Renewal Assessment Report

under Regulation (EC) 1107/2009

Zoxamide

Volume 3

Zoxium 240 SC

B.2 Physical and chemical properties

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

Version history

Date	Subject
July 2016	Initial RAR

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B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

GLP-certified laboratories have performed all tests using Zoxium 240 SC, batch BPL285, containing 21.7% w/w zoxamide (240 g/L) as active substance. The formulation not contains relevant impurities, hydrocarbon or H304 category 1 co- formulants. Zoxium 240 SC is presented in HDPE containers with capacities of 50 ml to 25 L.

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1. Appearance						
Physical state and colour **B.2.1/01**	Visual assessment	Zoxium 240 SC (21.7%) Batch: BPL285	Dense and homogeneous liquid	Acceptable.	Yes	A. P. Fifi, 2013
	Visual assessment	Zoxium 240 SC (21.7%) Batch: BPL285	Beige – RAL 1001	Acceptable. The formulation is clear beige liquid.	Yes	A. P. Fifi, 2013
B.2.2. Explosive and oxidizing properties						
Explosive properties **B.2.2/01**	Statement	Zoxium 240 SC (21.7%) Batch: BPL285	Study not required as neither the active substance nor any of the co-formulants contain any of the chemical groups associated with explosive properties listed in Appendix 6 of the United Nations' Recommendations on the Transport of Dangerous Goods Manual of Test and Criteria (United Nations, 2009). Additionally, neither the active substance nor any of the co-formulants are classified as explosive.	Acceptable. The formulation has no explosive properties		
Oxidizing	Statement	Zoxium 240 SC	Study not required as the active substance and all	Acceptable. The formulation has		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
properties **B.2.2/02**		(21.7%) Batch: BPL285	co formulants meet the requirements for non-testing as detailed in Appendix 6 of the United Nations' Recommendations on the Transport of Dangerous Goods Manual of Test and Criteria (United Nations, 2009), i.e. the active substance and co-formulants may contain oxygen, fluorine or chlorine, but these elements are only chemically bonded to carbon and/or hydrogen. Additionally, neither the active substance nor any of the co-formulants are classified as oxidising.	no oxidizing properties		
B.2.3. Flammability and auto-flammability						
Flammability of solid formulations **B.2.3/01**	Statement	Zoxium 240 SC (21.7%) Batch: BPL285	Study not required as the active substance and co-formulants are not classified as flammable.	Not required, the formulation is a liquid.		
Self-heating of formulation **B.2.3/02**	Statement	Zoxium 240 SC (21.7%) Batch: BPL285	Study not required as the active substance and co-formulants are not classified as self-heating.	Acceptable. The formulation is not self-heating.		
B.2.4. Acidity/alkalinity and pH value						
pH of a 1 % dilution of the solid or non aqueous formulation **B.2.4/01**	CIPAC MT 75.3	Zoxium 240 SC (21.7%) Batch: BPL285	pH of a 1% w/v dilution = 6.61 (19.1°C)	Acceptable. The pH of the 1% w/v dilution is 6.61 at 19.1°C.	Yes	A. P. Fifi, 2013
Acidity / Alkalinity **B.2.4/02**		Zoxium 240 SC (21.7%) Batch: BPL285	Acidity / alkalinity not required, as pH is > 4 and < 10.	Acidity and alkalinity not required as the pH of the test item is >4 and <10.	Yes	A. P. Fifi, 2013

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.5. Viscosity and surface tension						
Viscosity of the liquid formulation **B.2.5/01**	OECD 114 (rotational type of viscometer)	Zoxium 240 SC (21.7%) Batch: BPL285	**Viscosity at 20°C** **RPM** **Viscosity (cp)** 100 300.40 60 410.00 50 459.80 30 647.90 20 879.50 12 1262.80 10 1455.00 6 2137.30 5 2473.70 4 2955.50 **Viscosity at 40°C** **RPM** **Viscosity (cp)** 100 243.10 60 336.90 50 380.00 30 542.60 20 728.10 12 1067.50 10 1229.70 6 1808.20 5 2079.20 4 2460.20	Acceptable. The formulation is a non- Newtonian product.	Yes	A. P. Fifi, 2013
Surface tension of the formulation **B.2.5/02**	OECD 115 and EEC Method A5	Zoxium 240 SC (21.7%) Batch: BPL285	Surface tension (neat): 30.8 mN/m (25°C)	Acceptable. The formulation is a surface active product.	Yes	A. P. Fifi, 2011

<table>
<tr><th>Test or Study & Data point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Used methods / Results</th><th>Comments (Acceptable / Non acceptable)</th><th>GLP</th><th>Reference</th></tr>
<tr><td colspan="7">B.2.6. Relative density and bulk density</td></tr>
<tr><td>Relative density of the liquid formulation
B.2.6/01</td><td>OECD 109</td><td>Zoxium 240 SC (21.7%)
Batch: BPL285</td><td>Relative density: 1.110
Density: 1.110 g/mL</td><td>Acceptable. The density of the formulation is 1.11 g/mL</td><td>Yes</td><td>A. P. Fifi, 2013</td></tr>
<tr><td>Bulk density (pour and tap) of powder or granules
B.2.6/02</td><td></td><td></td><td></td><td>Not relevant, the formulation is a liquid.</td><td></td><td></td></tr>
<tr><td colspan="7">B.2.7. Storage stability and shelf-life: effects of temperature on technical characteristics of the plant protection product</td></tr>
<tr><td>Stability after accelerated storage (54°C during 14 days)
B.2.7/01</td><td>CIPAC MT 46.3
(2 weeks at 54°C)</td><td>Zoxium 240 SC (21.7%)
Batch: BPL285</td><td>No significant decrease in active substance content was observed following the 2 week storage period at 54ºC.
No significant variation in any technical characteristics of the product was observed following the 2 week storage period at 54ºC.
AI Content
<u>Before storage</u>
22.57% w/w
<u>After 2 weeks at 54°C</u>
22.47% w/w
Difference -0.44 % (acceptable decrease)
Accelerated Storage Stability Results Table
<table>
<tr><td>Test</td><td>Initial</td><td>After 14 Days at 54°C</td></tr>
</table></td><td>The study is acceptable. Formulation Zoxium 240 SC is stable after storage for 2 weeks at 54°C, the packaging material is not described.
The analytical method used for the determination of zoxamide is evaluated in the Volume 3CP Zoxium 240 SC B-5.</td><td>Yes</td><td>A. P. Fifi, 2011</td></tr>
</table>

<table>
<tr><th>Test or Study & Data point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Used methods / Results</th><th>Comments (Acceptable / Non acceptable)</th><th>GLP</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Physical state</td><td>See 2.1.</td><td>No changes</td></tr>
<tr><td>Colour</td><td>See 2.1.</td><td>No changes</td></tr>
<tr><td>Weight loss(gravimetric)</td><td></td><td>0.02%</td></tr>
<tr><td>pH value</td><td>6.61</td><td>6.48</td></tr>
<tr><td>Spontaneity of dispersion (5% v/v)</td><td>105.91%</td><td>107.54%</td></tr>
<tr><td>Suspensibility</td><td>0.06%: 97.4%
0.08%: 95.4%</td><td>0.06%: 97.5%
0.08%: 95.5%</td></tr>
<tr><td>Wet sieve test</td><td>0.09% residue remained</td><td>0.08% residue remained</td></tr>
<tr><td>Pourability</td><td>Residue:3.11%
Rinsed residue:0.32%</td><td>Residue:3.46%
Rinsed residue:0.37%</td></tr>
</table>
</td><td></td><td></td><td></td></tr>
<tr><td>Effect of low temperature on stability of liquid formulation
B.2.7/02</td><td>CIPAC MT 39.3 (7 days at 0°C)</td><td>Zoxium 240 SC (21.7%)
Batch: BPL285</td><td>No significant variation in any technical characteristics of the product was observed following cold storage for 7 days at 0 ± 2°C.
No separation or precipitation was observed following cold storage for 7 days at 0 ± 2°C
Results for individual parameters are presented below.

<u>Appearance</u>
<u>Before storage</u></td><td>Acceptable. The formulation is stable during storage at 0°C for one week as no modification of appearance, suspensibility and wet sieve test was observed.</td><td>Yes</td><td>A. P. Fifi, 2011</td></tr>
</table>

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			Dense and homogenous liquid After 7 days at 0°C Dense and homogenous liquid with no separation or precipitation **Suspensibility** In CIPAC water D Temperature 30°C after 30 minutes Before storage Concentration 0.06%: 97.4% Concentration 0.08%: 95.4% After 7 days at 0°C Concentration 0.06%: 96.6% Concentration 0.08%: 95.6% **Wet Sieve amount retained on 75 µm sieve** Before storage 0.09% residue remained After 7 days at 0°C 0.10% residue remained			
Shelf life following storage at ambient temperature **B.2.7/03**	GIFAP Monograph No. 17 (2 years at room temp.)	Zoxium 240 SC (21.7%) Batch: BPL285	The storage at ambient temperature for 2 years was performed in plastic bottle. No significant decrease in active substance content was observed following the 24 month storage period. No significant variation in any technical characteristics of the product was observed following the 24 month storage period. After 2 years at 20°C No modification of appearance but a small pack	The formulation has been found stable during storage at ambient temperature for 2 years as no modification of appearance, active substance content, pH, suspensibility, spontaneity, wet sieve test, pourability was observed. Product stable for at least 24 months in ambient storage, in the plastic packaging.	Yes	A. P. Fifi, 2013

<table>
<tr><th>Test or Study & Data point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Used methods / Results</th><th>Comments (Acceptable / Non acceptable)</th><th>GLP</th><th>Reference</th></tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>weight change.
AI Content
<u>Before storage</u>
22.57% w/w
<u>After 2 years at 20°C</u>
22.55% w/w
Difference =0.09% (acceptable decrease)
Shelf life Storage Stability Results Table
<table>
<tr><td>Test</td><td>Initial</td><td>After 24 months at Room Temperature</td></tr>
<tr><td>Physical state</td><td>See 2.1.</td><td>Dense and homogenous liquid</td></tr>
<tr><td>Colour</td><td>See 2.1.</td><td>No changes</td></tr>
<tr><td>pH value</td><td>6.61</td><td>6.69</td></tr>
<tr><td>Spontaneity of dispersion (5% v/v)</td><td>105.91%</td><td>102.76%</td></tr>
<tr><td>Suspensibility</td><td>0.06%: 97.4%
0.08%: 95.4%</td><td>0.06%: 100.2%
0.08%: 97.2%</td></tr>
<tr><td>Wet sieve test</td><td>0.09% residue remained</td><td>0.06% residue remained</td></tr>
<tr><td>Pourability</td><td>Residue:3.11%</td><td>Residue:2.47%</td></tr>
</table>
</td>
<td>For determination of zoxamide
The analytical method used for the determination of zoxamide is evaluated in the Volume 3CP Zoxium 240 SC B-5. The plastic bottle has been used for shelf life study, after 24 months the bottle still has the regular form. The persistent foaming test should be provided after storage. However, as the initial results are acceptable (V=0mL since 10 seconds), no more data is required.</td>
<td></td>
<td></td>
</tr>
</table>

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			Rinsed residue:0.32% / Rinsed residue:0.17%			
B.2.8. Technical characteristics of the plant protection product						
B.2.8.1. Wettability						
Wettability of solid formulation **B.2.8.1/01**			Not applicable for a SC formulation	Not required as formulation is a liquid		
B.2.8.2. Persistence foaming						
Persistence of foaming of the diluted formulation **B.2.8.2/01**	CIPAC MT 47.2	Zoxium 240 SC (21.7%) Batch: BPL285	In CIPAC water D at room temperature and 0.08% w/v 10 seconds - 0 mL Foam 1 minute - - 0 mL Foam 3 minutes - 0 mL Foam 12 minutes - 0 mL Foam	Acceptable. The formulation forms foam in the acceptable limits when it is diluted at 0.08%.	Yes	A. P. Fifi, 2011
B.2.8.3. Suspensibility						
Suspensibility of water dispersible formulation **B.2.8.3/01**	CIPAC MT 184	Zoxium 240 SC (21.7%) Batch: BPL285	In CIPAC water D Temperature 30°C after 30 minutes 0.06% w/v: 97.4% 0.08% w/v: 95.4%	The suspensibility of the formulation is acceptable.	Yes	A. P. Fifi, 2013

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Spontaneity of dispersion of water dispersible formulation **B.2.8.3/02**	CIPAC MT 160	Zoxium 240 SC (21.7%) Batch: BPL285	CIPAC Standard Water C 5% v/v: 105.91%	The spontaneity of the dispersion is slightly above the acceptable limit of 105% (0.91% higher). This increase not has influence on formulation stay homogeneity. The spontaneity of the formulation is acceptable.	Yes	A. P. Fifi, 2013
Dispersion stability of SE, OD or EG formulation **B.2.8.3/03**				Not required for SC formulations		
B.2.8.4. Degree of dissolution and dilution stability						
Degree of dissolution of water soluble formulation **B.2.8.4/01**				Not required for SC formulations		
Dilution stability of water soluble formulation **B.2.8.4/02**				Not required for SC formulations		
B.2.8.5. Particle size distribution, dust content, attrition and mechanical stability						
B.2.8.5.1. Particle size distribution						
Wet sieve test of water dispersible formulation **B.2.8.5.1/01**	CIPAC MT 185 (wet sieve test)	Zoxium 240 SC (21.7%) Batch: BPL285	0.09% residue remained on a 75µm sieve	Acceptable.	Yes	A. P. Fifi, 2013

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Nominal size range of granule **B.2.8.5.1/03**				Not required for SC formulations		
B.2.8.5.2. Dust content						
Dust content of granular formulation **B.2.8.5.2/01**				Not required for SC formulations		
B.2.8.5.3. Attrition						
Attrition characteristics of granules and tablets **B.2.8.5.3/01**				Not required for SC formulations		
B.2.8.5.4. Hardness and integrity						
Hardness of tablets **B.2.8.5.4/01**				Not required for SC formulations		
Integrity of tablets **B.2.8.5.4/02**				Not required for SC formulations		
B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability						
Emulsifiability, emulsion stability and re-emulsifiability of formulation **B.2.8.6/01**				Not required for SC formulations		

B.2.8.7. Flowability, pourability and dustability						
Flowability of granular formulation **B.2.8.7/01**				Not required for SC formulations		
Pourability of suspensions **B.2.8.7/02**	CIPAC MT 148	Zoxium 240 SC (21.7%) Batch: BPL285	Residue: 3.11% Rinsed residue: 0.32%	The residue value is acceptable. The rinsed residue exceeds acceptable value (max. 0.25% rinsed residue). So shall be recommended additional rinsing procedures.	Yes	A. P. Fifi, 2013
Dustability of dustable powders after accelerated storage **B.2.8.7/03**				Not required for SC formulations		
B.2.9. Physical and chemical compatibility with other products including plant protection products with which its use is to be authorised						
Physical and chemical compatibility of tank mixtures **B.2.9/01**		Zoxium 240 SC (21.7%) Batch: BPL285	52 mixtures of Zoxium 240 SC with other plant protection products were tested. All mixtures were determined to be physically compatible and the mixtures were all also miscible. Zoxium 240 SC is therefore physically compatable with the tested products. The mixtures tested at pH 7 (20°C) are detailed below: **Mixture 1: Aliette** Zoxium 240 SC 75 ml/hl Fosetyl AL 80% WG 250 g/hl	Zoxium 240 SC is compatible with tested products.	N	F. Borgo, 2011

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			Mixture 2: Aliette Zoxium 240 SC 75 ml/hl Fosetyl AL 80% WG 750 g/hl **Mixture 3: Aliette** Zoxium 240 SC 225 ml/hl Fosetyl AL 80% WG 250 g/hl **Mixture 4: Aliette** Zoxium 240 SC 225 ml/hl Fosetyl AL 80% WG 750 g/hl **Mixture 5: Prodeo 80 WG** Zoxium 240 SC 75 ml/hl Fosetyl AL 80% WG 250 g/hl **Mixture 6: Prodeo 80 WG** Zoxium 240 SC 75 ml/hl Fosetyl AL 80% WG 750 g/hl **Mixture 7: Prodeo 80 WG** Zoxium 240 SC 225 ml/hl Fosetyl AL 80% WG 250 g/hl **Mixture 8: Prodeo 80 WG** Zoxium 240 SC 225 ml/hl Fosetyl AL 80% WG 750 g/hl **Mixture 9: Sarmox 45 DG** Zoxium 240 SC 75 ml/hl Cymoxanil 45% WG 50 g/hl **Mixture 10: Sarmox 45 DG** Zoxium 240 SC 75 ml/hl Cymoxanil 45% WG 150 g/hl			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			Mixture 11: Sarmox 45 DG Zoxium 240 SC 225 ml/hl Cymoxanil 45% WG 50 g/hl **Mixture 12: Sarmox 45 DG** Zoxium 240 SC 225 ml/hl Cymoxanil 45% WG 150 g/hl **Mixture 13: Quantum** Zoxium 240 SC 75 ml/hl Dimetomorf 50% WG 50 g/hl **Mixture 14: Quantum** Zoxium 240 SC 75 ml/hl Dimetomorf 50% WG 150 g/hl **Mixture 15: Quantum** Zoxium 240 SC 225 ml/hl Dimetomorf 50% WG 50 g/hl **Mixture 16: Quantum** Zoxium 240 SC 225 ml/hl Dimetomorf 50% WG 150 g/hl **Mixture 17: Forum 50 WP** Zoxium 240 SC 75 ml/hl Dimetomorf 50% WP 50 g/hl **Mixture 18: Forum 50 WP** Zoxium 240 SC 75 ml/hl Dimetomorf 50% WP 150 g/hl **Mixture 19: Forum 50 WP** Zoxium 240 SC 225 ml/hl Dimetomorf 50% WP 50 g/hl			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			Mixture 20: Forum 50 WP Zoxium 240 SC 225 ml/hl Dimetomorf 50% WP 150 g/hl **Mixture 21: Pergado SC** Zoxium 240 SC 75 ml/hl Mandipropamid 250 g/l SC 60 ml/hl **Mixture 22: Pergado SC** Zoxium 240 SC 75 ml/hl Mandipropamid 250 g/l SC 180 ml/hl **Mixture 23: Pergado SC** Zoxium 240 SC 225 ml/hl Mandipropamid 250 g/l SC 60 ml/hl **Mixture 24: Pergado SC** Zoxium 240 SC 225 ml/hl Mandipropamid 250 g/l SC 180 ml/hl **Mixture 25: Furiak** Zoxium 240 SC 75 ml/hl Fosfito di K Liquid Solubile 300 ml/hl **Mixture 26: Furiak** Zoxium 240 SC 75 ml/hl Fosfito di K Liquid Solubile 900 ml/hl **Mixture 27: Furiak** Zoxium 240 SC 225 ml/hl Fosfito di K Liquid Solubile 300 ml/hl **Mixture 28: Furiak** Zoxium 240 SC 225 ml/hl Fosfito di K Liquid Solubile 900 ml/hl			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			Mixture 29: Magnifos K Zoxium 240 SC 75 ml/hl Fosfito di K + Mg Liquid Solubile 300 ml/hl **Mixture 30: Magnifos K** Zoxium 240 SC 75 ml/hl Fosfito di K + Mg Liquid Solubile 900 ml/hl **Mixture 31: Magnifos K** Zoxium 240 SC 225 ml/hl Fosfito di K + Mg Liquid Solubile 300 ml/hl **Mixture 32: Magnifos K** Zoxium 240 SC 225 ml/hl Fosfito di K + Mg Liquid Solubile 900 ml/hl **Mixture 33: Ferrifos** Zoxium 240 SC 75 ml/hl Fosfito di Fe Liquid Solubile 350 ml/hl **Mixture 34: Ferrifos** Zoxium 240 SC 75 ml/hl Fosfito di Fe Liquid Solubile 1050 ml/hl **Mixture 35: Ferrifos** Zoxium 240 SC 225 ml/hl Fosfito di Fe Liquid Solubile 350 ml/hl **Mixture 36: Ferrifos** Zoxium 240 SC 225 ml/hl Fosfito di Fe Liquid Solubile 1050 ml/hl **Mixture 37: Scudex** Zoxium 240 SC 75 ml/hl Pemconazolo 100 g/l EC 50 ml/hl			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			Mixture 38: Scudex Zoxium 240 SC 75 ml/hl Pemconazolo 100 g/l EC 150 ml/hl **Mixture 39: Scudex** Zoxium 240 SC 225 ml/hl Pemconazolo 100 g/l EC 50 ml/hl **Mixture 40: Scudex** Zoxium 240 SC 225 ml/hl Pemconazolo 100 g/l EC 150 ml/hl **Mixture 41: Basiram** Zoxium 240 SC 75 ml/hl Cu 195 g/l da Solfato tribasico SC 500 ml/hl **Mixture 42: Basiram** Zoxium 240 SC 75 ml/hl Cu 195 g/l da Solfato tribasico SC 1500 ml/hl **Mixture 43: Basiram** Zoxium 240 SC 225 ml/hl Cu 195 g/l da Solfato tribasico SC 500 ml/hl **Mixture 44: Basiram** Zoxium 240 SC 225 ml/hl Cu 195 g/l da Solfato tribasico SC 1500 ml/hl The mixtures tested at pH 7 (10°C) are detailed below: **Mixture 45: Prodeo 80 WG** Zoxium 240 SC 75 ml/hl Fosetyl AL 80% WG 250 g/hl			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			Mixture 46: Prodeo 80 WG Zoxium 240 SC 75 ml/hl Fosetyl AL 80% WG 750 g/hl **Mixture 47: Prodeo 80 WG** Zoxium 240 SC 225 ml/hl Fosetyl AL 80% WG 250 g/hl **Mixture 48: Prodeo 80 WG** Zoxium 240 SC 225 ml/hl Fosetyl AL 80% WG 750 g/hl The mixtures tested at pH 5.5 (10°C) are detailed below: **Mixture 49: Prodeo 80 WG** Zoxium 240 SC 75 ml/hl Fosetyl AL 80% WG 250 g/hl **Mixture 50: Prodeo 80 WG** Zoxium 240 SC 75 ml/hl Fosetyl AL 80% WG 750 g/hl **Mixture 51: Prodeo 80 WG** Zoxium 240 SC 225 ml/hl Fosetyl AL 80% WG 250 g/hl **Mixture 52: Prodeo 80 WG** Zoxium 240 SC 225 ml/hl Fosetyl AL 80% WG 750 g/hl			
B.2.9. Adherence and distribution to seeds						
Distribution and				Not required for SC formulations		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
adhesion to seeds **B.2.9.10/01**						
B.2.10. Other studies						
			None			

Conclusion RMS:

The formulation Zoxium 240 SC is a suspension concentrate (SC) containing 240 g/L zoxamide.
Its appearance is beige and homogeneous liquid. It is not explosive. It has no oxidizing properties. It has a relative density of 1.11 and the pH of a 1% dilution is 6.61. The product has good pourability, wet sieving, suspensibility and dispersion characteristics and does not produce excessive amounts of foam. The packaging of the product remained free from any corrosion or degradation for the duration of the two year study and the shelf life of the product is 24 months, nevertheless, kinds of plastic material should be indicated.
The technical properties of Zoxium 240 SC are acceptable for a suspension concentrate formulation.

B.2.11. References relied on

Data point	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed (Y/N)	Justification if data protection claimed	Owner
KCP 2, 2.1, 2.4, 2.5/01, 2.6, 2.7/03, 2.8.3/01, 2.8.3/02, 2.8.5, 2.8.7	Fifi A.P.	2013	Chemical-physical characterization of product ZOXIUM 240 SC after 2 years shelf life BioTecnologie BT SrL c/o Parco Tecnologico Agroalimentare dell'Umbria Report No. BT119/10 (Final Report) GLP, Not published	N	Y	Data to support new representative formulation	Gowan
KCP 2.9	Borgo F.	2011	Prove miscibilità Zoxium 240 SC Sipcam SPA Via Semplone, 195, 20016 Pero (MI), Italy. Not GLP, Not published	N	Y	Data to support new representative formulation	Gowan
KCP 2.5/02 KCP 2.7/01 KCP 2.7/02 KCP 2.8.2/01	Fifi A.P.	2011	Accelerated storage stability of product Zoxium 240 SC after 2 weeks at 54°C BioTecnologie BT SrL c/o Parco Tecnologico Agroalimentare dell'Umbria Report No. BT118/10 GLP, Not published	N	Y	Data to support new representative formulation	Gowan