

*European Commission*

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



**Oxamyl**

**Volume 3 (CA)  
ANNEX B.2 Physical and Chemical Properties**

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

**January 2018**

### VERSION HISTORY

<b>Date</b>	<b>Data points containing amendments or additions</b>	<b>Document identifier or version number</b>
May 2016	First RAR of Italy	
December 2017	Revised RAR after comment CoRMS (France)	

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## **B.2 PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE**

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

Tests have been conducted with PAI (Pure Active Ingredient) and or 42TK (active substance as manufactured) to comply with data requirements.

### B.2.1 Melting point and boiling point

Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
<b>Melting point</b>	EEC A.1. OECD 102 (capillary method) OPPTS Series 830.7200		The melting point study D1410.B, originally submitted under EU Rev8 Point IIA 2.1.1 and conducted with test material oxamyl analytical standard, was conducted under guideline EEC A.1. (1992) and OECD 102. A review of this study indicates that it does not meet the current guideline (OECD 102) and has been superceded with DuPont-13350.	Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted and Not Relied Upon.”  Acceptable		
	EEC A.1. OECD 102 (Heated block method) OPPTS Series 830.7200	DPX-D1410-376 (99.9%, PAI)	The melting point study DuPont-13350, originally submitted and included in the Oxamyl DAR Final Addendum 2004, Volume 3, B2, Point 2.1.1.1 and conducted with test material oxamyl pure active ingredient (PAI), was conducted under guideline OECD 102. A review of this study indicates that it fully meets the current guideline OECD 102.  98.5–100°C	Study included in the Oxamyl DAR Final Addendum 2004. Now cited in CA Master Reference List “Documents Not Submitted. Previously Submitted and Relied Upon.”  Acceptable		

Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
	EEC A.1. OECD 102 (DSC method) OPPTS Series 830.7200	DPX-D1410-196 (98.0%, PAI) (Document J)	A Differential Scanning Calorimetry (DSC) analysis of oxamyl PAI was done by heating a sample in a closed capsule at a rate of 10 K.min <sup>-1</sup> . The melting point was observed at 99.2°C. This study was performed to determine the boiling/decomposition point of oxamyl PAI. The melting point result is consistent with that observed in DuPont-13350.	Study submitted to the EU for the first time in this submission. Cited in Reference List “Documents Submitted.”  Acceptable	Y	DuPont-14983
Boiling point	EEC A.2 OECD 103 OPPTS Series 830.7220	DPX-D1410-196 (98.0%, PAI) (Document J)	A Differential Scanning Calorimetry (DSC) analysis of oxamyl PAI was done by heating a sample in a closed capsule at a rate of 10 K.min <sup>-1</sup> . This study was performed to determine the boiling/decomposition point of oxamyl PAI. No boiling point was observed for oxamyl, as it was observed to decompose at 165°C.	Study submitted to the EU for the first time in this submission. Cited in Reference List “Documents Submitted.”  Acceptable	Y	DuPont-14983

Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Temperature of decomposition or sublimation	EEC A.1 OECD 102		The temperature of decomposition or sublimation study D1410.B, originally submitted under EU Rev8 Point IIA 2.1.3 and conducted with test material oxamyl analytical standard, was conducted under EEC A.1. (1992) and OECD 102 (DSC and capillary method; 1981). A review of this study indicates that it does not meet the current guideline (EEC A.1 and OECD 102) and has been superceded with DuPont-14983.	Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted and Not Relied Upon.”  Acceptable		
	EEC A.1. OECD 103 (DSC method) OPPTS Series 830.7200	DPX-D1410-196 (98.0%, PAI) (Document J)	The decomposition temperature was measured in duplicate with a Differential Scanning Calorimeter (DSC) and determined to be >165°C.	Study submitted to the EU for the first time in this submission. Cited in Reference List “Documents Submitted.”  Acceptable	Y	DuPont-14983

### B.2.2 Vapour pressure and volatility

Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Vapour pressure of purified active substance	EPA 63-9		The vapour pressure of purified active substance study AMR 1267-88, originally submitted under EU Rev8 Point IIA 2.3.1 and conducted with test material oxamyl PAI, was conducted under EPA 63-9. A review of this study indicates that it does not meet the current guideline (OECD 104) and has been superceded with DuPont-26259.	Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted. Previously Submitted and Not Relied Upon.”  Acceptable		
	OECD 104 OPPTS Series 830.7950	DPX-D1410-196 (98.0%, PAI) (Document J)	Gas Saturation method: $1.80 \times 10^{-5}$ Pa at 20°C	Study submitted to the EU for the first time in this submission. Cited in Reference List “Documents Submitted.”  Acceptable	Y	DuPont-26259



Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Henry's law constant	Calculated using solubility and vapour pressure at 25°C		The Henry's law constant study AMR 592-86, Revision No. 2, originally submitted under EU Rev8 Point IIA 2.3.2 was a calculation. A review of this study indicates that it does not reflect the new vapour pressure value and has been superseded with DuPont-38270.	Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List "Documents Not Submitted and Not Relied Upon."  Acceptable		
	Calculated using water solubility and vapour pressure of the PAI at 20°C	DPX-D1410-196 (98.0%, PAI) (Document J)	Henry's Law constant of oxamyl PAI at 20°C (calculated): pH 5: $2.7 \times 10^{-8}$ Pa·m <sup>3</sup> /mol	Study submitted to the EU for the first time in this submission. Cited in Reference List "Documents Submitted."  Acceptable	N	DuPont-38270

### B.2.3 Appearance (physical state, colour)

Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
<b>Appearance (physical state, colour)</b>	OPPTS Series 830.6302, 830.6303  Visual assessment		The appearance (physical state, colour) study D1410.B, originally submitted under EU Rev8 Point IIA 2.4.1 and conducted with test material oxamyl analytical standard, was conducted under OPPTS 830.6302 and 830.6303. A review of the study indicates that it does not meet the current guideline and has been superseded with DuPont-2129.	Study submitted in the EU Dossier in 2001 and included in the first EU approval review Now cited in CA Master Reference List “Documents Not Submitted. Previously Submitted and Not Relied Upon.”  Acceptable		
	OPPTS Series 830.6302 and 830.6303 Visual assessment	DPX-D1410-376 (100.0%, PAI)	The appearance (physical state, colour) study DuPont–2129 originally submitted under EU Rev8 Point IIA 2.4.1 and conducted with test material oxamyl PAI, was conducted under OPPTS 830.6302 and 830.6303. A review of the study indicates that it fully meets the current guidelines (OPPTS 830.6302 and 830.6303).  Oxamyl PAI is a white, crystalline solid which corresponds to the Munsell colour N 9.5	Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted. Previously Submitted and Relied Upon.”  Acceptable		

Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
	OPPTS Series 830.6302 and 830.6303 Visual assessment	DPX-D1410-490 (420 g a.s./kg, 42TK)	The appearance of oxamyl as manufactured (42% technical concentrate TK) is a translucent liquid of light green color (Munsell 10Y 9/2)	Study submitted to the EU for the first time in this submission. Cited in Reference List “Documents Submitted.”  Acceptable	Y	RF – 0014.001.256. 06

#### B.2.4 Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths, optical purity

##### B.2.4.1 Spectra for the active substance

Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
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<b>Data Point Test or property</b>	<b>Guideline and method</b>	<b>Test material purity and specification</b>	<b>Findings</b>	<b>Comments</b>	<b>GLP Y/N</b>	<b>Reference</b>
<b>UV/Vis</b>	OECD 101 OPPTS Series 830.7050	DPX-D1410-376 (100.0%, PAI)	<p>The UV/Vis study DuPont-2163, originally submitted under EU Rev8 Point IIA 2.5.1 and conducted with test material oxamyl PAI, was conducted under OECD 101 and OPPTS 830.7050. A review of this study indicates that it fully meets the current guideline OECD 101.</p> <p>The UV spectrum at pH 7 is given in Figure 1.</p>	<p>Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		
<b>IR</b>		DPX-D1410-376 (100.0%, PAI)	<p>The IR study DuPont-7189, originally submitted under EU Rev8 Point IIA 2.5.1 and conducted with test material oxamyl PAI, was conducted under unspecified guidelines. A review of this study indicates that it is a scientifically valid study that does not need repeating.</p> <p>The IR spectrum for oxamyl showed key bands consistent with the structure. Instrument operating conditions and sample information, absorption bands and assignments in parentheses are given in Table 1 below. The spectrum is given in Figure 2.</p>	<p>Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		

Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
NMR - Proton		DPX-D1410-376 (100.0%, PAI)	<p>The <sup>1</sup>H NMR study DuPont-7188, originally submitted under EU Rev8 Point IIA 2.5.1 and conducted with test material oxamyl PAI, was conducted under unspecified guidelines. A review of this study indicates that it is a scientifically valid study that does not need repeating.</p> <p>The structure and the assignment of chemical shifts of protons in ppm are given in Figure 3 and Table 2 below. The spectrum is consistent with the structure.</p>	<p>Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		
NMR – <sup>13</sup> C		DPX-D1410-376, (100.0%, PAI) (Document J)	The structure and the assignment of chemical shifts of each carbon in ppm are given in Figure 4 and Table 3. The spectrum is consistent with the structure.	<p>Study submitted to the EU for the first time in this submission. Cited in Reference List “Documents Submitted.”</p> <p>Acceptable</p>	N	DuPont-11446, Revision No. 1

<b>Data Point Test or property</b>	<b>Guideline and method</b>	<b>Test material purity and specification</b>	<b>Findings</b>	<b>Comments</b>	<b>GLP Y/N</b>	<b>Reference</b>
<b>MS</b>		DPX-D1410-376 (100.0%, PAI)	<p>The MS study DuPont-7187, originally submitted under EU Rev8 Point IIA 2.5.1 and conducted with test material oxamyl PAI, was conducted under unspecified guidelines. A review of this study indicates that it is a scientifically valid study that does not need repeating.</p> <p>The results showed the M+ 18 ion (molecular weight 237) and confirmed the structure of oxamyl (molecular weight = 219). The spectrum is given in Figure 5.</p>	<p>Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		
<b>Molar extinction coefficient</b>	OECD 101 OPPTS Series 830.7050	DPX-D1410-376 (100.0%, PAI)	<p>The molar extinction coefficient is reported in the UV/Vis study DuPont-2163, originally submitted under EU Rev8 Point IIA 2.5.1 and conducted with test material oxamyl PAI, was conducted under OECD 101 and OPPTS 830.7050. A review of this study indicates that it fully meets the current guideline OECD 101.</p> <p>At 290 nm, the molar extinction coefficients were determined to be 61.6, 80.1, and 1150 L/mol/cm at pH 2, 7, and 10, respectively.</p>	<p>Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in Reference List Now cited in CA Master Reference List “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		

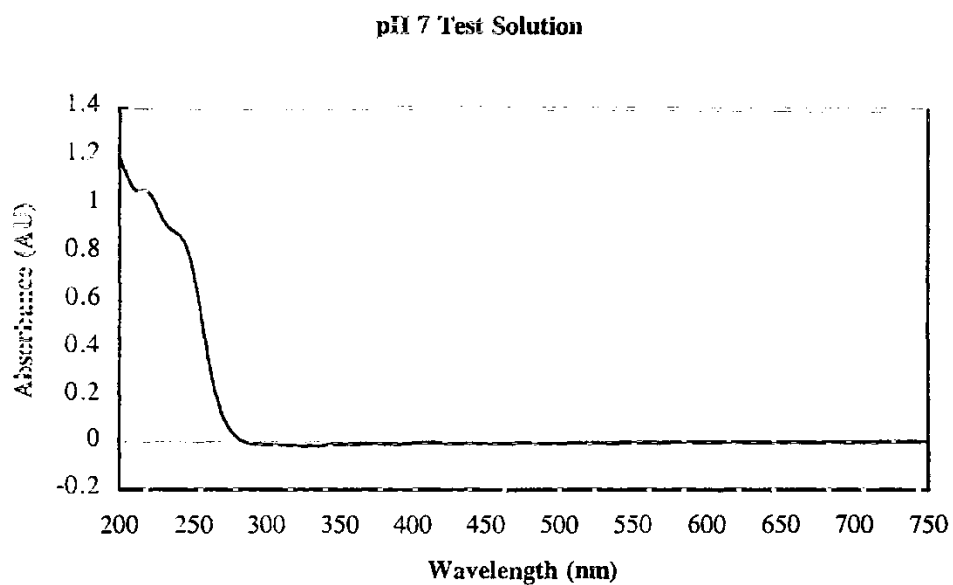
<b>Data Point Test or property</b>	<b>Guideline and method</b>	<b>Test material purity and specification</b>	<b>Findings</b>	<b>Comments</b>	<b>GLP Y/N</b>	<b>Reference</b>
<b>Optical purity</b>				Optical purity is not required since oxamyl is not a resolved isomer.  Acceptable		

#### B.2.4.2 Spectra for impurities

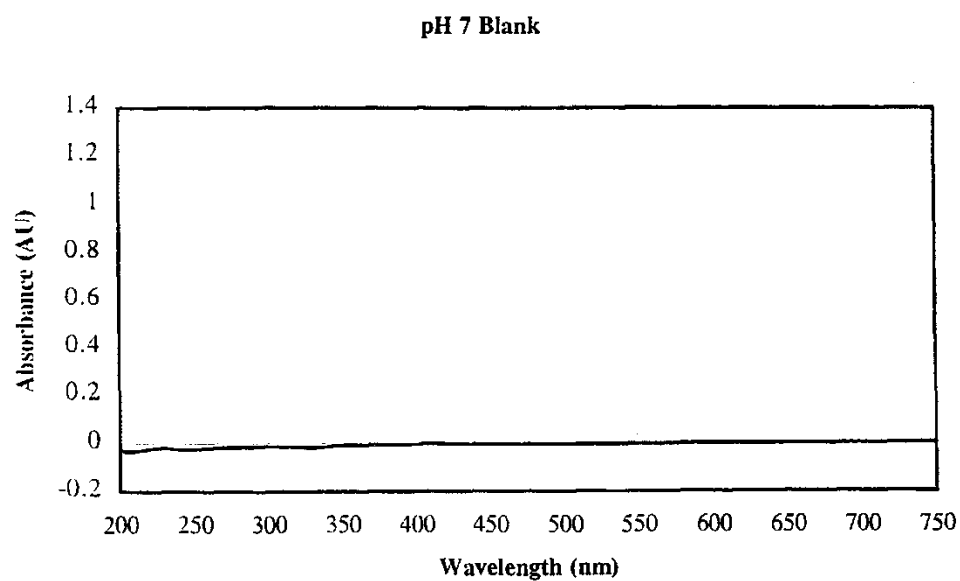
<b>Data Point Test or property</b>	<b>Guideline and method</b>	<b>Test material purity and specification</b>	<b>Findings</b>	<b>Comments</b>	<b>GLP Y/N</b>	<b>Reference</b>
<b>Spectra for impurities</b>			No data presented	There are no impurities which are considered to be of toxicological, ecotoxicological, or environmental significance.  Acceptable		

**Figure 1 UV/Visible spectrum at pH 7 of oxamyl PAI**

**(A) Oxamyl Solution pH 7**

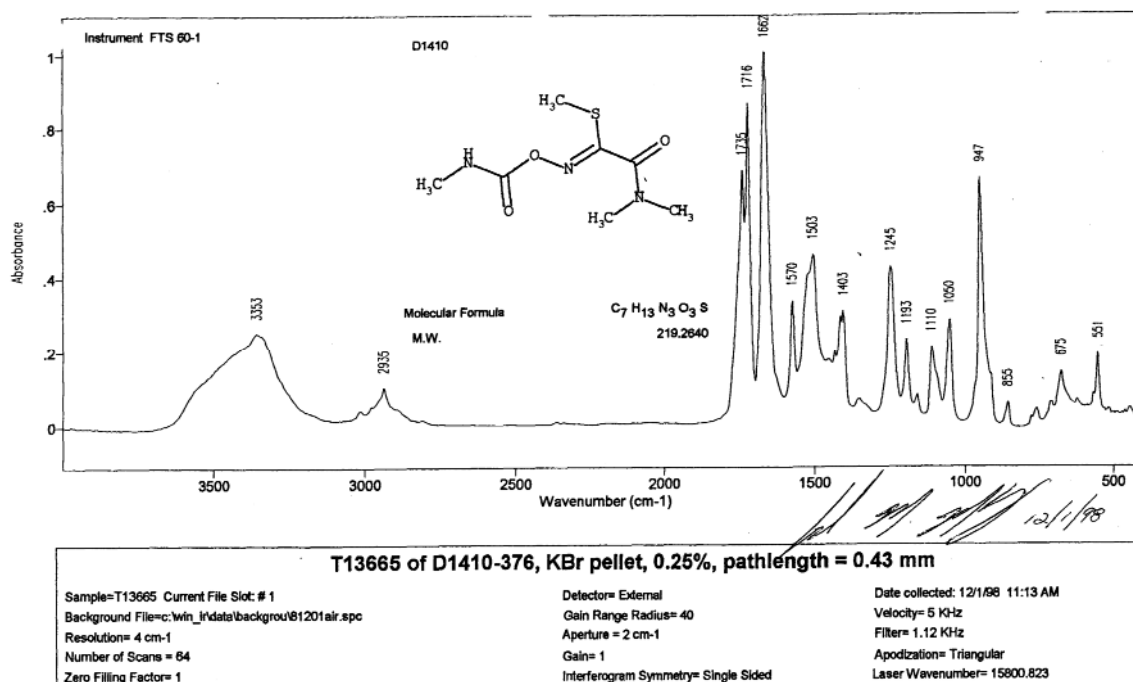


**(B) Blank pH 7**





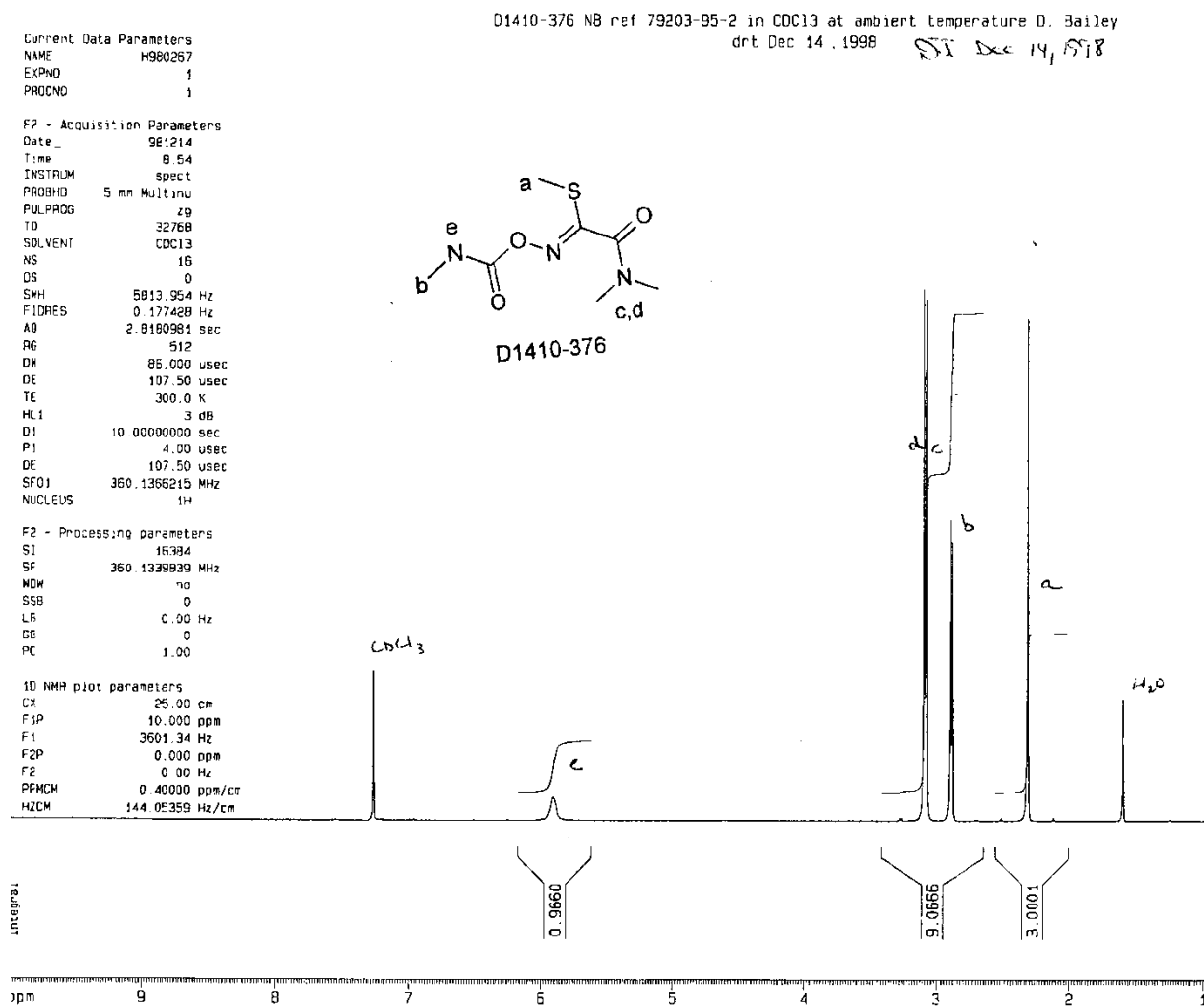
**Figure 2 Infrared spectrum of oxamyl PAI**



**Table 1 Interpretation of IR spectrum for oxamyl PAI**

Functional Group	Literature Data			Absorption Bands In Spectrum
	Bond	Range	Mode	
-NH-CO-O-C	N-H	3340-3250 H-bonded	stretch	3353 cm <sup>-1</sup>
		1740-1680	stretch	1735+1716 cm <sup>-1</sup>
	C=O	1540-1530	stretch	1570 cm <sup>-1</sup>
	C-O-C	1275-1185	stretch	1245 cm <sup>-1</sup>
	C-O-C	1160-1050	stretch	1096 cm <sup>-1</sup>
Amide	C=O	1670-1630	stretch	1662
-CH3	CH3	2975-2950	stretch	2935 cm <sup>-1</sup>

**Figure 3 Nuclear magnetic resonance spectrum of oxamyl PAI**



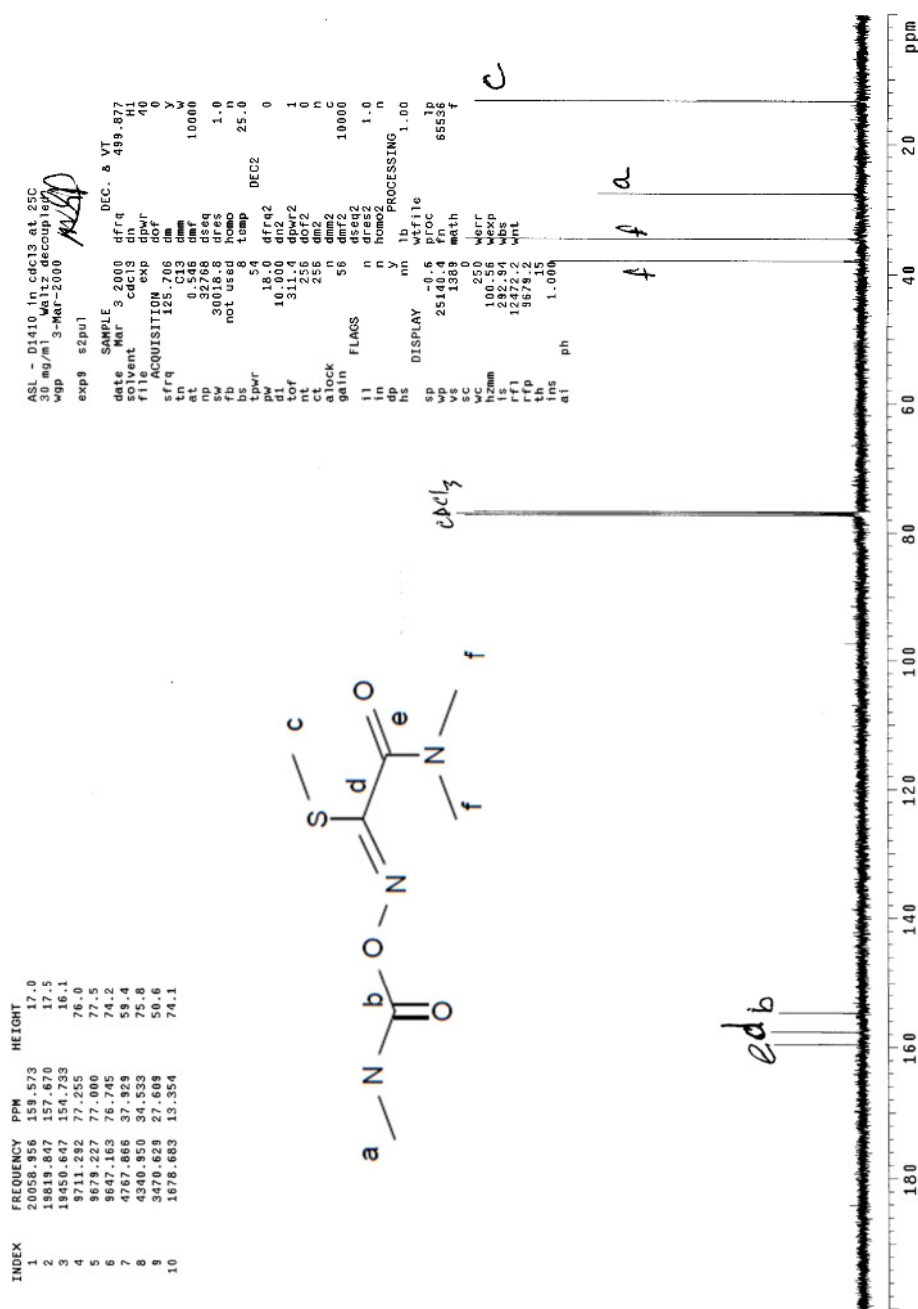
**Table 2 Chemical shifts of protons in the NMR spectrum of oxamyl PAI**

Proton	Chemical Shift	Multiplicity
a	2.31	s
b	2.88	d
c	3.07	s
d	3.08	s
e	~5.90	Broad

\* Solvent Chemical Shift: 7.26 ppm

\* Water Chemical Shift: 1.59 ppm

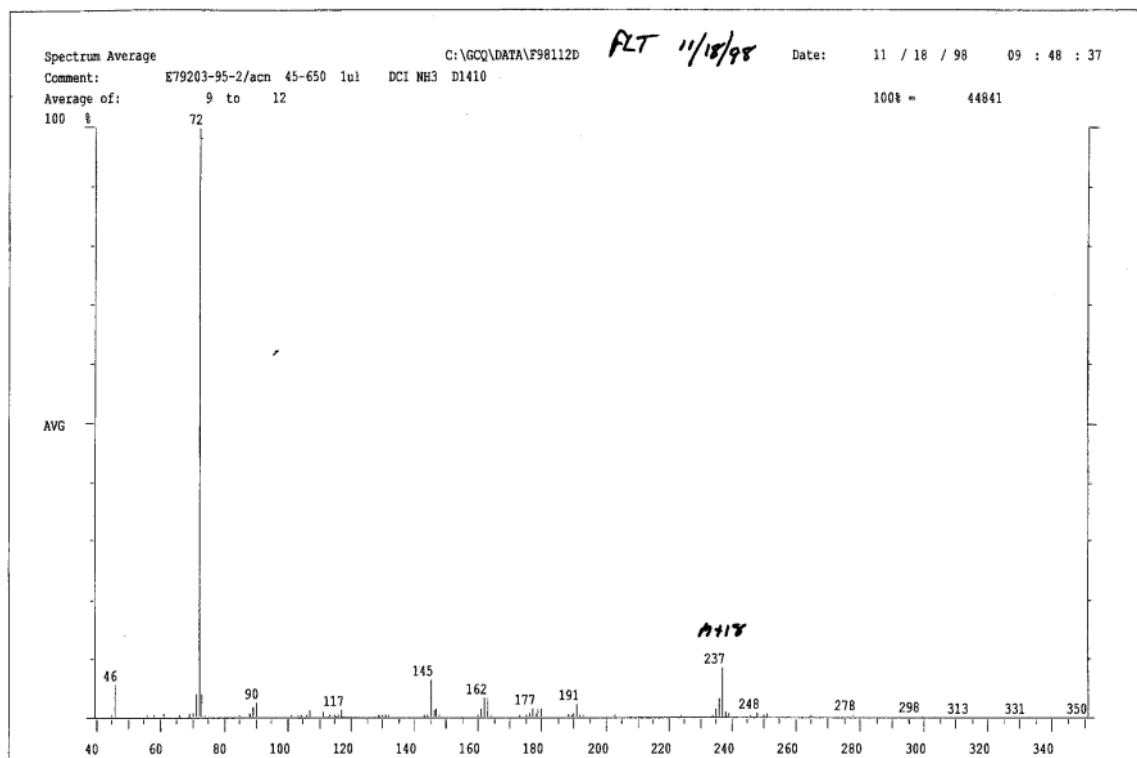
Figure 4  $^{13}\text{C}$  Nuclear magnetic resonance diagram of oxamyl PAI



**Table 3 Chemical shifts of carbons in the NMR spectrum of oxamyl PAI**

Carbon	Chemical shift (ppm)
a	27.61
b	154.73
c	13.35
d	157.67
e	159.57
f	37.3, 34.53
Solvent Chemical Shift: 77.0 (t) ppm	

**Figure 5 Mass spectrum of oxamyl PAI**



### B.2.5 Solubility in water

Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
<b>Solubility in water</b>	EPA 63-8		The solubility in water study D1410.E, originally submitted under EU Rev8 Point IIA 2.6 and conducted with test material oxamyl analytical standard, was conducted under EPA 63-8. A review of this study indicates that it does not meet the current guideline (OECD 105) and has been superceded with DuPont-13351.	Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted and Not Relied Upon.”  Acceptable		
	EEC A.6. (flask method) OECD 105 (flask method) OPPTS Series 830.7840 or 830.7860 CIPAC MT157	DPX-D1410-196 (98.3%, PAI)	The solubility in water study DuPont-13351, originally submitted under DAR Volume 3, B2, Point 2.1.6 and conducted with test material oxamyl PAI, was conducted under OECD 105 (shake flask method). A review of this study indicates that it fully meets the current guideline (OECD 105).  148.1 g/L at 20 ± 0.5°C at pH 5	Study included in the Oxamyl DAR Final Addendum 2004. Now cited in CA Master Reference List “Documents Not Submitted. Previously Submitted and Relied Upon.”  Acceptable		

### B.2.6 Solubility in organic solvents

Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
<b>Solubility in organic solvents</b>	OECD 105 (flask method) EEC A.6 OPPTS 830.7840	DPX-D1410-376 (100.0%, PAI)	<p>The solubility in organic solvents study DuPont-4513, originally submitted under EU Rev8 Point IIA 2.7 and conducted with test material oxamyl PAI, was conducted under OECD 105, EEC A.6, and OPPTS 830.7840. A review of this study indicates that it fully meets the current guideline CIPAC Method MT 181, OECD 105.</p> <p>Acetone: &gt;250 g/kg at 20°C  Dichloromethane: &gt;250 g/kg at 20°C  Ethyl acetate: <math>4.13 \times 10^4</math> mg/L at 20°C  n-heptane: 10.5 mg/L at 20°C  Methanol: &gt;250 g/kg at 20°C  o-xylene: <math>3.14 \times 10^3</math> mg/L at 20°C</p>	<p>Study submitted in the EU Dossier in 2001 and included in the first EU approval review Now cited in CA Master Reference List “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		

**B.2.7 Partition coefficient n-octanol/water**

<b>Data Point Test or property</b>	<b>Guideline and method</b>	<b>Test material purity and specification</b>	<b>Findings</b>	<b>Comments</b>	<b>GLP Y/N</b>	<b>Reference</b>
<b>n-octanol/ water partition coefficient</b>	EPA 63-11		The n-octanol/water partition coefficient study AMR 980-87, originally submitted under EU Rev8 Point IIA 2.8 and conducted with test material [ <sup>14</sup> C]oxamyl, was conducted under EPA 63-11. A review of this study indicates that it does not meet the current guideline (OECD 107) and has been superceded with DuPont-39338.	Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted and Not Relied Upon.”  Acceptable		
	EEC A.8./ OECD 107 (shake flask method)	DPX-D1410-532, (99.1%, PAI) (Document J)	The n-octanol/water partition coefficient ( $P_{ow}$ ) of oxamyl at 23°C was determined to be 0.37 (Log $P_{ow}$ -0.43). The n-octanol/water partition coefficient was measured using the shake flask method. Measurements were made in double distilled water only, since oxamyl is not an ionisable compound.	Study submitted to the EU for the first time in this submission. Cited in Reference List “Documents Submitted.”  Acceptable	Y	DuPont-39338

Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference										
	KOWWIN program	Calculation	<p>The n-octanol/water partition coefficients for the major metabolites of oxamyl were estimated based on their structure using the KOWWIN program.</p> <table><thead><tr><th>Metabolite</th><th>Log(K<sub>ow</sub>)</th></tr></thead><tbody><tr><td>IN-A2213</td><td>-0.71</td></tr><tr><td>IN-D2708</td><td>-1.72</td></tr><tr><td>IN-N0079</td><td>-1.95</td></tr><tr><td>IN-T2921</td><td>-1.77</td></tr></tbody></table>	Metabolite	Log(K <sub>ow</sub> )	IN-A2213	-0.71	IN-D2708	-1.72	IN-N0079	-1.95	IN-T2921	-1.77	<p>Study submitted to the EU for the first time in this submission. Cited in Reference List “Documents Submitted.”</p> <p>Acceptable</p>	N	DuPont-4358
Metabolite	Log(K <sub>ow</sub> )															
IN-A2213	-0.71															
IN-D2708	-1.72															
IN-N0079	-1.95															
IN-T2921	-1.77															
Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference										
Effect of pH on the n-octanol/water partition coefficient			Oxamyl does not ionise, thus investigations into the effect of pH on n-octanol/water partition coefficient were not performed.	Acceptable												



### B.2.8 Dissociation in water

Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
<b>Dissociation in water</b>			Detailed summaries of the hydrolysis and aqueous photolysis studies are presented in the Oxamyl EU Renewal Dossier, Document M-CA, Section 7, DuPont-40934 EU, Points CA 7.2.1.1 and CA 7.2.1.2.	Acceptable		
<b>Dissociation constant</b>	None		The dissociation constant study DuPont-7158, was originally submitted under EU Rev8 Point IIA 2.9.4. A review of this study indicates that it does not meet the current guideline (OECD 112) and has been superceded with DuPont-26918.	Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted and Not Relied Upon.”  Acceptable		
	OECD 112 OPPTS Series 830.7370	DPX-D1410-196, (98.0%, PAI) (Document J)	Oxamyl does not dissociate between pH 2.4 to pH 11.6 at 20 ± 0.5°C.	Study submitted to the EU for the first time in this submission. Cited in Reference List “Documents Submitted.”  Acceptable	Y	DuPont-26918

### B.2.9 Flammability and self-heating

Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Flammability	EEC A.9 in lieu of EEC A.10	DPX-D1410-409, (420 g a.s./kg, 42TK)	<p>The flammability study DuPont-3655, originally submitted under EU Rev8 Point IIA 2.11.1 and conducted with test material oxamyl technical concentrate 42TK, was conducted under EEC A.9. A review of this study indicates that it fully meets the current data requirement. Since oxamyl as manufactured is a liquid, the flash point (the lowest temperature at which a liquid evolves vapours) under the conditions of the test was used to assess the flammability of oxamyl technical concentrate 42TK.</p> <p>The flash point was 57.4°C (135.26°F). The 42% technical concentrate material is dissolved in cyclohexanone (flash-point 44°C) and water. Cyclohexanone is a flammable liquid.</p>	<p>Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		

<b>Data Point Test or property</b>	<b>Guideline and method</b>	<b>Test material purity and specification</b>	<b>Findings</b>	<b>Comments</b>	<b>GLP Y/N</b>	<b>Reference</b>
<b>Auto- flammability</b>	EEC A.15	DPX-D1410-409, (420 g a.s./kg, 42TK)	<p>The auto-flammability study 550/77-D2141, originally submitted under EU Rev8 Point IIA 2.11.2 and conducted with test material oxamyl technical concentrate 42% (42TK), was conducted under EEC A.15. A review of this study indicates that it fully meets the current guideline (EEC A.15).</p> <p>The auto-ignition temperature was determined to be 303°C (± 5°C) with a sample volume of 0.1 mL, and atmospheric pressure 101.2 kPa.</p>	<p>Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		

Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Auto- flammability (continued)	EEC A.16. OPPTS Series 830.6315	DPX-D1410-196, (98.0%, PAI) (Document J)	<p>No self-ignition (auto-flammability). A known volume of test substance was placed in an oven at room temperature and the oven temperature increased at 0.5°C/min to 400°C (~300°C above the mp). Both the temperatures of the oven and the sample were recorded. The temperature/time curve relating to conditions in the centre of the sample showed no exotherm of sufficient magnitude to constitute a self-ignition temperature. Endothermic activity was observed at ~100°C, which is attributed to the melting of the test substance. After heating, the sample basket was observed to be empty, which is consistent with the test substance having melted during the test.</p> <p>The results of this study should be considered with those from 550/77-D2141. Together these studies demonstrate that the auto-flammability exhibited by the oxamyl technical concentrate (42TK) can be attributed to the solvent and not to oxamyl itself.</p>	<p>Study submitted to the EU for the first time in this submission. Cited in Reference List “Documents Submitted.”</p> <p>Acceptable</p>	Y	DuPont-14828

**B.2.10 Flash point**

<b>Data Point Test or property</b>	<b>Guideline and method</b>	<b>Test material purity and specification</b>	<b>Findings</b>	<b>Comments</b>	<b>GLP Y/N</b>	<b>Reference</b>
<b>Flash Point</b>	EEC A.9.	DPX-D1410-409, (420 g a.s./kg, 42TK)	<p>The flash point study DuPont-3655, originally submitted under EU Rev8 Point IIA 2.12 and conducted with test material oxamyl technical concentrate (42TK), was conducted under EEC A.9. A review of this study indicates that it fully meets the current guideline (EEC A.9).</p> <p>The flash point of oxamyl technical concentrate (42TK) was 57.4°C.</p>	<p>Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		

**B.2.11 Explosive properties**

<b>Data Point Test or property</b>	<b>Guideline and method</b>	<b>Test material purity and specification</b>	<b>Findings</b>	<b>Comments</b>	<b>GLP Y/N</b>	<b>Reference</b>
<b>Explosive properties</b>	EEC A.14.	DPX-D1410-409, (420 g a.s./kg, 42TK)	<p>The explosive properties study 550/77-D2141, originally submitted under EU Rev8 Point IIA 2.13 and conducted with test material oxamyl technical concentrate (42TK), was conducted under EEC A.14. A review of this study indicates that it fully meets the current guideline (EEC A.14).</p> <p>Oxamyl technical concentrate (42TK) is not explosive.</p>	<p>Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		

**B.2.12 Surface tension**

<b>Data Point Test or property</b>	<b>Guideline and method</b>	<b>Test material purity and specification</b>	<b>Findings</b>	<b>Comments</b>	<b>GLP Y/N</b>	<b>Reference</b>
<b>Surface Tension</b>	EEC A.5.	DPX-D1410-376 (100.0%, PAI)	<p>The surface tension study DuPont-4318, originally submitted under EU Rev8 Point IIA 2.14 and conducted with test material oxamyl PAI, was conducted under EEC A.5. A review of this study indicates that it fully meets the current guideline (EEC A.5 and OECD 115).</p> <p>The true surface tension of oxamyl was determined to be <math>73.1 \pm 0.3</math> dynes/cm at an average temperature of <math>20.4 \pm 0.1^\circ\text{C}</math>.</p>	<p>Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		

### B.2.13 Oxidising properties

Data Point Test or property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
<b>Oxidising properties</b>	EEC A.17. Structural argument		The oxidising properties study DuPont-7197, originally submitted under EU Rev8 Point IIA 2.15 was presented as a structural argument. A review of this study indicates that it does not meet the current guideline (EEC A.17) and has been superceded with DuPont-40352.	Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted and Not Relied Upon.”  Acceptable		
<b>Oxidising properties (continued)</b>	EEC A.17.	DPX-D1410-532, (99.1%, PAI) (Document J)	The results from this experiment demonstrated that the active substance, oxamyl, is not considered to be an oxidizing substance, because the test item/cellulose mixture showed no independent burning or glowing in an inert argon atmosphere.  None of the solvents in the oxamyl technical concentrate (42% oxamyl in cyclohexanone and water) are classified as oxidizing substances, and thus the manufactured technical concentrate (42TK) is determined to be non-oxidizing.	Study submitted to the EU for the first time in this submission. Cited in Reference List “Documents Submitted.”  Acceptable	Y	DuPont-40352



**B.2.14 Other studies**

<b>Data Point Test or property</b>	<b>Guideline and method</b>	<b>Test material purity and specification</b>	<b>Findings</b>	<b>Comments</b>	<b>GLP Y/N</b>	<b>Reference</b>
<b>Other studies</b>			The following studies were performed on oxamyl PAI.			
<b>Relative Density</b>	EEC A.3. OECD 109 EPA 830.7300	DPX-D1410-376 (100.0%, PAI)	<p>The relative density study DuPont-2165, originally submitted under EU Rev8 Point IIA 2.2 and conducted with test material oxamyl PAI, was conducted under EEC A.3., OECD 109, and EPA 830.7300. A review of this study indicates that it fully meets the current guideline (OECD 109).</p> <p>The relative density measured was 1313 kg/m<sup>3</sup> at 23.6 ± 0.1°C.</p>	<p>Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted and Not Relied Upon.”</p> <p>This study is no longer required according to Regulation 1107/2009.</p> <p>Acceptable</p>		

<b>Data Point Test or property</b>	<b>Guideline and method</b>	<b>Test material purity and specification</b>	<b>Findings</b>	<b>Comments</b>	<b>GLP Y/N</b>	<b>Reference</b>
<b>Odour</b>	US EPA 63-4	NB7292-112 (95.7%, oxamyl analytical standard)	The odour study D1410.B, originally submitted under EU Rev8 Point IIA 2.4.2 and conducted with test material oxamyl analytical standard, was conducted under US EPA 63-4. A review of this study indicates that it fully meets the current guideline (OPPTS 830.6304).  Odour is slightly sulfurous.	Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Now cited in CA Master Reference List “Documents Not Submitted and Not Relied Upon.”  This study is no longer required according to Regulation 1107/2009.  Acceptable		

### **B.2.15 Overview of the physical and chemical properties of the active substance**

The pure active substance of oxamyl is a white, crystalline solid that melts at 99.2°C. Oxamyl does not exhibit a pKa and thus would not be expected to ionise in the relevant environmental pH range. The aqueous solubility of oxamyl is 148.1 g/L and is not dependent upon pH. The vapour pressure ( $1.80 \times 10^{-5}$  Pa at 20°C) and the Henry's Law Constant ( $2.7 \times 10^{-8}$  Pa·m<sup>3</sup>/mol at 20°C) indicate that volatilisation is not a significant route of dissipation for oxamyl. The oxamyl technical concentrate as manufactured (42TK) exhibits a flash point of 57.4°C and an auto-ignition temperature of 303°C due to the presence of cyclohexanone as a solvent. This manufactured technical concentrate was demonstrated to be safe with respect to explosivity and oxidising properties.

#### **B.2.16 References relied on**

Unless otherwise specified data submitted with this dossier are necessary for the renewal of the approval of oxamyl because they address standard data requirements or reflect changes in scientific and/or technical knowledge or changes in uses since the first inclusion of the active substance. The reasons why individual studies are necessary are specified in a separate column below. The corresponding studies were conducted according to GLP or GEP standards and did not benefit from a previous period of protection or if previously protected the period of data protection has not expired at the time of submission of this dossier.

In line with Article 60(1) of Regulation (EC) No. 1107/2009, the Rapporteur Member State shall prepare a list of the test and study reports necessary for the renewal of the approval of oxamyl and the reference list below can be used as a basis.

DuPont will make final claims of data protection for these necessary active substance and plant protection product data at application for authorisation or renewal of authorisation of our plant protection products after the approval renewal of oxamyl in line with the provisions set in Articles 33.4 and 59 of Regulation (EC) No. 1107/2009.

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.

**List of documents submitted sorted by Annex Point**

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
B.2.1	Jackson, W.A.	2004	DPX-D1410: Laboratory study of melting point and decomposition point Syngenta Technology and Projects DuPont-14983 GLP: Yes Published: No	N	Y	Conducted to meet guidelines. The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted.	DuPont
B.2.2	Harsh, N.V.	2009	Oxamyl (DPX-D1410-196): Laboratory study of vapour pressure International Institute of Biotechnology and Toxicology (IIBAT) DuPont-26259 GLP: Yes Published: No	N	Y	Conducted to meet guidelines. The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted.	DuPont
B.2.2	Malin, J.N.	2014	Oxamyl (DPX-D1410): Volatility, calculation of Henry's law constant DuPont Stine-Haskell Research Center DuPont-38270 GLP: No Published: No	N	N		DuPont
B.2.3	Piasentini de Campos, L.F.	2006	Physical state, appearance and color of oxamil técnico BIOAGRI Laboratories RF - 0014.001.256.06 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>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
B.2.4.1	Schmuckler, M.E.	2002	Oxamyl (DPX-D1410): <sup>13</sup> C-NMR spectrum DuPont Stine-Haskell Research Center DuPont-11446, Revision No. 1 GLP: No Published: No	N	N		DuPont
B.2.7	Birnschein, K.	2014	Oxamyl (DPX-D1410): Partition coefficient (shake flask method) Eurofins Agrosience Services EcoChem GmbH DuPont-39338 GLP: Yes Published: No	N	Y	Conducted to meet guidelines. The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted.	DuPont
B.2.7	Schmuckler, M.E.	2000	Bioconcentration factor (BCF) of IN-A2213, IN-D2708, IN-N0079, and IN-T2921 DuPont Stine-Haskell Research Center DuPont-4358 GLP: No Published: No	N	N		DuPont
B.2.8	Harsh, N.V.	2009	Oxamyl (DPX-D1410): Laboratory study of dissociation constant International Institute of Biotechnology and Toxicology (IIBAT) DuPont-26918 GLP: Yes Published: No	N	Y	Conducted to meet guidelines. The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted.	DuPont

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
B.2.9	Jackson, W.	2004	Relative self-ignition temperature of oxamyl (DPX-D1410) technical (98% w/w) Syngenta Technology and Projects DuPont-14828 GLP: Yes Published: No	N	Y	Conducted to meet guidelines. The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted.	DuPont
B.2.13	Birnschein, K.	2014	Oxamyl (DPX-D1410): Oxidizing properties (solids) Eurofins Agrosience Services EcoChem GmbH DuPont-40352 GLP: Yes Published: No	N	Y	Conducted to meet guidelines. The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted.	DuPont

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B.2.7	Birnschein, K.	2014	Oxamyl (DPX-D1410): Partition coefficient (shake flask method) Eurofins Agrosience Services EcoChem GmbH DuPont-39338 GLP: Yes Published: No	N	Y	Conducted to meet guidelines. The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted.	DuPont
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B.2.2	Harsh, N.V.	2009	Oxamyl (DPX-D1410-196): Laboratory study of vapour pressure International Institute of Biotechnology and Toxicology (IIBAT) DuPont-26259 GLP: Yes Published: No	N	Y	Conducted to meet guidelines. The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted.	DuPont
B.2.8	Harsh, N.V.	2009	Oxamyl (DPX-D1410): Laboratory study of dissociation constant International Institute of Biotechnology and Toxicology (IIBAT) DuPont-26918 GLP: Yes Published: No	N	Y	Conducted to meet guidelines. The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted.	DuPont



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B.2.1	Jackson, W.A.	2004	DPX-D1410: Laboratory study of melting point and decomposition point Syngenta Technology and Projects DuPont-14983 GLP: Yes Published: No	N	Y	Conducted to meet guidelines. The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted.	DuPont
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<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
B.2.4.1	Schmuckler, M.E.	2002	Oxamyl (DPX-D1410): <sup>13</sup> C-NMR spectrum DuPont Stine-Haskell Research Center DuPont-11446, Revision No. 1 GLP: No Published: No	N	N		DuPont
B.2.7	Schmuckler, M.E.	2000	Bioconcentration factor (BCF) of IN-A2213, IN-D2708, IN-N0079, and IN-T2921 DuPont Stine-Haskell Research Center DuPont-4358 GLP: No Published: No	N	N		DuPont