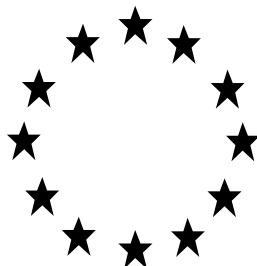


Draft Renewal Assessment Report
under Regulation (EC) 1107/2009



CLOPYRALID

Volume 3 – B.2 (PPP) – GF-1374

RMS: Finland
Co-RMS: Poland

May 2017

Volume 1

Level 1: Statement of subject matter and purpose for which this report has been prepared and background information on the application

Level 2: Summary of active substance hazard and of product risk assessment

Level 3: Proposed decision with respect to the application

Appendix 1: Guidance documents used in this assessment

Appendix 2: Reference list

Volume 2

Annex A: List of the tests, studies and information submitted

Volume 3

Annex B (Active Substance): Summary, evaluation and assessment of the data and information

Annex B.1 (AS): Identity

Annex B.2 (AS): Physical and chemical properties of the active substance

Annex B.3 (AS): Data on application

Annex B.4 (AS): Further information

Annex B.5 (AS): Methods of analysis

Annex B.6 (AS): Toxicology and metabolism data

Annex B.7 (AS): Residue data

Annex B.8 (AS): Environmental fate and behaviour

Annex B.9 (AS): Ecotoxicology data

Volume 3

Annex B (Plant Protection Product): Summary, evaluation and assessment of the data and information

Annex B.1 (PPP): Identity

Annex B.2 (PPP): Physical and chemical properties of the plant protection product

Annex B.3 (PPP): Data on application and efficacy

Annex B.4 (PPP): Further information

Annex B.5 (PPP): Methods of analysis

Annex B.6 (PPP): Toxicology and metabolism data and assessment of risks to humans

Annex B.7 (PPP): Residue data

Annex B.8 (PPP): Environmental fate and behaviour and environmental exposure assessment

Annex B.9 (PPP): Ecotoxicology data and assessment of risks for non-target species

Volume 4

Annex C: Confidential information and, where relevant, details of any task force formed for the purpose of generating tests and studies submitted

List of Endpoints

Version History

When	What
2017/May	DRAR- First version submitted to EFSA

Table of contents

B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT NAME	5
B.2.1. APPEARANCE.....	5
B.2.2. EXPLOSIVE AND OXIDISING PROPERTIES	5
B.2.3. FLAMABILITY AND AUTO-FLAMABILITY	5
B.2.4. ACIDITY/ALKALINITY AND PH VALUE	6
B.2.5. VISCOSITY AND SURFACE TENSION.....	7
B.2.6. RELATIVE DENSITY AND BULK DENSITY.....	7
B.2.7. STORAGE STABILITY AND SHELF-LIFE: EFFECTS OF TEMPERATURE ON TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT.....	8
B.2.8. TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT.....	12
B.2.8.1. Wettability	12
B.2.8.2. Persistence foaming.....	12
B.2.8.3. Suspensibility	14
B.2.8.4. Degree of dissolution and dilution stability	14
B.2.8.5. Particle size distribution, dust content, attrition and mechanical stability	14
B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability	16
B.2.8.7. Flowability, pourability and dustability.....	23
B.2.9. PHYSICAL COMPATIBILITY WITH OTHER PRODUCT INCLUDING PLANT PROTECTION PRODUCTS WITH WHICH ITS USE IS TO BE AUTHORISED.....	24
B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS	24
B.2.11. OTHER STUDIES.....	24
B.2.12. REFERENCES RELIED ON.....	25

B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT GF-1374

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 (olefactory)	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	Brown liquid at ambient temperature (with a mild odour)	Acceptable.	Y	Cathie, C.A. (2005) 05-683-G
B.2.2. EXPLOSIVE AND OXIDIZING PROPERTIES						
Explosive properties B.2.2/01	EEC Method A.14	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	Not explosive.	Acceptable.	Y	Turner, B. (2006) DOS/0470; NAFST-05-118
Oxidizing properties B.2.2/02	EEC Method A.21	GF-1374 (Lot IC03150102) (7.84 wt% clopyralid, 0.23 wt% florasulam, 13.9 wt% fluroxypyr meptyl)	GF-1374 was found to be non-oxidising.	Acceptable.	Y	Comb, A.L. (2012) NAFST-12-159
B.2.3. FLAMMABILITY AND AUTO-FLAMMABILITY						
Flash point of the liquids formulations B.2.3/01	CIPAC MT 12.3	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	No flash point was observed up to 100 °C.	Acceptable.	Y	Cathie, C.A. (2005) 05-683-G

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Flammability of solid formulations B.2.3/02	EEC Method A10	-	Not required as the product is an EC		-	-
Self-heating of formulation B.2.3/03	EEC Method A.15	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	Auto ignition temperature: none below 400 °C.	Acceptable.	Y	Turner, B. (2006) NAFST-05-118
B.2.4. ACIDITY/ALKALINITY AND PH VALUE						
pH of the neat aqueous formulation B.2.4/01	CIPAC MT 75.3	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	pH = 1.93 initial pH = 2.78 after 2 weeks at 54 °C	Acceptable.	Y	Cathie, C.A. (2005) 05-683-G
pH of a 1 % dilution of the solid or non aqueous formulation B.2.4/02	CIPAC MT 75.3	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	pH = 2.49 initial pH = 2.50 after 2 weeks at 54 °C	Acceptable.	Y	Cathie, C.A. (2005) 05-683-G
Acidity / Alkalinity B.2.4/03	CIPAC MT 31.2.3	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	Acidity = 2.2 initial Acidity = 2.3 after 2 weeks at 54 °C (% w/w calculated as H ₂ SO ₄)	Acceptable.	Y	Cathie, C.A. (2005) 05-683-G

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	GF-1374 (Lot XA30777703) (7.8% w/w clopyralid, 0.20% w/w florasulam and 13.6% w/w fluroxypyr-meptyl)	Dynamic viscosity: GF-1374 is a Newtonian substance with a viscosity of 17.1 mPa.s at 20 °C and 8.22 mPa.s at 40 °C.	Acceptable.	Y	Koors, B. (2009) FOR-09-98
	CIPAC MT 22.3	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	Kinematic viscosity: 0.0000078 m ² /sec at 40 °C	Acceptable. The product has aspiration hazard (see Vol. 4 as well as CLP regulation).	Y	Cathie, C.A. (2005) 05-683-G
Surface tension of the formulation B.2.5/02	EEC A.5	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	Neat = 36.1 mN/m at 24.9 °C Diluted = 29.5 mN/m at 20.0 °C	Acceptable.	Y	Cathie, C.A. (2005) 05-683-G
B.2.6. RELATIVE DENSITY AND BULK DENSITY						
Relative density of the liquid formulation B.2.6/01	EEC A.3	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	D ²⁰ ₄ = 1.0399 initial D ²⁰ ₄ = 1.0398 after 2 weeks at 54 °C	Acceptable.	Y	Cathie, C.A. (2005) 05-683-G
Bulk density (pour and tap) of powder or granules B.2.6/02	CIPAC MT 186	-	Not required as the product is an EC			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.7. STORAGE STABILITY AND SHELF-LIFE: EFFECTS OF TEMPERATURE ON TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT						
Stability after accelerated storage (54°C during 14 days, 8 weeks at 40°C, 12 weeks at 35°C or 18 weeks at 30°C) B.2.7/01	CIPAC MT 46.3	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	Stability after storage for 2 weeks at 54 °C in glass : Clopyralid : 7.7% w/w initial, 7.6% w/w after 2 weeks Florasulam : 0.25% w/w initial, 0.25% w/w after 2 weeks Fluroxypyr meptyl : 13.3% initial, 12.9% w/w after 2 weeks.	Acceptable.	Y	Cathie, C.A. (2005) 05-683-G
	CIPAC MT 46.3	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	Stability after storage for 8 weeks at 40 °C in 1-L nitrogen-purged PET : Clopyralid : 80 g/L initial, 79 g/L after 8 weeks Florasulam : 2.6 g/L initial, 2.6 g/L after 8 weeks Fluroxypyr meptyl : 138 g/L initial, 134 g/L after 8 weeks.	Acceptable.	Y	Kendall, P.A. and Tidswell, J.N. (2005) 05-676-G

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference																																																																																																																				
			<p>Table 1. GF-1374 Stability Results after 8 Weeks 40°C Storage in PET Bottles</p> <table><tr><td>Test</td><td colspan="2">Initial</td><td colspan="2">Nitrogen purged 1L PET bottle 676-8W40-1000</td></tr><tr><td>Appearance</td><td colspan="2">Clear amber liquid</td><td colspan="2">Clear amber liquid</td></tr><tr><td>Clopyralid Content (g/L)</td><td colspan="2">80*²</td><td colspan="2">79</td></tr><tr><td>% Clopyralid Retention *¹</td><td colspan="2">Not applicable</td><td colspan="2">98.8</td></tr><tr><td>Florasulam Content (g/L)</td><td colspan="2">2.6*²</td><td colspan="2">2.6</td></tr><tr><td>% Florasulam Retention *¹</td><td colspan="2">Not applicable</td><td colspan="2">100</td></tr><tr><td>Fluroxypyr-meptyl Content (g/L)</td><td colspan="2">138*²</td><td colspan="2">134</td></tr><tr><td>% Fluroxypyr-meptyl Retention *¹</td><td colspan="2">Not applicable</td><td colspan="2">97.1</td></tr><tr><td>Relative Density (D₄²⁰)</td><td colspan="2">1.040</td><td colspan="2">1.040</td></tr><tr><td>pH (1%w/v)</td><td colspan="2">2.4</td><td colspan="2">2.4</td></tr><tr><td colspan="2">Persistent Foam (mL) (Concentration 7.5g/L)</td><td colspan="2"></td><td colspan="2"></td></tr><tr><td colspan="2">10 second</td><td colspan="2">9</td><td colspan="2">12</td></tr><tr><td colspan="2">1 minute</td><td colspan="2">9</td><td colspan="2">12</td></tr><tr><td colspan="2">3 minutes</td><td colspan="2">8</td><td colspan="2">12</td></tr><tr><td colspan="2">12 minutes</td><td colspan="2">6</td><td colspan="2">12</td></tr><tr><td colspan="2">Emulsion Stability 1%, 342ppm water @ 30°C</td><td>%cream</td><td>%oil</td><td>%cream</td><td>%oil</td></tr><tr><td colspan="2">30min</td><td>0.1</td><td>Nil</td><td>0.1</td><td>Nil</td></tr><tr><td colspan="2">1hr</td><td>0.25</td><td>Nil</td><td>0.25</td><td>Nil</td></tr><tr><td colspan="2">2hr</td><td>0.5</td><td>Nil</td><td>0.5</td><td>Nil</td></tr><tr><td colspan="2">24hr</td><td>1.0</td><td>0.05</td><td>1.0</td><td>0.05</td></tr><tr><td colspan="2">24½hr</td><td>0.5</td><td>Nil</td><td>0.5</td><td>Nil</td></tr></table> <p>*¹ % Retention = Final content + Initial content x 100 *² Initial results from Method Validation DAS-AM-05-004 Validation of a Method for the Determination of Clopyralid, Florasulam and Fluroxypyr meptyl in GF-1374.</p>	Test	Initial		Nitrogen purged 1L PET bottle 676-8W40-1000		Appearance	Clear amber liquid		Clear amber liquid		Clopyralid Content (g/L)	80* ²		79		% Clopyralid Retention * ¹	Not applicable		98.8		Florasulam Content (g/L)	2.6* ²		2.6		% Florasulam Retention * ¹	Not applicable		100		Fluroxypyr-meptyl Content (g/L)	138* ²		134		% Fluroxypyr-meptyl Retention * ¹	Not applicable		97.1		Relative Density (D ₄ ²⁰)	1.040		1.040		pH (1%w/v)	2.4		2.4		Persistent Foam (mL) (Concentration 7.5g/L)						10 second		9		12		1 minute		9		12		3 minutes		8		12		12 minutes		6		12		Emulsion Stability 1%, 342ppm water @ 30°C		%cream	%oil	%cream	%oil	30min		0.1	Nil	0.1	Nil	1hr		0.25	Nil	0.25	Nil	2hr		0.5	Nil	0.5	Nil	24hr		1.0	0.05	1.0	0.05	24½hr		0.5	Nil	0.5	Nil			
	Test	Initial		Nitrogen purged 1L PET bottle 676-8W40-1000																																																																																																																						
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30min		0.1	Nil	0.1	Nil																																																																																																																					
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	CIPAC MT 46.3	GF-1374 (Lot 2E01150101) (7.8% Clopyralid, 0.24% florasulam, 13.6% fluroxypyr-meptyl)	Stability after storage for 2 weeks at 54 °C in 1 L F-HDPE : Clopyralid: 7.54% w/w initial, 7.50% w/w after 2 weeks Florasulam: 0.252% w/w initial, 0.248% w/w after 2 weeks Fluroxypyr meptyl: 13.1% initial, 12.8% w/w after 2 weeks. (for other properties see the respective test)	Acceptable.	Y	Elliott, T. (2013) NAFST-13-163																																																																																																																				
Effect of low temperature on stability of liquid formulation B.2.7/02	CIPAC MT 39.3	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam,142 g/L fluroxypyr meptyl)	No separated material was observed after 7 days of storage at 0°C (total storage period of 9 days included 50 hours at temperature >2 °C)	Acceptable.	Y	Cathie, C.A (2005) 05-683-G																																																																																																																				

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference																																																																																										
Shelf life following storage at ambient temperature B.2.7/03	CropLife Technical Monograph 17	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam,142 g/L fluroxypyr meptyl)	Active substance content after 30 months at ambient temperature in 1 L PET:	Acceptable.	Y	Kendall, P.A. (2008) 05-678-G																																																																																										
			Clopyralid: 80 g/L initial; 78 g/L after 30 months.																																																																																													
			Florasulam: 2.58 g/L initial; 2.43 g/L after 30 months																																																																																													
			Fluroxypyr meptyl: 95.8 g a.e/L initial; 84.3 g a.e/L after 30 months																																																																																													
			Free fluroxypyr acid content: 4.9 g/L initial; 13.2 g/L after 30 months																																																																																													
			Total Fluroxypyr acid Content: 100.7 g/L initial; 97.5 g/L after 30 months.																																																																																													
			The PET container mass and dimensional changes observed during this study indicate no significant interaction with the formulation that may affect the stability of the packaging during normal storage, transit or use.																																																																																													
			Table II. GF-1374 Physical Stability Results after Twenty Seven Months Ambient Storage in PET Bottles																																																																																													
			<table><tr><td>Test</td><td>Initial</td><td>1L PET bottle 678-2YA-1001</td></tr><tr><td>Appearance</td><td>Clear amber liquid</td><td>Clear amber liquid</td></tr><tr><td>Density @ 20°C</td><td>1.040*⁵</td><td>1.040</td></tr><tr><td>pH</td><td>2.5 (1%v/v)*⁵</td><td>2.5 (1%w/v)</td></tr><tr><td>Free Acidity (%m/m)</td><td>0.22</td><td>0.24</td></tr><tr><td>Persistent Foam (mL) (Concentration 7.5mL/L)</td><td></td><td></td></tr><tr><td>10 second</td><td>9*⁵</td><td>24</td></tr><tr><td>1 minute</td><td>9*⁵</td><td>20</td></tr><tr><td>3 minutes</td><td>8*⁵</td><td>20</td></tr><tr><td>12 minutes</td><td>6*⁵</td><td>18</td></tr><tr><td>Emulsion Stability 5%, 20ppm water @ 30°C</td><td>%cream</td><td>%oil</td><td>%cream</td><td>%oil</td></tr><tr><td>30min</td><td><0.05*⁵</td><td>Nil*⁵</td><td>Nil</td><td>Nil</td></tr><tr><td>1hr</td><td><0.05*⁵</td><td>Nil*⁵</td><td>Nil</td><td>Nil</td></tr><tr><td>2hr</td><td><0.05o/c*⁵</td><td>Nil*⁵</td><td>Nil</td><td>Nil</td></tr><tr><td>24hr</td><td>0.05o/c*⁵</td><td>Nil*⁵</td><td>Nil</td><td>Nil</td></tr><tr><td>24½hr</td><td>Nil*⁵</td><td>Nil*⁵</td><td>Nil</td><td>Nil</td></tr><tr><td>Emulsion Stability 5%, 342ppm water @ 30°C</td><td>%cream</td><td>%oil</td><td>%cream</td><td>%oil</td></tr><tr><td>30min</td><td>Nil*⁵</td><td>Nil*⁵</td><td>Nil</td><td>Nil</td></tr><tr><td>1hr</td><td>Nil*⁵</td><td>Nil*⁵</td><td>Nil</td><td>Nil</td></tr><tr><td>2hr</td><td>Trace o/c*⁵</td><td>Nil*⁵</td><td>Nil</td><td>Nil</td></tr><tr><td>24hr</td><td>5*⁵</td><td>Nil*⁵</td><td>5.0o/c</td><td>Nil</td></tr><tr><td>24½hr</td><td>0.05*⁵</td><td>Nil*⁵</td><td>5.0o/c</td><td>Nil</td></tr></table>				Test	Initial	1L PET bottle 678-2YA-1001	Appearance	Clear amber liquid	Clear amber liquid	Density @ 20°C	1.040* ⁵	1.040	pH	2.5 (1%v/v)* ⁵	2.5 (1%w/v)	Free Acidity (%m/m)	0.22	0.24	Persistent Foam (mL) (Concentration 7.5mL/L)			10 second	9* ⁵	24	1 minute	9* ⁵	20	3 minutes	8* ⁵	20	12 minutes	6* ⁵	18	Emulsion Stability 5%, 20ppm water @ 30°C	%cream	%oil	%cream	%oil	30min	<0.05* ⁵	Nil* ⁵	Nil	Nil	1hr	<0.05* ⁵	Nil* ⁵	Nil	Nil	2hr	<0.05o/c* ⁵	Nil* ⁵	Nil	Nil	24hr	0.05o/c* ⁵	Nil* ⁵	Nil	Nil	24½hr	Nil* ⁵	Nil* ⁵	Nil	Nil	Emulsion Stability 5%, 342ppm water @ 30°C	%cream	%oil	%cream	%oil	30min	Nil* ⁵	Nil* ⁵	Nil	Nil	1hr	Nil* ⁵	Nil* ⁵	Nil	Nil	2hr	Trace o/c* ⁵	Nil* ⁵	Nil	Nil	24hr	5* ⁵	Nil* ⁵	5.0o/c	Nil	24½hr	0.05* ⁵	Nil* ⁵	5.0o/c	Nil
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24hr	5* ⁵	Nil* ⁵	5.0o/c	Nil																																																																																												
24½hr	0.05* ⁵	Nil* ⁵	5.0o/c	Nil																																																																																												
* ⁵ % Initial results from Dow AgroSciences Study 05-683-G Physical and Chemical Propenies of Bofix MCPA Free EC Formulation. GF-I 374																																																																																																

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
	CropLife Technical Monograph 17	GF-1374 (Lot 2E01150101) (7.8% Clopyralid, 0.24% florasulam, 13.6% fluroxypyr-meptyl)	Active substance content after 24 months at ambient temperature in 1 L F-HDPE: Clopyralid: 7.54wt% initial; 7.71wt% after 24 months. Florasulam: 0.252wt% initial; 0.236wt% after 24 months Fluroxypyr meptyl: 13.1wt% initial; 12.2 wt% after 24 months; decrease in fluroxypyr-meptyl concentration was accompanied by an increase in the fluroxypyr acid concentration	Acceptable.	Y	Elliott, T. (2016) NAFST-13-164
	MT191		<u>Acidity or alkalinity:</u> Initial: 2.21% After two years at ambient in F-HDPE: 2.13% (% w/w calculated as H ₂ SO ₄)			
	MT 75.3		<u>pH:</u> Initial: pH = 2.56 at 20.9°C After 2 years ambient in F-HDPE: 2.60 at 20.3°C			
	MT 47.2		<u>Persistent foam in CIPAC water D at 2% v/v:</u> Acceptable (< 60 mL after 1 min) before and after 2 year ambient storage in F-HDPE			
	MT 36.3		<u>Emulsion stability:</u> No significant changes in emulsion stability at 0.18% v/v and 2.0% v/v in standard waters A and D were observed after storage for 2 years at ambient temperature in F-HDPE. For each timepoint, the emulsion stability was within acceptable limits (<2 mL cream after 30 minutes, trace oil). Following the two year storage period, the container did not show any signs of corrosion, degradation, or interaction with the test substance.			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8. TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT						
B.2.8.1. Wettability						
Wettability of solid formulation B.2.8.1/01	CIPAC MT 53.3	-	Not required as formulation is an EC			
B.2.8.2. Persistence foaming						
Persistence of foaming of the diluted formulation B.2.8.2/01	CIPAC MT 47.1	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	After 1 min (at the use rate of 7.5 mL/L in CIPAC water C): 9 ml	Not acceptable. The test should be performed at the maximum use rate which is 1.5 % v/v. Here the use rate is only 0.75 % v/v which is inadequate.	Y	Cathie, C.A. (2005) 05-683-G
	CIPAC MT 47.1	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	After 1 min (at the use rate of 7.5 mL/L in standard water C): 9 ml before and 12 ml after 8wk at 40 °C	Not acceptable. The test should be performed at the maximum use rate which is 1.5 % v/v. Here the use rate is only 0.75 % v/v which is inadequate.	Y	Kendall, P.A. and Tidswell, J.N. (2005) 05-676-G

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
	CIPAC MT 47.2	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	After 1 min (at the use rate of 7.5 mL/L in standard water D): 9 ml before and 20 ml after 27 month ambient storage	Not acceptable. The test should be performed at the maximum use rate which is 1.5 % v/v. Here the use rate is only 0.75 % v/v which is inadequate.	Y	Kendall, P.A. (2008) 05-678-G
	CIPAC MT 47.2	GF-1374 (Lot XA30777703) (7.8% w/w clopyralid, 0.20% w/w florasulam and 13.6% w/w fluroxypyr-meptyl)	After 1 min (at the maximum use rate of 1.5% v/v in CIPAC water D): 41 ml before and 44 ml after 2 year ambient storage	Acceptable.	Y	Koors, B. (2009) FOR-09-98
	CIPAC MT 47.2	GF-1374 (Lot XA30777703) (7.8% w/w clopyralid, 0.20% w/w florasulam and 13.6% w/w fluroxypyr-meptyl)	After 1 min (at the maximum use rate of 1.5% v/v in CIPAC water D): 41 ml before and 51 ml (in f-HDPE packaging) or 41 ml (in PET Packaging) after 2 year ambient storage	Acceptable.	Y	Cobb, J. (2014) FOR-09-99
	CIPAC MT 47.2	GF-1374 (Lot 2E01150101) (7.8% Clopyralid, 0.24% florasulam, 13.6% fluroxypyr-meptyl)	After 1 min (at the use rate of 2 % v/v in standard water D): 60 ml before and 55 ml after 2 weeks at 54 °C (in f-HDPE packaging).	Acceptable. However, here the use rate is above the maximum use rate.	Y	Elliott, T. (2013) NAFST-13-163

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8.3. Suspensibility						
Suspensibility of water dispersible formulation B.2.8.3/01	-	-	Not required as formulation is an EC			
Spontaneity of dispersion of water dispersible formulation B.2.8.3/02	-	-	Not required as formulation is an EC			
Dispersion stability of SE, OD or EG formulation B.2.8.3/03	-	-	Not required as formulation is an EC			
B.2.8.4. Degree of dissolution and dilution stability						
Degree of dissolution of water soluble formulation B.2.8.4/01	-	-	Not required as formulation is an EC			
Dilution stability of water soluble formulation B.2.8.4/02	-	-	Not required as formulation is an EC			
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	-	-	Not required as formulation is an EC			
Size distribution of particles of	-	-	Not required as formulation is an EC			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
powder or suspension concentrate formulation B.2.8.5.1/02						
Nominal size range of granule B.2.8.5.1/03	-	-	Not required as formulation is an EC			
B.2.8.5.2. Dust content						
Dust content of granular formulation B.2.8.5.2/01	-	-	Not required as formulation is an EC			
B.2.8.5.3. Attrition						
Attrition characteristics of granules and tablets B.2.8.5.3/01	-	-	Not required as formulation is an EC			
B.2.8.5.4. Hardness and integrity						
Hardness of tablets B.2.8.5.4/01	-	-	Not required as formulation is an EC			
Integrity of tablets B.2.8.5.4/02	-	-	Not required as formulation is an EC			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability						
Emulsifiability, emulsion stability and re-emulsifiability of formulation B.2.8.6/01	CIPAC MT 36.1	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	<p><u>5% v/v in CIPAC water A at 30 °C:</u></p> <p>Initial emulsification was uniform.</p> <p>30 min: nil oil, <0.05 mL cream 1 hr: nil oil, <0.05 mL cream 2 hr: <0.05 mL oily cream 24 hr: 0.05 mL oily cream</p> <p>Re-emulsification was uniform.</p> <p>24 hr + 30 sec: nil oil, nil cream 24 hr + 30 min: nil oil, nil cream</p> <p>No changes, except 0.1 mL oily cream at 24 hours, were observed after storage for 2 weeks at 54 °C.</p> <p><u>5% v/v in CIPAC water D at 30 °C:</u></p> <p>Initial emulsification was uniform.</p> <p>30 min: nil oil, nil cream 1 hr: nil oil, nil cream 2 hr: trace oily cream</p> <p>24 hr: 5 mL oily cream 24 hr + 30 sec: nil oil, nil cream 24 hr + 30 min: 0.05 mL cream</p> <p>No changes, except 1.45 mL cream at 24 hr + 30 min, were observed after storage for 2 weeks at 54 °C.</p>	Acceptable.	Y	Cathie, C.A. (2005) 05-683-G

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
	CIPAC MT 36.1.1	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	<u>1% in CIPAC water D @ 30 °C:</u> 30 min: nil oil, 0.1% cream 1 hr: nil oil 0.25% cream 2 hr: nil oil, 0.5% cream 24 hr: 0.05% oil, 1.0% cream 24 hr + 30 min: nil oil, 0.5% cream No changes were observed after storage for 8 weeks at 40 °C in PET.	Acceptable.	Y	Kendall, P.A. and Tidswell, J.N. (2005) 05-676-G
	CIPAC MT 36.1.1	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	Initial results recorded in Study No.05-683-G. <u>5% v/v in CIPAC water A at 30 °C:</u> 30 min to 24.5 hr: all measurement recorded nil oil and nil cream following storage for 2 years at ambient temperature. <u>5% v/v in CIPAC water D at 30 °C:</u> After storage at ambient temperature for 27 months. 30 min: nil oil, nil cream 1 hr: nil oil, nil cream 2 hr: nil oil, nil cream 24 hr: 5% oily cream, nil oil 24 hr + 30 min: 5% oily cream, nil oil Although a change in emulsion stability is noted from the initial results (see 05-683-G), the final emulsification performance is not expected to negatively impact on product application and performance.	Acceptable.	Y	Kendall, P.A. (2008) 05-678-G

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference																																			
	CIPAC MT 36.3	GF-1374 (Lot 2E01150101) (7.8% Clopyralid, 0.24% florasulam, 13.6% fluroxypyr-meptyl)	<div>No changes in emulsion stability were observed following storage for 2 weeks at 54 °C:</div> <table><tr><td>Sample ID:</td><td>H-A</td><td>H-D</td><td>L-A</td><td>L-D</td></tr><tr><td>Initial Emulsification (30 seconds after inversion)</td><td>Cream (mL): No Oil (mL): No Spontaneously Emulsified: Yes</td><td>Cream (mL): No Oil (mL): No Spontaneously Emulsified: Yes</td><td>Cream (mL): No Oil (mL): No Spontaneously Emulsified: Yes</td><td>Cream (mL): No Oil (mL): No Spontaneously Emulsified: Yes</td></tr><tr><td>30 minutes</td><td>Cream (mL): No Oil (mL): No</td><td>Cream (mL): No Oil (mL): No</td><td>Cream (mL): No Oil (mL): No</td><td>Cream (mL): No Oil (mL): No</td></tr><tr><td>2 hours</td><td>Cream (mL): No Oil (mL): No</td><td>Cream (mL): No Oil (mL): No</td><td>Cream (mL): No Oil (mL): No</td><td>Cream (mL): No Oil (mL): No</td></tr><tr><td>24 hours</td><td>Cream (mL): No Oil (mL): No</td><td>Cream (mL): No Oil (mL): No</td><td>Cream (mL): No Oil (mL): No</td><td>Cream (mL): No Oil (mL): No</td></tr><tr><td>Re-emulsification (30 seconds after inversion)</td><td>Cream (mL): No Oil (mL): No Emulsified: Yes</td><td>Cream (mL): No Oil (mL): No Emulsified: Yes</td><td>Cream (mL): No Oil (mL): No Emulsified: Yes</td><td>Cream (mL): No Oil (mL): No Emulsified: Yes</td></tr><tr><td>Final Emulsion Stability (30 minutes)</td><td>Cream (mL): No Oil (mL): No Solid matter: No</td><td>Cream (mL): No Oil (mL): No Solid matter: No</td><td>Cream (mL): No Oil (mL): No Solid matter: No</td><td>Cream (mL): No Oil (mL): No Solid matter: No</td></tr></table> <div>H – High use rate = 2.0% v/v L – Low use rate = 0.18% v/v A – Standard water A D – Standard water D</div>	Sample ID:	H-A	H-D	L-A	L-D	Initial Emulsification (30 seconds after inversion)	Cream (mL): No Oil (mL): No Spontaneously Emulsified: Yes	Cream (mL): No Oil (mL): No Spontaneously Emulsified: Yes	Cream (mL): No Oil (mL): No Spontaneously Emulsified: Yes	Cream (mL): No Oil (mL): No Spontaneously Emulsified: Yes	30 minutes	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No	2 hours	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No	24 hours	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No	Re-emulsification (30 seconds after inversion)	Cream (mL): No Oil (mL): No Emulsified: Yes	Cream (mL): No Oil (mL): No Emulsified: Yes	Cream (mL): No Oil (mL): No Emulsified: Yes	Cream (mL): No Oil (mL): No Emulsified: Yes	Final Emulsion Stability (30 minutes)	Cream (mL): No Oil (mL): No Solid matter: No	Cream (mL): No Oil (mL): No Solid matter: No	Cream (mL): No Oil (mL): No Solid matter: No	Cream (mL): No Oil (mL): No Solid matter: No	Acceptable.	Y	Elliott, T. (2013) NAFST-13-163
Sample ID:	H-A	H-D	L-A	L-D																																					
Initial Emulsification (30 seconds after inversion)	Cream (mL): No Oil (mL): No Spontaneously Emulsified: Yes	Cream (mL): No Oil (mL): No Spontaneously Emulsified: Yes	Cream (mL): No Oil (mL): No Spontaneously Emulsified: Yes	Cream (mL): No Oil (mL): No Spontaneously Emulsified: Yes																																					
30 minutes	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No																																					
2 hours	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No																																					
24 hours	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No	Cream (mL): No Oil (mL): No																																					
Re-emulsification (30 seconds after inversion)	Cream (mL): No Oil (mL): No Emulsified: Yes	Cream (mL): No Oil (mL): No Emulsified: Yes	Cream (mL): No Oil (mL): No Emulsified: Yes	Cream (mL): No Oil (mL): No Emulsified: Yes																																					
Final Emulsion Stability (30 minutes)	Cream (mL): No Oil (mL): No Solid matter: No	Cream (mL): No Oil (mL): No Solid matter: No	Cream (mL): No Oil (mL): No Solid matter: No	Cream (mL): No Oil (mL): No Solid matter: No																																					

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference																																			
	CIPAC MT 36.3	GF-1374 (Lot XA30777703) (7.8% w/w clopyralid, 0.20% w/w florasulam and 13.6% w/w fluroxpyr-meptyl)	<p>No significant changes in emulsion stability were observed during storage. For each timepoint, the emulsion stability was within acceptable limits after 2wks at 54 °C (< 2 mL cream after 30 minutes, trace oil).</p> <p>Table 2. Emulsion Characteristics of GF-1374 - Time Zero</p> <table><tr><th>Sample ID:</th><th>H-A</th><th>H-D</th><th>L-A</th><th>L-D</th></tr><tr><td>Initial Emulsification (30 seconds after inversion)</td><td>Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes</td><td>Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes</td><td>Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes</td><td>Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes</td></tr><tr><td>30 minutes</td><td>Cream: 0 mL Oil: 0 mL</td><td>Cream: 0 mL Oil: 0 mL</td><td>Cream: 0 mL Oil: 0 mL</td><td>Cream: 0 mL Oil: 0 mL</td></tr><tr><td>2 hours</td><td>Cream: 0.05 mL on bottom Oil: 0 mL</td><td>Cream: 0.2 mL on bottom Oil: 0 mL</td><td>Cream: 0.05 mL on bottom Oil: 0 mL</td><td>Cream: 0.15 mL on bottom Oil: 0 mL</td></tr><tr><td>24 hours</td><td>Cream: 1.0 mL on bottom Oil: 0 mL</td><td>Cream: 0.85 mL on bottom Oil: 0 mL</td><td>Cream: 0.65 mL on bottom Oil: 0 mL</td><td>Cream: 0.5 mL on bottom Oil: 0 mL</td></tr><tr><td>Re-emulsification (30 seconds after inversion)</td><td>Cream: trace on bottom Oil: 0 mL Emulsified : no</td><td>Cream: trace on bottom Oil: 0 mL Emulsified : no</td><td>Cream: trace on bottom Oil: 0 mL Emulsified : no</td><td>Cream: 0.1 mL on bottom Oil: 0 mL Emulsified : no</td></tr><tr><td>Final Emulsion Stability (30 minutes)</td><td>Cream: 0.1 mL on bottom Oil: 0 mL Solid matter: no</td><td>Cream: 0.15 mL on bottom Oil: 0 mL Solid matter: no</td><td>Cream: trace on bottom Oil: 0 mL Solid matter: no</td><td>Cream: 0.15 mL on bottom Oil: 0 mL Solid matter: no</td></tr></table> <p>H – High use rate L – Low use rate A – Standard water A D – Standard water D</p> <p>H ~ 1.5 % v/v ; L ~ 0.4 % v/v</p>	Sample ID:	H-A	H-D	L-A	L-D	Initial Emulsification (30 seconds after inversion)	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	30 minutes	Cream: 0 mL Oil: 0 mL	Cream: 0 mL Oil: 0 mL	Cream: 0 mL Oil: 0 mL	Cream: 0 mL Oil: 0 mL	2 hours	Cream: 0.05 mL on bottom Oil: 0 mL	Cream: 0.2 mL on bottom Oil: 0 mL	Cream: 0.05 mL on bottom Oil: 0 mL	Cream: 0.15 mL on bottom Oil: 0 mL	24 hours	Cream: 1.0 mL on bottom Oil: 0 mL	Cream: 0.85 mL on bottom Oil: 0 mL	Cream: 0.65 mL on bottom Oil: 0 mL	Cream: 0.5 mL on bottom Oil: 0 mL	Re-emulsification (30 seconds after inversion)	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: 0.1 mL on bottom Oil: 0 mL Emulsified : no	Final Emulsion Stability (30 minutes)	Cream: 0.1 mL on bottom Oil: 0 mL Solid matter: no	Cream: 0.15 mL on bottom Oil: 0 mL Solid matter: no	Cream: trace on bottom Oil: 0 mL Solid matter: no	Cream: 0.15 mL on bottom Oil: 0 mL Solid matter: no	Acceptable.	Y	Koors, B. (2009) FOR-09-98
Sample ID:	H-A	H-D	L-A	L-D																																					
Initial Emulsification (30 seconds after inversion)	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes																																					
30 minutes	Cream: 0 mL Oil: 0 mL	Cream: 0 mL Oil: 0 mL	Cream: 0 mL Oil: 0 mL	Cream: 0 mL Oil: 0 mL																																					
2 hours	Cream: 0.05 mL on bottom Oil: 0 mL	Cream: 0.2 mL on bottom Oil: 0 mL	Cream: 0.05 mL on bottom Oil: 0 mL	Cream: 0.15 mL on bottom Oil: 0 mL																																					
24 hours	Cream: 1.0 mL on bottom Oil: 0 mL	Cream: 0.85 mL on bottom Oil: 0 mL	Cream: 0.65 mL on bottom Oil: 0 mL	Cream: 0.5 mL on bottom Oil: 0 mL																																					
Re-emulsification (30 seconds after inversion)	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: 0.1 mL on bottom Oil: 0 mL Emulsified : no																																					
Final Emulsion Stability (30 minutes)	Cream: 0.1 mL on bottom Oil: 0 mL Solid matter: no	Cream: 0.15 mL on bottom Oil: 0 mL Solid matter: no	Cream: trace on bottom Oil: 0 mL Solid matter: no	Cream: 0.15 mL on bottom Oil: 0 mL Solid matter: no																																					

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference																																								
			<table><tr><td colspan="5">Table 3. Emulsion Characteristics of GF-1374 - Two Weeks 54°C in Glass</td></tr><tr><td>Sample ID:</td><td>H-A</td><td>H-D</td><td>L-A</td><td>L-D</td></tr><tr><td>Initial Emulsification (30 seconds after inversion)</td><td>Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes</td><td>Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes</td><td>Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes</td><td>Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes</td></tr><tr><td>30 minutes</td><td>Cream: trace on bottom Oil: 0 mL</td><td>Cream: trace on bottom Oil: 0 mL</td><td>Cream: 0 mL Oil: 0 mL</td><td>Cream: 0 mL Oil: 0 mL</td></tr><tr><td>2 hours</td><td>Cream: trace on bottom Oil: 0 mL</td><td>Cream: 0.25 mL on bottom Oil: 0 mL</td><td>Cream: trace on bottom Oil: 0 mL</td><td>Cream: 0.25 mL on bottom Oil: 0 mL</td></tr><tr><td>24 hours</td><td>Cream: 0.25 mL on bottom Oil: 0 mL</td><td>Cream: 1.90 mL on bottom Oil: 0 mL</td><td>Cream: 0.25 mL on bottom Oil: 0 mL</td><td>Cream: 0.8 mL on bottom Oil: 0 mL</td></tr><tr><td>Re-emulsification (30 seconds after inversion)</td><td>Cream: trace on bottom Oil: 0 mL Emulsified : no</td><td>Cream: trace on bottom Oil: 0 mL Emulsified : no</td><td>Cream: trace on bottom Oil: 0 mL Emulsified : no</td><td>Cream: 0.05 mL on bottom Oil: 0 mL Emulsified : no</td></tr><tr><td>Final Emulsion Stability (30 minutes)</td><td>Cream: trace on bottom Oil: 0 mL Solid matter: no</td><td>Cream: 0.25 mL on bottom Oil: 0 mL Solid matter: no</td><td>Cream: trace on bottom Oil: 0 mL Solid matter: no</td><td>Cream: 0.25 mL on bottom Oil: 0 mL Solid matter: no</td></tr></table>	Table 3. Emulsion Characteristics of GF-1374 - Two Weeks 54°C in Glass					Sample ID:	H-A	H-D	L-A	L-D	Initial Emulsification (30 seconds after inversion)	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	30 minutes	Cream: trace on bottom Oil: 0 mL	Cream: trace on bottom Oil: 0 mL	Cream: 0 mL Oil: 0 mL	Cream: 0 mL Oil: 0 mL	2 hours	Cream: trace on bottom Oil: 0 mL	Cream: 0.25 mL on bottom Oil: 0 mL	Cream: trace on bottom Oil: 0 mL	Cream: 0.25 mL on bottom Oil: 0 mL	24 hours	Cream: 0.25 mL on bottom Oil: 0 mL	Cream: 1.90 mL on bottom Oil: 0 mL	Cream: 0.25 mL on bottom Oil: 0 mL	Cream: 0.8 mL on bottom Oil: 0 mL	Re-emulsification (30 seconds after inversion)	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: 0.05 mL on bottom Oil: 0 mL Emulsified : no	Final Emulsion Stability (30 minutes)	Cream: trace on bottom Oil: 0 mL Solid matter: no	Cream: 0.25 mL on bottom Oil: 0 mL Solid matter: no	Cream: trace on bottom Oil: 0 mL Solid matter: no	Cream: 0.25 mL on bottom Oil: 0 mL Solid matter: no			
Table 3. Emulsion Characteristics of GF-1374 - Two Weeks 54°C in Glass																																														
Sample ID:	H-A	H-D	L-A	L-D																																										
Initial Emulsification (30 seconds after inversion)	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes																																										
30 minutes	Cream: trace on bottom Oil: 0 mL	Cream: trace on bottom Oil: 0 mL	Cream: 0 mL Oil: 0 mL	Cream: 0 mL Oil: 0 mL																																										
2 hours	Cream: trace on bottom Oil: 0 mL	Cream: 0.25 mL on bottom Oil: 0 mL	Cream: trace on bottom Oil: 0 mL	Cream: 0.25 mL on bottom Oil: 0 mL																																										
24 hours	Cream: 0.25 mL on bottom Oil: 0 mL	Cream: 1.90 mL on bottom Oil: 0 mL	Cream: 0.25 mL on bottom Oil: 0 mL	Cream: 0.8 mL on bottom Oil: 0 mL																																										
Re-emulsification (30 seconds after inversion)	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: 0.05 mL on bottom Oil: 0 mL Emulsified : no																																										
Final Emulsion Stability (30 minutes)	Cream: trace on bottom Oil: 0 mL Solid matter: no	Cream: 0.25 mL on bottom Oil: 0 mL Solid matter: no	Cream: trace on bottom Oil: 0 mL Solid matter: no	Cream: 0.25 mL on bottom Oil: 0 mL Solid matter: no																																										

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference																																			
	CIPAC MT 36.3	GF-1374 (Lot XA30777703) (7.8% w/w clopyralid, 0.20% w/w florasulam and 13.6% w/w fluroxpyr-meptyl)	<p>No significant changes in emulsion stability were observed during storage. For each timepoint, the emulsion stability was within acceptable limits after 2 year ambient storage (< 2 mL cream after 30 minutes, trace oil).</p> <p>Table 3. Emulsion Characteristics of GF-1374 - Time Zero*</p> <table><tr><th>Sample ID:</th><th>H-A</th><th>H-D</th><th>L-A</th><th>L-D</th></tr><tr><td>Initial Emulsification (30 seconds after inversion)</td><td>Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes</td><td>Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes</td><td>Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes</td><td>Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes</td></tr><tr><td>30 minutes</td><td>Cream: 0 mL Oil: 0 mL</td><td>Cream: 0 mL Oil: 0 mL</td><td>Cream: 0 mL Oil: 0 mL</td><td>Cream: 0 mL Oil: 0 mL</td></tr><tr><td>2 hours</td><td>Cream: 0.05 mL on bottom Oil: 0 mL</td><td>Cream: 0.2 mL on bottom Oil: 0 mL</td><td>Cream: 0.05 mL on bottom Oil: 0 mL</td><td>Cream: 0.15 mL on bottom Oil: 0 mL</td></tr><tr><td>24 hours</td><td>Cream: 1.0 mL on bottom Oil: 0 mL</td><td>Cream: 0.85 mL on bottom Oil: 0 mL</td><td>Cream: 0.65 mL on bottom Oil: 0 mL</td><td>Cream: 0.5 mL on bottom Oil: 0 mL</td></tr><tr><td>Re-emulsification (30 seconds after inversion)</td><td>Cream: trace on bottom Oil: 0 mL Emulsified : no</td><td>Cream: trace on bottom Oil: 0 mL Emulsified : no</td><td>Cream: trace on bottom Oil: 0 mL Emulsified : no</td><td>Cream: 0.1 mL on bottom Oil: 0 mL Emulsified : no</td></tr><tr><td>Final Emulsion Stability (30 minutes)</td><td>Cream: 0.1 mL on bottom Oil: 0 mL Solid matter: no</td><td>Cream: 0.15 mL on bottom Oil: 0 mL Solid matter: no</td><td>Cream: trace on bottom Oil: 0 mL Solid matter: no</td><td>Cream: 0.15 mL on bottom Oil: 0 mL Solid matter: no</td></tr></table> <p>H – High use rate L – Low use rate A – Standard water A D – Standard water D *Time Zero Testing Referenced from DAS Report FOR-09-98</p> <p>H ~ 1.5 % v/v ; L ~ 0.4 % v/v</p>	Sample ID:	H-A	H-D	L-A	L-D	Initial Emulsification (30 seconds after inversion)	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	30 minutes	Cream: 0 mL Oil: 0 mL	Cream: 0 mL Oil: 0 mL	Cream: 0 mL Oil: 0 mL	Cream: 0 mL Oil: 0 mL	2 hours	Cream: 0.05 mL on bottom Oil: 0 mL	Cream: 0.2 mL on bottom Oil: 0 mL	Cream: 0.05 mL on bottom Oil: 0 mL	Cream: 0.15 mL on bottom Oil: 0 mL	24 hours	Cream: 1.0 mL on bottom Oil: 0 mL	Cream: 0.85 mL on bottom Oil: 0 mL	Cream: 0.65 mL on bottom Oil: 0 mL	Cream: 0.5 mL on bottom Oil: 0 mL	Re-emulsification (30 seconds after inversion)	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: 0.1 mL on bottom Oil: 0 mL Emulsified : no	Final Emulsion Stability (30 minutes)	Cream: 0.1 mL on bottom Oil: 0 mL Solid matter: no	Cream: 0.15 mL on bottom Oil: 0 mL Solid matter: no	Cream: trace on bottom Oil: 0 mL Solid matter: no	Cream: 0.15 mL on bottom Oil: 0 mL Solid matter: no	Acceptable.	Y	Cobb, J. (2014) FOR-09-99
Sample ID:	H-A	H-D	L-A	L-D																																					
Initial Emulsification (30 seconds after inversion)	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes																																					
30 minutes	Cream: 0 mL Oil: 0 mL	Cream: 0 mL Oil: 0 mL	Cream: 0 mL Oil: 0 mL	Cream: 0 mL Oil: 0 mL																																					
2 hours	Cream: 0.05 mL on bottom Oil: 0 mL	Cream: 0.2 mL on bottom Oil: 0 mL	Cream: 0.05 mL on bottom Oil: 0 mL	Cream: 0.15 mL on bottom Oil: 0 mL																																					
24 hours	Cream: 1.0 mL on bottom Oil: 0 mL	Cream: 0.85 mL on bottom Oil: 0 mL	Cream: 0.65 mL on bottom Oil: 0 mL	Cream: 0.5 mL on bottom Oil: 0 mL																																					
Re-emulsification (30 seconds after inversion)	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: trace on bottom Oil: 0 mL Emulsified : no	Cream: 0.1 mL on bottom Oil: 0 mL Emulsified : no																																					
Final Emulsion Stability (30 minutes)	Cream: 0.1 mL on bottom Oil: 0 mL Solid matter: no	Cream: 0.15 mL on bottom Oil: 0 mL Solid matter: no	Cream: trace on bottom Oil: 0 mL Solid matter: no	Cream: 0.15 mL on bottom Oil: 0 mL Solid matter: no																																					

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference																																				
			Table 4. Emulsion Characteristics of GF-1374 - Two years Ambient in F-HDPE																																							
			<table><tr><td>Sample ID:</td><td>H-A</td><td>H-D</td><td>L-A</td><td>L-D</td></tr><tr><td>Initial Emulsification (30 seconds after inversion)</td><td>Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes</td><td>Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : no</td><td>Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes</td><td>Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : no</td></tr><tr><td>30 minutes</td><td>Cream: 0 ml Oil: 0 mL</td><td>Cream: trace on bottom* Oil: 0 mL</td><td>Cream: 0 mL* Oil: 0 mL</td><td>Cream: trace on bottom* Oil: 0 mL</td></tr><tr><td>2 hours</td><td>Cream: 0 ml* Oil: 0 mL</td><td>Cream: trace on bottom* Oil: 0 mL</td><td>Cream: trace on bottom* Oil: 0 mL</td><td>Cream: trace on bottom* Oil: 0 mL</td></tr><tr><td>24 hours</td><td>Cream: trace on bottom Oil: 0 mL</td><td>Cream: trace on bottom* Oil: 0 mL</td><td>Cream: trace on bottom* Oil: 0 mL</td><td>Cream: trace on bottom* Oil: 0 mL</td></tr><tr><td>Re-emulsification (30 seconds after inversion)</td><td>Cream: 0 ml Oil: 0 mL Emulsified : yes</td><td>Cream: trace on bottom* Oil: 0 mL Emulsified : no</td><td>Cream: 0 ml trace on bottom* Oil: 0 mL Emulsified :no</td><td>Cream: trace on bottom* Oil: 0 mL Emulsified : no</td></tr><tr><td>Final Emulsion Stability (30 minutes)</td><td>Cream: 0 ml Oil: 0 mL Solid matter: no</td><td>Cream: trace on bottom* Oil: 0 mL Solid matter: no</td><td>Cream: trace on bottom* Oil: 0 mL Solid matter: no</td><td>Cream: trace on bottom* Oil: 0 mL Solid matter: no</td></tr></table>					Sample ID:	H-A	H-D	L-A	L-D	Initial Emulsification (30 seconds after inversion)	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : no	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : no	30 minutes	Cream: 0 ml Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL	Cream: 0 mL* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL	2 hours	Cream: 0 ml* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL	24 hours	Cream: trace on bottom Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL	Re-emulsification (30 seconds after inversion)	Cream: 0 ml Oil: 0 mL Emulsified : yes	Cream: trace on bottom* Oil: 0 mL Emulsified : no	Cream: 0 ml trace on bottom* Oil: 0 mL Emulsified :no	Cream: trace on bottom* Oil: 0 mL Emulsified : no	Final Emulsion Stability (30 minutes)	Cream: 0 ml Oil: 0 mL Solid matter: no	Cream: trace on bottom* Oil: 0 mL Solid matter: no	Cream: trace on bottom* Oil: 0 mL Solid matter: no	Cream: trace on bottom* Oil: 0 mL Solid matter: no
			Sample ID:	H-A	H-D	L-A	L-D																																			
			Initial Emulsification (30 seconds after inversion)	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : no	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : no																																			
			30 minutes	Cream: 0 ml Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL	Cream: 0 mL* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL																																			
			2 hours	Cream: 0 ml* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL																																			
			24 hours	Cream: trace on bottom Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL																																			
			Re-emulsification (30 seconds after inversion)	Cream: 0 ml Oil: 0 mL Emulsified : yes	Cream: trace on bottom* Oil: 0 mL Emulsified : no	Cream: 0 ml trace on bottom* Oil: 0 mL Emulsified :no	Cream: trace on bottom* Oil: 0 mL Emulsified : no																																			
			Final Emulsion Stability (30 minutes)	Cream: 0 ml Oil: 0 mL Solid matter: no	Cream: trace on bottom* Oil: 0 mL Solid matter: no	Cream: trace on bottom* Oil: 0 mL Solid matter: no	Cream: trace on bottom* Oil: 0 mL Solid matter: no																																			
			H – High use rate L – Low use rate A – Standard water A D – Standard water D *flocculation was present																																							

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference			
			Table 5. Emulsion Characteristics of GF-1374 - Two years Ambient in PET						
			Sample ID:	H-A			H-D	L-A	L-D
			Initial Emulsification (30 seconds after inversion)	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes			Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : no	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : yes	Cream: 0 mL Oil: 0 mL Spontaneously Emulsified : no
			30 minutes	Cream: trace on bottom* Oil: 0 mL			Cream: trace on bottom* Oil: 0 mL	Cream: 0 mL* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL
			2 hours	Cream: trace on bottom* Oil: 0 mL			Cream: trace on bottom* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL
			24 hours	Cream: trace on bottom* Oil: 0 mL			Cream: trace on bottom* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL	Cream: trace on bottom* Oil: 0 mL
			Re-emulsification (30 seconds after inversion)	Cream: 0 ml Oil: 0 mL Emulsified : yes			Cream: trace on bottom* Oil: 0 mL Emulsified : no	Cream: 0 ml* Oil: 0 mL Emulsified : yes	Cream: trace on bottom* Oil: 0 mL Emulsified : no
			Final Emulsion Stability (30 minutes)	Cream: trace on bottom Oil: 0 mL Solid matter: no			Cream: trace on bottom* Oil: 0 mL Solid matter: no	Cream: trace on bottom* Oil: 0 mL Solid matter: no	Cream: trace on bottom* Oil: 0 mL Solid matter: no
			H – High use rate L – Low use rate A – Standard water A D – Standard water D *floculation was present						
			B.2.8.7. Flowability, pourability and dustability						
Flowability of granular formulation B.2.8.7/01	-	-	Not required as formulation is an EC						
Pourability of suspensions B.2.8.7/02	-	-	Not required as formulation is an EC						
Dustability of	-	-	Not required as formulation is an EC						

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
dustable powders after accelerated storage B.2.8.7/03						
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	SOP / FORMS / 16	GF-1374 (Batch 190/24-A) (79 g/L clopyralid, 2.6 g/L florasulam, 142 g/L fluroxypyr meptyl)	Classified as compatible with Fury 10 EW, Decis Expert, Dursban WG, Karate Zeon, Amistar, Impulse, Proline, Fandango, Juwel Top, Pronto Plus, Fortress, Fortress Duo, Sphere, Moddus, Cycocel C5, Terpal C, Atlantis WG, Celio, Aleron 500, Puma LS, Baghera, Attribut, Axial + FHS, Grasp, GF-1274, Ally, Loreda This work was conducted at the 100L/ha spray volume rate. No tank mix partner mixture showed any oiling or material retained on a sieve that could not be washed through.	Not acceptable. For instance, nothing is mentioned about persistent foaming.	N	Corbett, M. and Hopkins, D.J. (2006) DN0019531
	-	-	The chemical compatibility of GF-1374 with other products in tank-mix has not been directly analysed but is covered by biological efficacy studies and the appearance of the mixture(s) during the physical compatibility testing. If both efficacy and physical stability of the mixture are acceptable, then it is justifiable to assume that no adverse chemical reaction has occurred. For GF-1374 no indications of chemical reactivity were observed.	Not acceptable. No information is given here.	-	no reference
B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS						
Distribution and adhesion to seeds B.2.9.10/01	-	-	Not required as formulation is an EC			
B.2.11. OTHER STUDIES						
			There are no other studies required or submitted			

B.2.12. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Source (where different from company) Company Report No. Date GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed^{*)}	Owner^{**)}	Previous evaluation
CP 2.1/1 CP 2.3/1 CP 2.4/1-3 CP 2.5/1-2 CP 2.6/1 CP 2.7/1-2 CP 2.8.2/1 CP 2.8.6/1	Cathie, C.A.	2005	Physical and Chemical Properties of Bofix MCPA Free EC Formulation, GF-1374, 144 g/L Fluroxypyr meptyl, 80 g/L clopyralid and 2.5 g/L florasulam nominal Dow AgroSciences (NZ) Ltd., New Plymouth, New Zealand DAS Report No: 05-683-G 1.11.2005 GLP/GEP (Y/N): Y Published (Y/N): N	No	Yes	H	DAS	Submitted for the purpose of renewal
CP 2.2/1 CP 2.3/3	Turner, B.	2006	Determination of Explosive Properties and Auto-Ignition Temperature for GF-1374 Huntingdon Life Sciences Ltd, Cambridgeshire, UK DAS Report No: NAFST-05-118, DOS/0470 2.3.2006 GLP/GEP (Y/N): Y Published (Y/N): N	No	Yes	H	DAS	Submitted for the purpose of renewal
CP 2.2/2	Comb, A.L.	2012	Determination of Oxidising Properties (liquids) for GF-1374 Huntingdon Life Sciences Ltd, Suffolk, England DAS Report No: NAFST-12-159 2.11.2012 GLP/GEP (Y/N): Y Published (Y/N): N	No	Yes	H	DAS	Submitted for the purpose of renewal

Data Point	Author(s)	Year	Title Source (where different from company) Company Report No. Date GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed^{*)}	Owner^{**))}	Previous evaluation
CP 2.5/1 CP 2.8.2/1 CP 2.8.6/1	Koors, B.	2009	Persistent Foaming and Emulsion Stability on GF-1374 - Two Week Accelerated Storage Dow AgroSciences LLC, Indianapolis, Indiana, USA DAS Report No: FOR-09-98 4.12.2009 GLP/GEP (Y/N): Y Published (Y/N): N	No	Yes	H	DAS	Submitted for the purpose of renewal
CP 2.7/1	Elliott, T	2013	GF-1374: Two Week Accelerated Storage Stability in F-HDPE ABC Laboratories, Inc., Columbia, Missouri, USA DAS Report No: NAFST-13-163 3.12.2013 GLP/GEP (Y/N): Y Published (Y/N): N	No	Yes	H	DAS	Submitted for the purpose of renewal
CP 2.7/1 CP 2.8.2/1 CP 2.8.6/1	Kendal, P.A. and Tidswell, J.N.	2005	GF-1374 (80 g/L clopyralid, 2.5g/L florasulam, 100g.a.e/L Fluroxypyr-meptyl) Eight Week 40°C Stability in and Compatibility with PET Bottle Packaging Dow AgroSciences (NZ) Ltd., New Plymouth, New Zealand DAS Report No: 05-676-G 9.12.2005 GLP/GEP (Y/N): Y Published (Y/N): N	No	Yes	H	DAS	Submitted for the purpose of renewal

Data Point	Author(s)	Year	Title Source (where different from company) Company Report No. Date GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed^{*)}	Owner^{**)}	Previous evaluation
CP 2.7/3 CP 2.8.2/1	Kendall, P.A.	2008	GF-1374 (80g/L clopyralid, 2.5g/L florasulam, 100g.a.e/L fluroxypyr-meptyl) Two Years Ambient Stability in and Compatibility with PET Bottle Packaging Dow AgroSciences (NZ) Ltd., New Plymouth, New Zealand DAS Report No: 05-678-G 19.3.2008 GLP/GEP (Y/N): Y Published (Y/N): N	No	Yes	H	DAS	Submitted for the purpose of renewal
CP 2.7/3 CP 2.8.2/1 CP 2.8.6/1	Elliott, T.	2016	GF-1374: Two Year Ambient Shelf-life in F-HDPE Packaging Dow AgroSciences LLC, Indianapolis, Indiana, USA DAS Report No: NAFST-13-164 13.6.2016 GLP/GEP (Y/N): Y Published (Y/N): N	No	Yes	H	DAS	Submitted for the purpose of renewal
CP 2.8.2/1 CP 2.8.6/1	Cobb, J.	2014	Persistent Foaming and Emulsion Stability on GF-1374 - Two Year Ambient Study Dow AgroSciences LLC, Indianapolis, Indiana, USA DAS Report No: FOR-09-99 2.6.2014 GLP/GEP (Y/N): Y Published (Y/N): N	No	Yes	H	DAS	Submitted for the purpose of renewal

Data Point	Author(s)	Year	Title Source (where different from company) Company Report No. Date GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed^{*)}	Owner^{**)}	Previous evaluation
CP 2.9/1	Corbett, M. and Hopkins, D.J.	2006	Physical Compatibility of GF-1374 Herbicide with European Cereal Market Tank Mix Partners Dow AgroSciences (NZ) Ltd., New Plymouth, New Zealand DAS Report No: DN0019531 22.2.2006 GLP/GEP (Y/N): N Published (Y/N): N	No	Yes	H	DAS	Submitted for the purpose of renewal

^{*)} H = Product data submitted with an application for renewal of authorisation under Article 43 of the Regulation – containing at least one active considered under AIR2 onwards.

^{**)} Data owner: DAS = Dow AgroSciences