is claimed	Owner
B.2.5	Bates, M.L.	2001	Oxamyl 100 g/L solubile concentrate (SL) insecticide/nematicide formulation [DPX-D1410-424]: Evaluaton of surface tension Covance Laboratories (UK) DuPont-6605 GLP: Yes Published: No	N	Y	Data protection on a MS by MS basis. The study provides additional data for the regulatory decision, conducted according to GLP and has not previously been protected or submitted in all MS	DuPont
B.2.1 B.2.4 B.2.5 B.2.6 B.2.7 B.2.8.2 B.2.8.4	Bloemer, D.S.	2002	Oxamyl 100g/liter soluble concentrate insecticide formulation: Laboratory study of physical, chemical and technical properties DuPont Stine-Haskell Research Center DuPont-6603, Revision No. 1 GLP: Yes Published: No	N	Y	Data protection on a MS by MS basis. The study provides additional data for the regulatory decision, conducted according to GLP and has not previously been protected or submitted in all MS	DuPont
B.2.2 B.2.3	Livingston, I.	2015	Oxamyl 100 g/L soluble concentrate (SL) formulation: Laboratory study of flash point, autoflammability, oxidizing and explosive properties of liquids Chilworth Technology Limited DuPont-41655 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont

Data Requirement No., Reference No.	Author(s)	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Y/N	Justification if data protection is claimed	Owner
B.2.4	Robson, D.D.	2012	Oxamyl (DPX-D1410 100 g/L SL) and Methomyl (DPX-X1179 200g/L SL): Laboratory study undiluted pH DuPont Stine-Haskell Research Center DuPont-35139 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted	DuPont
B.2.7	Robson, D.D.	2012	Oxamyl 100g/liter soluble concentrate insecticide formulation: Laboratory study of storage stability DuPont Stine-Haskell Research Center DuPont-6604, Revision No. 1 GLP: No Published: No	N	N		DuPont
B.2.1 B.2.4 B.2.7 B.2.8.4	Shanthaveerappa, K.S.	2011	Oxamyl 100 g/L soluble concentrate (SL) insecticide formulation: Laboratory study of physical chemical and technical properties with accelerated storage performed in a high density polyethylene (HDPE) container Advinus Therapeutics Limited DuPont-32987 GLP: Yes Published: No	N	Y	Data protection on a MS by MS basis. The study provides additional data for the regulatory decision, conducted according to GLP and has not previously been protected or submitted in all MS	DuPont

Data Requirement No., Reference No.	Author(s)	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	Vertebrate study Y/N	Data Protection Y/N	Justification if data protection is claimed	Owner
B.2.7	Shanthaveerappa, K.S.	2013	Oxamyl 100 g/L soluble concentrate (SL) insecticide formulation: Laboratory study of shelf-life stability in a high density polyethylene (HDPE) container Advinus Therapeutics Limited DuPont-32988 GLP: Yes Published: No	N	Y	Data protection on a MS by MS basis. The study provides additional data for the regulatory decision, conducted according to GLP and has not previously been protected or submitted in all MS	DuPont

REFERENCE LIST, CP, SECTION 2, PHYSICAL AND CHEMICAL PROPERTIES - DOCUMENTS SUBMITTED. VERTEBRATE STUDIES.

No vertebrate studies submitted.

REFERENCE LIST, CP, SECTION 2, PHYSICAL AND CHEMICAL PROPERTIES - DOCUMENTS NOT SUBMITTED. PREVIOUSLY SUBMITTED AND RELIED UPON.

No studies previously submitted and relied upon.