



Draft Assessment Report

Evaluation of Active Substances

Plant Protection Products

Prepared according to **Regulation (EC) 1107/2009**
as it applies in Great Britain

Pydiflumetofen

Volume 3 – B.2 (PPP) – Miravis Plus

Physical & Chemical Properties

Great Britain

June 2023

Version History

When	What
October 2022	Initial GB DAR
June 2023	Post Expert Committee on Pesticides (ECP) Independent Scientific Advice (ISA)

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B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT ‘MIRAVIS PLUS’

The in use concentration range of ‘Miravis Plus’ is 0.88-3.2% (v/v).

‘Miravis Plus’ = A21857B

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 and olfactory assessment	Test item: A21857B Batch JEA001-118-001	‘Miravis Plus’ is a light yellow liquid with a ‘solvent-like’ odour.	Acceptable.	Y	Study Report Number: SMG13921 ██████████ 2016
B.2.2. EXPLOSIVE AND OXIDIZING PROPERTIES						
Explosive properties B.2.2/01	ASTM E537 (DSC)	Test item: A21857B Batch JEA001-118-001	The DSC trace showed two exothermic regions at 182 – 244 °C and 353 – 408 °C. The total heat of decomposition is 69 J/g.	Not classified as an explosive substance. Acceptable.	Y	Study Report Number: HT16/548 ██████████ 2016
Oxidizing properties B.2.2/02	UN Test Test O.2	Test item: A21857B Batch JEA001-118-001	<div>TestTime taken for pressure to reach 2070 kPa (s)</div>	Not classified as an oxidising substance. Acceptable.	Y	Study Report Number: HT16/548 ██████████ 2016
			<div>Ref.Test item</div>			
			1.3.628.2			
			2.3.956.3			
			3.4.841.3			
			4.4.426.9			
			5.5.5> 90			
			Max. 1124 kPa			
Mean4.438.2 (tests 1-4)						

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.3. FLAMMABILITY AND AUTO-FLAMMABILITY						
Flash point of the liquids formulations B.2.3/01	ASTM D93 (Pensky-Martens closed cup)	Test item: A21857B Batch JEA001-118-001	Flash point of 80 ± 4 °C. from two determinations.	Not classified as a flammable substance. Acceptable.	Y	Study Report Number: HT16/548 [REDACTED] 2016
Flammability of solid formulations B.2.3/02	-	-	-	Not relevant to EC formulations	-	-
Self-heating of formulation B.2.3/03	EC Test A.15 IEC 60079-20-1	Test item: A21857B Batch JEA001-118-001	Auto-ignition temperature 400 ± 20 °C	Acceptable.	Y	Study Report Number: HT16/548 [REDACTED] 2016
B.2.4. ACIDITY/ALKALINITY AND PH VALUE						
pH of the neat aqueous formulation B.2.4/01	-	-	-	Not relevant to EC formulations	-	-
pH of a 1 % dilution of the solid or non aqueous formulation B.2.4/02	CIPAC MT 75.3	Test item: A21857B Batch JEA001-118-001	1% (w/v) dilution in deionised water tested at 25 °C. pH = 5.8	Acceptable.	Y	Study Report Number: SMG13921 [REDACTED] 2016
Acidity / Alkalinity B.2.4/03	CIPAC MT 191	Test item: A21857B Batch JEA001-118-001	The test sample was mixed with deionised water and the acidity, calculated as H ₂ SO ₄ , was determined to be 0.01%.	Acceptable.	Y	Study Report Number: SMG13921 [REDACTED] 2016
B.2.5. VISCOSITY AND SURFACE TENSION						
Viscosity of the liquid formulation B.2.5/01	OECD 114	Test item: A21857B Batch JEA001-118-001	The product was tested using a dynamic viscometer at 20 and 40 °C and shear rates ranging from 200 to 100 s ⁻¹ . The data showed a shear-independent (Newtonian) viscosity of 58.7 and 20.8 mPa.s at 20 and 40 °C respectively.	Acceptable. When considered together with the composition of the product a classification for aspiration hazard is not required.	Y	Study Report Number: SMG13919 [REDACTED] 2016

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference	
Surface tension of the formulation B.2.5/02	EC A5	Test item: A21857B Batch JEA001-118-001	Tested in duplicate, at 20 °C, for 10 minutes. The appearance of all diluted test solutions was ‘white coloured turbid liquid’.	‘Miravis Plus’ is surface active. Acceptable.	Y	Study Report Number: SMG13919 ██████████ 2016	
			Concentration				Surface Tension
			0.1% (w/v)				36.8 mN/m
			0.5% (w/v)				32.8 mN/m
			3.2% (w/v)*				31.7 mN/m
Undiluted	31.4 mN/m						
			* Equivalent to the maximum in-use concentration of ‘Miravis Plus’				
B.2.6. RELATIVE DENSITY AND BULK DENSITY							
Relative density of the liquid formulation B.2.6/01	OECD 109	Test item: A21857B Batch JEA001-118-001	Relative density = 1.097 g/cm³ at 20 °C.	Acceptable.	Y	Study Report Number: SMG13920	
Bulk density (pour and tap) of powder or granules B.2.6/02	-	-	-	Not relevant to EC formulations	-	-	
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	Test item: A21857B Batch JEA001-118-001	The formulation was stored in a one litre HDPE container for two weeks at 54 ± 2 °C. The physical and chemical properties before and after storage are reported in Appendix 1.	No significant changes on storage. Acceptable.	Y	Study Report Number: 300074164 ██████████ 2017	
Effect of low temperature on stability of liquid formulation B.2.7/02	CIPAC MT 39.3	Test item: A21857B Batch JEA001-118-001	The formulation was stored for 7 days at 0 ± 2 °C. No separation was observed. After allowing the sample to reach room temperature over 24 hours, and a single inversion, no separation was observed. The physical and chemical properties before and after storage are reported in Appendix 2.	No significant changes on storage. Acceptable.	Y	Study Report Number: SMG13919 ██████████ 2016	

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		Test item: A21857B Batch JEA001-118-001	The formulation was stored in a one litre HDPE container for two years at 20 ± 2 °C. The physical and chemical properties before and after storage are reported in Appendix 3.	No significant changes on storage. Acceptable.	Y	Study Report Number: 300140168 [REDACTED] 2019
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 relevant to EC formulations	-	-
B.2.8.2. Persistence foaming						
Persistence of foaming of the diluted formulation B.2.8.2/01	CIPAC MT 47.3	Test item: A21857B Batch JEA001-118-001	Persistent Foaming in CIPAC water D after 1 minute 3.2% (v/v): 0 ml 0.5% (v/v): 0 ml	Acceptable.	Y	Study Report Number: SMG13921 [REDACTED] 2016
B.2.8.3. Suspensibility						
Suspensibility of water dispersible formulation B.2.8.3/01	-	-	-	Not relevant to EC formulations	-	-
Spontaneity of dispersion of water dispersible formulation B.2.8.3/02	-	-	-	Not relevant to EC formulations	-	-
Dispersion stability of SE, OD or EG formulation B.2.8.3/03	-	-	-	Not relevant to EC formulations	-	-
B.2.8.4. Degree of dissolution and dilution stability						
Degree of dissolution of water soluble formulation B.2.8.4/01	-	-	-	Not relevant to EC formulations	-	-

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Dilution stability of water soluble formulation B.2.8.4/02	-	-	-	Not relevant to EC 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	-	-	-	Not relevant to EC formulations	-	-
Size distribution of particles of powder or suspension concentrate formulation B.2.8.5.1/02	-	-	-	Not relevant to EC formulations	-	-
Nominal size range of granule B.2.8.5.1/03	-	-	-	Not relevant to EC formulations	-	-
B.2.8.5.2. Dust content						
Dust content of granular formulation B.2.8.5.2/01	-	-	-	Not relevant to EC formulations	-	-
B.2.8.5.3. Attrition						
Attrition characteristics of granules and tablets B.2.8.5.3/01	-	-	-	Not relevant to EC formulations	-	-
B.2.8.5.4. Hardness and integrity						
Hardness of tablets B.2.8.5.4/01	-	-	-	Not relevant to EC formulations	-	-
Integrity of tablets B.2.8.5.4/02	-	-	-	Not relevant to EC formulations	-	-

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 36.3	Test item: A21857B Batch JEA001-118-001	Tested under four conditions:	Acceptable.	Y	Study Report Number: SMG13921 ██████████ 2016	
			3.2 % v/v in CIPAC water A at 30 °C				
			3.2 % v/v in CIPAC water D at 30 °C				
			0.5 % v/v in CIPAC water A at 30 °C				
			0.5 % v/v in CIPAC water D at 30 °C				
			All test conditions yielded identical results, tabulated below:				
			Emulsifiability				spontaneous
			Emulsion Stability after 0.5 h				trace cream at the bottom, no oil
After 2 h	trace cream at the bottom, no oil						
After 24 h	trace cream at the bottom, no oil						
Re-emulsifiability	complete						
Separation after 0.5 h	trace cream at the bottom, no oil						
B.2.8.7. Flowability, pourability and dustability							
Flowability of granular formulation B.2.8.7/01	-	-	-	Not relevant to EC formulations	-	-	
Pourability of suspensions B.2.8.7/02	-	-	-	Not relevant to EC formulations	-	-	
Dustability of dustable powders after accelerated storage B.2.8.7/03	-	-	-	Not relevant to EC formulations	-	-	

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
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	-	-	-	No data submitted	-	-
B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS						
Distribution and adhesion to seeds B.2.9.10/01	-	-	-	Not relevant to EC formulations	-	-
B.2.11. OTHER STUDIES						

The representative formulation ‘Miravis Plus’ (A21857B) is an emulsifiable concentrate (EC) containing 62.5 g/L pydiflumetofen with proposed in-use concentrations of 0.88 – 3.2 % v/v.

The appearance of the product is that of light-yellow liquid with a ‘solvent-like’ odour. It is considered not to have explosive and oxidising properties and is not classified as flammable. It has an auto-ignition temperature of 400 °C, which indicates that the formulation is not self-heating. When diluted with 1 % deionised water the pH value is 5.8. The dynamic viscosity at 40 °C is 20.8 mPa/s, which would indicate a kinematic viscosity < 20.5 mm²/s, however when considered together with the composition of the product a classification for aspiration hazard is not required. The surface tension of the neat product is 31.4 mN/m and 36.8 mN/m at a dilution of 0.1 %, indicating that the product is surface active. It’s technical characteristics are acceptable for a EC formulation.

Following both 7 days at 0 °C and 2 weeks at 54 °C, neither the active substance content nor the physical, chemical, and technical properties were changed, indicating acceptable stability at low and high temperatures. Data to support a shelf life of 2 years at ambient temperature when stored in HDPE containers were also submitted demonstrating acceptable stability of both the active substance content and the physical, chemical, and technical properties.

No data on physical or chemical compatibility of tank mixes were submitted. The draft label submitted for ‘Miravis Plus’ (A21857B) indicates that it must always be used in mixture with another product for resistance management reasons on cereal crops. Therefore, compatibility data will be required to support the authorisation of the product.

Appendix 1 - Summary of accelerated storage stability data (2 weeks at 54 °C) in HDPE (2017)

Test Description	Method	Initial Results	Results after 2 weeks 54 ± 2 °C
Color	Visual	light yellow	light yellow
Odor	Organoleptic	solvent-like	solvent-like
Physical State	Visual	liquid	liquid
Appearance	Visual	---	clear
Active content	Method SF-861/1 (See Vol 3 CP B5)	5.62% (w/w) 61.7 g/L	5.62% (w/w) 61.7 g/L
pH Value Concentration: 1% Deionized Water 25 °C	CIPAC MT 75.3	5.8	5.1
Relative Density Temperature: 20 °C	OECD 109	1.097 g/cm ³	1.097 g/cm ³
Emulsifiability, Emulsion Stability, Re-emulsifiability Spontaneity of the Emulsion Emulsion Stability after 0.5 h after 2 h after 24 h Re-emulsification Emulsion Stability 0.5 h after Re-emulsification	CIPAC MT 36.3 Concentration: 0.5% & 3.2% CIPAC Water A and D Temperature: 30 °C	Identical results were reported for all four test conditions spontaneous trace cream at the bottom, no oil trace cream at the bottom, no oil trace cream at the bottom, no oil complete trace cream at the bottom, no oil	Identical results were reported for all four test conditions spontaneous trace cream at the bottom, no oil trace cream at the bottom, no oil trace cream at the bottom, no oil complete trace cream at the bottom, no oil
Packaging evaluation	-	-	No changes to colour or odour. No ballooning, panelling, pimples or cracks. Container remained tight and reclosable. No permeation through container walls. 0.01% weight loss.

Appendix 2 - Summary of low temperature storage stability data (7 days at 0 ± 2 °C) (■■■■■ 2016)

Test Description	Method	Initial Results	Results after 7 days at 0 ± 2 °C
pH Value Concentration: 1% Deionized Water 25 °C	CIPAC MT 75.3	5.8	5.2
Emulsifiability, Emulsion Stability, Re-emulsifiability Spontaneity of the Emulsion Emulsion Stability after 0.5 h after 2 h after 24 h Re-emulsification Emulsion Stability 0.5 h after Re-emulsification	 CIPAC MT 36.3 Concentration: 0.5% & 3.2% CIPAC Water A and D Temperature: 30 °C	Identical results were reported for all four test conditions spontaneous trace cream at the bottom, no oil trace cream at the bottom, no oil trace cream at the bottom, no oil complete trace cream at the bottom, no oil	Identical results were reported for all four test conditions spontaneous trace cream at the bottom, no oil trace cream at the bottom, no oil trace cream at the bottom, no oil complete trace cream at the bottom, no oil

Appendix 3 - Summary of accelerated storage stability data (2 years at 20 °C) in HDPE (2019)

Test Description	Method	Initial Results	Results after 2 years 20 ± 2 °C
Color	Visual	light yellow	light yellow
Odor	Organoleptic	solvent-like	solvent-like
Physical State	Visual	liquid	liquid
Appearance	Visual	clear	clear
Active content	Method SF-861/1 (See Vol 3 CP B5)	5.62% (w/w) 61.7 g/L	5.70% (w/w) 62.5 g/L
pH Value Concentration: 1% Deionized Water 25 °C	CIPAC MT 75.3	5.8	4.9
Relative Density Temperature: 20 °C	OECD 109	1.097 g/cm ³	1.097 g/cm ³
Emulsifiability, Emulsion Stability, Re-emulsifiability Spontaneity of the Emulsion Emulsion Stability after 0.5 h after 2 h after 24 h Re-emulsification Emulsion Stability 0.5 h after Re-emulsification	 CIPAC MT 36.3 Concentration: 0.5% & 3.2% CIPAC Water A and D Temperature: 30 °C	Identical results were reported for all four test conditions spontaneous trace cream at the bottom, no oil trace cream at the bottom, no oil trace cream at the bottom, no oil complete trace cream at the bottom, no oil	Identical results were reported for all four test conditions spontaneous trace cream at the bottom, no oil trace cream at the bottom, no oil trace cream at the bottom, no oil complete trace cream at the bottom, no oil
Packaging evaluation	-	-	No changes to colour or odour. No ballooning, panelling, pimples or cracks. Container remained tight and reclosable. No permeation through container walls. 0.03% weight gain.

B.2.12. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) 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
KCP 2.1/01 2.4/02 2.4/03 2.7/01 2.7/03	██████	2016	A21857B - Physical and Technical Properties of Batch JEA001-118-001 Report No. SMG13921 Document No. VV-468701, A21857B_10031 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to this country	Syngenta	N
KCP 2.2/01 2.2/02 2.3/01 2.3/03	██████ ██	2016	A21857B - Safety study Report No. HT16/548 Document No. VV-468702 , A21857B_10032 Test Facility Syngenta Technology & Engineering GLP Unpublished	N	Y	Data/study report never submitted before to this country	Syngenta	N
KCP 2.5/01 2.5/02 2.7/02	██████	2016	A21857B - Physico-Chemical Characteristics of Batch JEA001-118-001 Report No. SMG13919 Document No. VV-468698, A21857B_10027 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to this country	Syngenta	N

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) 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
KCP 2.6/01 2.7/01 2.7/03	■■■■■	2016	A21857B - Chemical Characterization of Batch JEA001-118-001 Report No. SMG13920 Document No. VV-468700, A21857B_10029 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to this country	Syngenta	N
KCP 2.7/01	■■■■■ ■	2017	A21857B - Storage Stability and Shelf Life Statement (2 Weeks 54 °C) in Packaging Made of HDPE according to CIPAC MT 46.3 Report No. 300074164 Document No. VV-468697, A21857B_10025 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	Y	Data/study report never submitted before to this country	Syngenta	N
KCP 2.7/01 (appended to study)	■■■■■	2016a	A21857B – Content of Active Ingredient(s) of Batch JEA001-118-001 after Storage in Packaging Made of HDPE for 2 Weeks at 54°C Report No. SMG13922 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	-	Syngenta	N

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) 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
KCP 2.7/01 (appended to study)	██████	2016b	A21857B – Physical and Technical Properties and Packaging Evaluation of Batch JEA001-118-001 after Storage in Packaging Made of HDPE for 2 Weeks at 54°C Report No. SMG13923 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	-	Syngenta	N
KCP 2.7/02	██████ █	2019	A21857B - Storage Stability and Shelf Life Statement (2 Years 20°C) in Packaging Made of HDPE Report No. 300140168 Document No. VV-471984 , A21857B_10166 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	Y	Data/study report never submitted before to this country	Syngenta	N
KCP 2.7/02 (appended to study)	██████	2018	A21857B – Content of Active Ingredient(s) of Batch JEA001-118-001 after Storage in Packaging Made of HDPE for 2 Years at 20°C Report No. SMG13930 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	-	Syngenta	N

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) 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
KCP 2.7/02 (appended to study)	██████	2018a	A21857B – Physical and Technical Properties and Packaging Evaluation of Batch JEA001-118-001 after Storage in Packaging Made of HDPE for 2 Years at 20°C Report No. SMG13931 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	-	Syngenta	N