

*European Commission*

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



**Oxamyl 10GR**

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

Rapporteur Member State: Italia  
Co-Rapporteur Member State: 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**

<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>Appearance</b>	Visual assessment		<p>The appearance study DuPont-2491, originally submitted under EU Rev8 Point IIIA 2.1.1 and conducted with test material Oxamyl 10GR, was conducted under unspecified guidelines. A review of this study indicates that it fully meets the current guideline (Visual Assessment).</p> <p>Oxamyl 10GR is a blue-green granule. This product has a slight solvent odour.</p>	<p>Study submitted during the 2001 Annex I review.</p> <p>Now cited in Reference List, Document M-CP Section 2 “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		
		Oxamyl 10GR (DPX-D1410-565) (Document J)	Oxamyl 10GR is a granular solid, sold as a Granule (GR). It is turquoise (10BG 7/6)	<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-39557

**B.2.2 Explosive and oxidising 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		<p>The explosive properties study (550/71D-2141), originally submitted under EU Rev8 Point IIIA 2.2.1 and conducted with test material Oxamyl 10GR, was conducted under EEC A.14. A review of this study indicates that it fully meets the current guideline (EEC A.14).</p> <p>No explosive properties.</p>	<p>Study submitted during the 2001 Annex I review.</p> <p>Now cited in Reference List Document M-CP Section 2 “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
<b>Oxidising properties</b>	EEC A.17		<p>The oxidizing properties study DuPont-7197, originally submitted under EU Rev8 Point IIIA 2.2.2 and conducted with test material Oxamyl 10GR, was conducted under unspecified guidelines. A review of this study indicates that it fully meets the current guideline based on the scientific explanation.</p> <p>Based on its thermodynamic properties, Oxamyl 10GR does not have oxidising properties. In oxamyl, the two amide nitrogens are in the –3 oxidation state, while the oxime nitrogen is in the –1 oxidation state. This nitrogen is not so highly reduced as amide or amine nitrogens; however, it is still more reduced than elemental nitrogen (zero oxidation state) and certainly more so than oxidizing states of nitrogen such as nitrate (+3) or nitrate (+5). Therefore, oxamyl should not be oxidizing. All Material Safety Data Sheets for formulation components were reviewed. None of the components was classified as an oxidiser.</p>	<p>Study submitted during the 2001 Annex I review.</p> <p>Now cited in Reference List Document M-CP Section 2 “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p><b>Acceptable</b></p>		

**B.2.3 Flammability and auto-flammability**

<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		Not applicable to a solid preparation	Not applicable to solid preparations		
<b>Flammability</b>	EEC A.10		<p>The flammability study (550/71D-2141), originally submitted under EU Rev8 Point IIIA 2.3 and conducted with test material Oxamyl 10GR, was conducted under EEC A.10. A review of this study indicates that it fully meets the current guideline (EEC A.10).</p> <p>Not highly flammable, material does not ignite. Mean moisture content: 7.1%</p>	<p>Study submitted during the 2001 Annex I review.</p> <p>Now cited in Reference List Document M-CP Section 2 “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
<b>Auto flammability</b>	EEC A.16		<p>The auto flammability study (550/71D-2141), originally submitted under EU Rev8 Point IIIA 2.3 and conducted with test material Oxamyl 10GR, was conducted under EEC A.16. A review of this study indicates that it fully meets the current guideline (EEC A.16).</p> <p>No self ignition below 400°C</p>	<p>Study submitted during the 2001 Annex I review.</p> <p>Now cited in Reference List Document M-CP Section 2 “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		

**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
<b>Free acidity/ alkalinity</b>	CIPAC MT 191			Not applicable as pH of a 1% dilution with de-ionised water is not lower than 4 or greater than 10.		

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
<b>pH of a 1% aqueous dilution</b>	CIPAC MT 75.3 EPA FIFRA Guideline 63-12		<p>The pH of a 1% aqueous dilution study DuPont-2491, originally submitted under EU Rev8 Point IIIA 2.4.2 and conducted with test material Oxamyl 10GR, was conducted under CIPAC MT 75. A review of this study indicates that it fully meets the current guideline (CIPAC MT 75.3).</p> <p>6.8 at 25°C</p>	<p>Study submitted during the 2001 Annex I review.</p> <p>Now cited in Reference List Document M-CP Section 2 “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		
		Oxamyl 10GR (DPX-D1410-565) (Document J)	<p>The pH of Oxamyl 10GR in a 1% aqueous dispersion was determined to be <math>7.28 \pm 0.14</math> at <math>20 \pm 2^\circ\text{C}</math></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-39557

**B.2.5 Viscosity and 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>Kinematic viscosity</b>	OECD 114			Viscosity not required, as this preparation was not designed for Ultra Low Volume (ULV) use  Acceptable		
<b>Viscosity</b>	CIPAC 192			Not applicable to solid preparations.		
<b>Surface tension</b>	EEC A.5 OECD 115			Surface tension not applicable to solid preparations.		

**B.2.6 Relative density and bulk density**

<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>Relative density</b>	EEC A.3 OECD 109 (1995)			Relative density is not required for solid preparations.		
<b>Bulk/tap density</b>	CIPAC MT 186		<p>The bulk/tap density study DuPont-2491, originally submitted under EU Rev8 Point IIIA 2.6.2 and conducted with test material Oxamyl 10GR, was conducted under CIPAC MT 159. A review of this study indicates that it fully meets the current guideline (CIPAC MT 186).</p> <p>Loose bulk density: 0.72 g/cm<sup>3</sup> Tapped bulk density: 0.81 g/cm<sup>3</sup></p>	<p>Study submitted during the 2001 Annex I review.</p> <p>Now cited in Reference List Document M-CP Section 2 “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
<b>Bulk/tap density (continued)</b>	CIPAC MT 186	Oxamyl 10GR (DPX-D1410-565) (Document J)	<p>The loose density of Oxamyl 10GR was recorded as 0.7541 g/mL. The tapped density was measured at 0.8286 g/mL.</p> <p>Eighty grams of the test substance were placed into a 250 mL measuring cylinder that was raised and allowed to fall vertically a distance of 2.5 cm onto a rubber pad. The procedure was repeated 50 times.</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-39557

**B.2.7 Storage 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)		<p>The stability after storage for 14 days at 54°C study DuPont-2491, originally submitted under EU Rev8 Point IIIA 2.7.1.1 and conducted with test material Oxamyl 10GR, was conducted under CIPAC MT 46. A review of this study indicates that it fully meets the current guideline (CIPAC MT 46.3).</p> <p>Chem assay: Initial: 9.86% a.s. After 2 weeks at 54°C: 9.38% a.s.</p> <p>The results indicate that Oxamyl 10GR is stable following storage for 2 weeks at 54°C.</p> <p>Additional test results after accelerated storage:</p> <p>pH (MT 75): 7.6</p> <p>Attrition resistance (MT 178): 100%</p> <p>Dustiness (MT171): 6.2 mg (0.02%)</p> <p>Size Range of Granules (MT58.2 Dry Sieve):</p> <table><tr><td>850–250 µm</td><td>97.0%</td></tr><tr><td>250–150 µm</td><td>0.9%</td></tr><tr><td>&lt;150 µm (+ loss)</td><td>2.1%</td></tr><tr><td>total &lt;250 µm</td><td>3.0%</td></tr></table>	850–250 µm	97.0%	250–150 µm	0.9%	<150 µm (+ loss)	2.1%	total <250 µm	3.0%	<p>Study submitted during the 2001 Annex I review.</p> <p>Now cited in Reference List Document M-CP Section 2 “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		
850–250 µm	97.0%													
250–150 µm	0.9%													
<150 µm (+ loss)	2.1%													
total <250 µm	3.0%													

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Stability after storage for other periods and/or temperatures	CIPAC MT 46.3 (accelerated storage)	Oxamyl 10GR (DPX-D1410-565) (Document J)	Oxamyl 10GR was stored for 8 weeks at 40°C temperature in either polypropylene containers or LPDE/Aluminium/PET multilayer bags. The following tests were conducted.	Study submitted to the EU for the first time in this submission. Cited in Reference List “Documents Submitted.”  Acceptable	Y	DuPont-39557
	ASTM D1535-89          None		Colour:  <u>@ 8 weeks in Polypropylene container:</u> 7.5BG 8/4 (Turquoise) <u>@ 8 weeks in LPDE/Aluminium/PET bag:</u> 10BG 8/4 (Turquoise)  Physical State:  <u>@ 8 weeks in Polypropylene container:</u> Granular solid <u>@ 8 weeks in LPDE/Aluminium/PET bag:</u> Granular solid  Odour: Not performed (extreme hazard)	Acceptable		

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
	CIPAC MT 75.3		pH of 1% dilution:  <u>@ 8 weeks in Polypropylene container:</u> 7.53 ± 0.02 <u>@ 8 weeks in LPDE/Aluminium/PET bag:</u> 7.60 ± 0.00	Acceptable		
Stability after storage for other periods and/or temperatures (continued)	CIPAC MT 186		Bulk Density (g/cm <sup>3</sup> )  <u>@ 8 weeks in Polypropylene container</u> Pour = 0.7037 Tap = 0.7504 <u>@ 8 weeks in LPDE/Aluminium/PET bag</u> Pour = 0.7567 Tap = 0.8133	Acceptable		
	CIPAC MT 170		Nominal Size Range  <u>@ 8 weeks in Polypropylene container</u> Rx ≥90% @ 500 µm Rx ≤10% @ 1000 µm <u>@ 8 weeks in LPDE/Aluminium/PET bag</u> Rx ≥90% @ 500 µm Rx ≤10% @ 1000 µm	Acceptable		
	CIPAC MT 171		Dust Content:  <u>@ 8 weeks in Polypropylene container</u> Nearly dust free <u>@ 8 weeks in LPDE/Aluminium/PET bag</u> Nearly dust free	Acceptable		



Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
	CIPAC MT 178		Attrition Resistance (%):  <u>@ 8 weeks in Polypropylene container</u> 98.96 <u>@ 8 weeks in LPDE/Aluminium/PET bag</u> 99.46	Acceptable		
Stability after storage for other periods and/or temperatures (continued)	CIPAC MT 172		Flowability:  <u>@ 8 weeks in Polypropylene container</u> Passed through sieve spontaneously <u>@ 8 weeks in LPDE/Aluminium/PET bag</u> Passed through sieve spontaneously	Acceptable		
	DuPont Method D1410.220.02.ES		Active ingredient content (g/Kg):  <u>@ 8 weeks in Polypropylene container</u> 91.5 ± 0.2 <u>@ 8 weeks in LPDE/Aluminium/PET bag</u> 92.4 ± 0.8	Acceptable		

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
<b>Minimum content after heat stability testing</b>	CIPAC MT 46.3 (accelerated storage)		<p>The minimum content after heat stability testing study DuPont-2491, originally submitted under EU Rev8 Point IIIA 2.7.1.3 and conducted with test material Oxamyl 10GR, was conducted under CIPAC MT 46. A review of this study indicates that it fully meets the current guideline (CIPAC MT 46.3).</p> <p>Not heat sensitive: Chem assay: Initial: 9.86% a.s. After 2 weeks at 54°C: 9.38% a.s.</p>	<p>Study submitted during the 2001 Annex I review.</p> <p>Now cited in Reference List M-CP Section 2 “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		
		Oxamyl 10GR (DPX-D1410-565) (Document J)	<p>Initial active ingredient content (g/kg): 98.0 ± 0.9</p> <p>Active ingredient content (g/Kg):</p> <p><u>@ 8 weeks at 40°C in Polypropylene container</u> 91.5 ± 0.2</p> <p><u>@ 8 weeks at 40°C in LPDE/Aluminium/PET bag</u> 92.4 ± 0.8</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-39557
<b>Effect of low temperature on stability</b>	CIPAC MT 39.3			Low temperature stability is not applicable to solid preparations		

Oxamyl 10GR - Annex D.2: Physical and chemical properties														
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	In line with GIFAP Monograph No 17 (Using CIPAC methods 58.2, 75, 171, and 178)		<p>The shelf life following storage at ambient temperature for 2 years in study DuPont-2671, originally submitted under EU Rev8 Point IIIA 2.7.3 and conducted with test material Oxamyl 10GR, was conducted under CIPAC methods 58.2, 75, 171, and 178. A review of this study indicates that it fully meets the current shelf life stability guidelines.</p> <p>Shelf-Life Stability Test Results:</p> <p>Chemical Assay: 9.1% a.s.</p> <p>Appearance and Packaging: Material remains a free flowing, solid. Package seals were intact with no apparent seepage or leakage.</p> <p>pH (MT75): 6.5</p> <p>Dust (MT171): 6 mg (0.02%)</p> <p>Attrition Resistance (MT178): 100%</p> <p>Dry Sieve:</p> <table><tr><td>840 µm to &gt;250 µm:</td><td>97.65%</td></tr><tr><td>&gt;150 µm</td><td>0.74%</td></tr><tr><td>&lt;150 µm</td><td>1.59% (includes loss)</td></tr><tr><td>total &lt;250 µm</td><td>2.34%</td></tr></table>	840 µm to >250 µm:	97.65%	>150 µm	0.74%	<150 µm	1.59% (includes loss)	total <250 µm	2.34%	<p>Study submitted during the 2001 Annex I review.</p> <p>Now cited in Reference List M-CP Section 2 “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		
840 µm to >250 µm:	97.65%													
>150 µm	0.74%													
<150 µm	1.59% (includes loss)													
total <250 µm	2.34%													

<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>Shelf life in months</b>				Not applicable as test substance has been demonstrated to be stable for a minimum of 2-years.		

**B.2.8 Technical characteristics of the plant protection product****B.2.8.1 Wettability**

<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>Wettability</b>	CIPAC MT 53.3.1			Not required for granular formulations.		

### 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			Not required for granular formulations.		

### 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 granular formulations.		
Dispersibility (WG) or Spontaneity of dispersion (SC)	CIPAC MT 174  CIPAC MT 160			Not applicable to granular formulations.		

**B.2.8.4 Degree of dissolution and dilution stability**

<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>Degree of dissolution and dilution stability</b>	CIPAC MT 179  CIPAC MT 41			Only applicable to Water Soluble Products.		

**B.2.8.5 Particle size distribution, dust content, attrition and mechanical stability****B.2.8.5.1 Particle size distribution, dust content, attrition and mechanical stability**

<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>Dry sieve test</b>	CIPAC MT 59.1			The dry sieve test required in this section is only applicable to dustable powders.		
<b>Wet sieve test</b>	CIPAC MT 185			Not required for granular formulations.		

**B.2.8.5.2 Particle size distribution**

<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>Size distribution of particles</b>	OECD 110			Only required for powder formulations.		
<b>Nominal size range of granules</b>	CIPAC MT 170		<p>The nominal size range of granules study DuPont-2491, originally submitted under EU Rev8 Point IIIA 2.8.6.1 and conducted with test material Oxamyl 10GR, was conducted under CIPAC MT 58.2. A review of this study indicates that it fully meets the current guideline (CIPAC MT 170).</p> <p>850–250 µm: 97.3%  250–150 µm: 0.7%  &lt;150 µm (+ loss): 2.1%  Total &lt;250 µm: 2.7%</p>	<p>Study submitted during the 2001 Annex I review.</p> <p>Now cited in Reference List M-CP Section 2 “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		DuPont-2491

Data Point Test or Property	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference														
Nominal size range of granules (continued)	CIPAC MT 170	Oxamyl 10GR (DPX-D1410-565) (Document J)	<p>The granule size distribution of Oxamyl 10GR is as follows:</p> <table><tr><td>75 µm</td><td>0.21%</td></tr><tr><td>125 µm</td><td>0.74%</td></tr><tr><td>250 µm</td><td>5.68%</td></tr><tr><td>500 µm</td><td>91.6%</td></tr><tr><td>1000 µm</td><td>0.96%</td></tr><tr><td>2000 µm</td><td>0.06%</td></tr><tr><td>3350 µm</td><td>0.04%</td></tr></table> <p>Nominal size range of granules: Approximately 116 grams of Oxamyl 10GR were sieved on a Retsch Sieve Machine Shaker for a period of 5 minutes. The testing was conducted with the following sieves: 3350 µm, 2000 µm, 1000 µm, 500 µm, 250 µm, 125 µm and 75 µm.</p> <p>The smallest sieve, upon which ≥90% of the material was retained, was 500 microns</p> <p>The largest sieve, upon which ≤10% of the material was retained, was 1000 microns.</p>	75 µm	0.21%	125 µm	0.74%	250 µm	5.68%	500 µm	91.6%	1000 µm	0.96%	2000 µm	0.06%	3350 µm	0.04%	<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-39557
75 µm	0.21%																			
125 µm	0.74%																			
250 µm	5.68%																			
500 µm	91.6%																			
1000 µm	0.96%																			
2000 µm	0.06%																			
3350 µm	0.04%																			



**B.2.8.5.3 Dust content**

<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>Dust content</b>	CIPAC MT 171		<p>The dust content study DuPont-2491, originally submitted under EU Rev8 Point IIIA 2.8.6.2 and conducted with test material Oxamyl 10GR, was conducted under CIPAC 171. A review of this study indicates that it fully meets the current guideline (CIPAC MT 171).</p> <p>3.2 mg (0.01%)</p>	<p>Study submitted during the 2001 Annex I review.</p> <p>Now cited in Reference List M-CP Section 2 “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		DuPont-2491
<b>Dust content</b>	CIPAC MT 171	Oxamyl 10GR (DPX-D1410-565) (Document J)	<p>After the airflow was adjusted to a rate of 15 L per minute, a 30-gram sample of the test material was introduced into the gravimetric dust testing apparatus. After a period of 60 seconds the airflow was stopped and the amount of airborne dust collected on a filter was measured.</p> <p>Oxamyl 10GR was nearly dust free.</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-39557
<b>Particle size of dust</b>	OECD 110			Not required since it is not relevant for operator exposure		

**B.2.8.5.4 Attrition**

<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>Attrition</b>	CIPAC MT 178		<p>The attrition study DuPont-2491, originally submitted under EU Rev8 Point IIIA 2.8.6.3 and conducted with test material Oxamyl 10GR, was conducted under CIPAC MT 178. A review of this study indicates that it fully meets the current guideline (CIPAC MT 178).</p> <p>100%</p>	<p>Study submitted during the 2001 Annex I review.</p> <p>Now cited in Reference List M-CP Section 2 “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		DuPont-2491
	CIPAC MT 178	Oxamyl 10GR (DPX-D1410-565) (Document J)	<p>The attrition resistance of Oxamyl 10GR was 98.45%.</p> <p>A representative sample of Oxamyl 10GR was pre-sieved as directed by the method. Fifty grams of this material was placed into a glass jar. The jar was rotated at a speed between 75 and 125 rpm. The test substance was separated from the beads, placed on a 125 µm sieve and agitated for 3 minutes. The material remaining on the sieve was weighed and the attrition resistance calculated.</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-39557

#### B.2.8.5.5 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 granular 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 solid or suspension concentrate preparations.		
Emulsion stability	CIPAC MT 20 (EC)			Not applicable to solid or suspension concentrate preparations.		

<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>Re-emulsifiability</b>	CIPAC MT 36.3			Not applicable to solid or suspension concentrate preparations		
<b>Stability of dilute emulsions</b>	CIPAC MT 20 (EO, EW)			Not applicable to solid or suspension concentrate preparations		
<b>Stability of emulsions</b>				Not applicable to solid or suspension concentrate preparations		

**B.2.8.7 Flowability, pourability and dustability**

<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>
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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>Flowability</b>	CIPAC MT 172		<p>The flowability study DuPont-2491, originally submitted under EU Rev8 Point IIIA 2.8.8.1 and conducted with test material Oxamyl 10GR, was conducted under CIPAC MT 172. A review of this study indicates that it fully meets the current guideline (CIPAC MT 172).</p> <p>Sample dropped through the sieve spontaneously.</p>	<p>Study submitted during the 2001 Annex I review.</p> <p>Now cited in Reference List M-CP Section 2 “Documents Not Submitted. Previously Submitted and Relied Upon.”</p> <p>Acceptable</p>		DuPont-2491
<b>Pourability</b>	CIPAC MT 148.1			Not applicable since Oxamyl 10GR is not a suspension		
<b>Dustability following accelerated storage</b>	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**

<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>Physical compatibility of tank mixes</b>			No tank mix recommendations are included in the label.	Acceptable		
<b>Chemical compatibility of tank mixes</b>			See physical compatibility above.	Acceptable		

**B.2.10 Adherence and distribution to seeds**

<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>Distribution (seed treatment)</b>				Not required since Oxamyl 10GR is not a seed treatment		
<b>Adhesion (seed treatment)</b>				Not required since Oxamyl 10GR is not a seed treatment		

**B.2.11 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>				None required		

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

**Safety:** Oxamyl 10GR is non-flammable, non-explosive and not an oxidizer. The pH of a 1% concentration of the preparation in water was consistently measured between 6.5 and 7.6 pH units. The preparation was tested for dustiness in accordance with CIPAC Method MT 171 and found to be “essentially dust free.”

**Performance:** The active substance content of Oxamyl 10GR as manufactured was 9.86%. The physical and chemical properties of the preparation were measured using CIPAC Methods or other accepted 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 10GR is stable under normal storage conditions for a minimum of two years.

Oxamyl 10GR is applied to the soil in a broadcast or in-furrow pattern, followed by soil incorporation when crops are planted or transplanted. Equipment cleanout is easily accomplished using standard wash out procedures.

**Environmental Impact:** The plant protection product is a non-dusty, dry flowable granule that can easily be recovered (scooped up using a shovel) if spilled.



### 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.

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.2.6 B.2.7 B.2.8.5.2 B.2.8.5.3 B.2.8.5.4	Clipston, A.S.	2015	Oxamyl 10G granular formulation (DPX-D1410): Laboratory study of physical and chemical properties Charles River Laboratories (UK) DuPont-39557 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