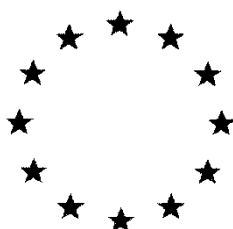


European Commission



**Draft Renewal Assessment Report prepared according to the Commission
Regulation (EU) N° 1107/2009**

24-Epibrassinolide

Volume 3 – B.2 (PPP) – Sunergist

Rapporteur Member State: Austria

Version History

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

Concentrations according to proposed GAP: Min. conc.: 0.05% v/v, Max. conc.: 0.25% v/v

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	Sunergist Batch No.: 002-20150506 (0.01 %)	Colourless liquid	Acceptable	Y	Gao, J. (2016)
B.2.2. EXPLOSIVE AND OXIDIZING PROPERTIES						
Explosive properties B.2.2/01	statement		Neither the active nor any co-formulant has explosive properties The test item Sunergist has no explosive properties	Acceptable	Y	Feyrer, A.; Goerg, J. (2017)
Oxidizing properties B.2.2/02	statement		Neither the active nor any co-formulant has oxidising properties The test item Sunergist is not considered to be an oxidising substance.	Acceptable	Y	Feyrer, A.; Goerg, J. (2017)
B.2.3. FLAMMABILITY AND AUTO-FLAMMABILITY						
Flash point of the liquids formulations B.2.3/01	OCSPP: 830.6315	Sunergist Batch No.: 002-20150506 (0.01 %)	No flash point was obtained until boiling at 92.7 °C.	Acceptable	Y	Gao, J. (2016)
Flammability of solid formulations B.2.3/02			Not relevant for liquid formulations			
Self-heating of formulation B.2.3/03			No test according to EC A.15 was conducted. Considering the results of B2.3/01 and the co-furmulants present in Sunergist (see Volume 4), it can be concluded that no auto-ignition occurs.	Acceptable		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.4. ACIDITY/ALKALINITY AND PH VALUE						
pH of the neat aqueous formulation B.2.4/01	CIPAC MT 75.3	Sunergist Batch No.: 002-20150506 (0.01 %)	pH of the neat formulation is 5.5	Acceptable	Y	Gao, J. (2016)
pH of a 1 % dilution of the solid or non-aqueous formulation B.2.4/02	CIPAC MT 75.3	Sunergist Batch No.: 002-20150506 (0.01 %)	pH of a 1% suspension in water is 6.1	Acceptable	Y	Gao, J. (2016)
Acidity / Alkalinity B.2.4/03			Not relevant as the pH value > 4 and < 10	Acceptable		
B.2.5. VISCOSITY AND SURFACE TENSION						
Viscosity of the liquid formulation B.2.5/01	OECD 114 Rotational viscometer	Sunergist Batch No.: 002-20150506 (0.01 %)	2.24-2.59 mPa·s within the speed range of 100-250 rpm (20 ± 0.2 °C) 2.42-2.63 mPa·s within the speed range of 100-250 rpm (40 ± 0.2 °C)	Acceptable	Y	Gao, J. (2016)
Surface tension of the formulation B.2.5/02	OECD 114	Sunergist Batch No.: 002-20150506 (0.01 %)	39.0 mN/m at a concentration of 0.1%w/v	Acceptable	Y	Gao, J. (2016)
B.2.6. RELATIVE DENSITY AND BULK DENSITY						
Relative density of the liquid formulation B.2.6/01	OECD 109	Sunergist Batch No.: 002-20150506 (0.01 %)	0.993 g/ml at 20 °C 0.987 g/ml at 40 °C	Acceptable	Y	Gao, J. (2016)

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
Bulk density (pour and tap) of powder or granules B.2.6/02			Not relevant for liquid 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	Sunergist Batch No.: 002-20150506 (0.01 %)	Stable throughout the test period of 2 weeks at 54°C in COEX HDPE containers. No changes were observed. There was no evidence of leaks or panelling after storage.			Acceptable	Y	Gao, J. (2016)
			Test	Initial	After 2 weeks at 54 °C			
			Colour	colourless	colourless			
	CP B.5.2.1.		Content 24-Epibrassinolide	0.01%	0.01%			
	CIPAC MT 75.3		pH (1% dilution)	6.1	6.1			
	CIPAC MT 41		Dilution Stability	Transparent, homogeneous and non-layered	Transparent, homogeneous and non-layered			
Effect of low temperature on stability of liquid formulation B.2.7/02	CIPAC MT 39.3	Sunergist Batch No.: 002-20150506 (0.01 %)	No separated material after storage for 0°C for 7 days			Acceptable	Y	Gao, J. (2016)
Shelf life following storage at ambient temperature B.2.7/03	CIPAC MT 46.3	Sunergist Batch No.: 002-20150506 (0.01 %)	Stable throughout the test period of 2 years at ambient temperature in COEX HDPE container. No changes were observed. There was no evidence of leaks or panelling after storage.			Acceptable	Y	Shao D. (2018)
			Test	Initial	2 years ambient			
			Colour	colourless	colourless			
	CP B.5.2.1.		Content 24-Epibrassinolide	0.01%	0.01%			
	CIPAC MT 75.3		pH (1% dilution)	6.1	6.1			
	CIPAC MT 41		Dilution Stability	Transparent, homogeneous and non-layered	Transparent, homogeneous and non-layered			

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			Not required for SL formulations			
B.2.8.2. Persistence foaming						
Persistence of foaming of the diluted formulation B.2.8.2/01	CIPAC MT 47.2	Sunergist Batch 91131606 81% w/w	At 0.1% (v/v) aqueous suspension in standard water C: 1 min → 36 mL	Not acceptable The test was performed at 0.1 % concentration, but the maximum concentration according to the GAP is 0.25%.	Y	Gao, J. (2016)
B.2.8.3. Suspensibility						
Suspensibility of water dispersible formulation B.2.8.3/01			Not required for SL formulations			
Spontaneity of dispersion of water dispersible formulation B.2.8.3/02			Not required for SL formulations			
Dispersion stability of SE, OD or EG formulation B.2.8.3/03			Not required for SL 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 SL 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	CIPAC MT 41	Sunergist Batch No.: 002-20150506 (0.01 %)	Transparent, homogeneous and non-layered appearance after dilution in CIPAC Standard Water C at 20 °C, thus confirming dilution stability.	Acceptable	Y	Gao, J. (2016)
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 for SL formulations			
Size distribution of particles of powder or granules B.2.8.5.1/02			Not required for SL formulations			
Nominal size range of granule B.2.8.5.1/03			Not required for SL formulations			
B.2.8.5.2. Dust content						
Dust content of granular formulation B.2.8.5.2/01			Not required for SL formulations			
B.2.8.5.3. Attrition						
Attrition characteristics of granules and tablets B.2.8.5.3/01			Not required for SL formulations			
B.2.8.5.4. Hardness and integrity						
Hardness of tablets B.2.8.5.4/01			Not required for SL formulations			
Integrity of tablets B.2.8.5.4/02			Not required for SL 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			Not required for SL formulations			
B.2.8.7. Flowability, pourability and dustability						
Flowability of granular formulation B.2.8.7/01			Not required for SL formulations			
Pourability of suspensions B.2.8.7/02			Not required for SL formulations			
Dustability of dustable powders after accelerated storage B.2.8.7/03			Not required for SL 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			Not intended to be used with other products.	Acceptable		
B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS						
Distribution and adhesion to seeds B.2.9.10/01			Not required for SL formulations			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.11. OTHER STUDIES						
			None			

The appearance of the plant protection product Sunergist (24-Epibrassinolide 0.01% Soluble Liquid (SL)) is that of colourless clear liquid. It has neither explosive nor oxidising properties. No flash point could be determined until boiling at 92.7 °C. A 1% aqueous solution shows a pH value of 6.13, while the neat formulation has a pH of 5.5. The density was found to be 0.993 g/ml at 20 °C. Persistent foam was measured to be 36 ml after 1 min at a concentration of 0.1%v/v. Transparent, homogeneous and non-layered appearance after dilution of Sunergist (24-Epibrassinolide 0.01% SL) in water confirms dilution stability of the formulation.

Moreover, the product is stable at 54°C for two weeks (accelerated storage stability test), for 7 days at 0°C and for 2 years at 20°C.

Its technical characteristics are acceptable for a SL formulation.

Data Gap: no foaming stability was determined at the maximum concentration of 0.25% v/v.

B.2.12. REFERENCES RELIED ON

DataPoint	Author(s)	Year	Title Compagny 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 KCP 2.3/01 KCP 2.4/01 KCP 2.4/02 KCP 2.5/01 KCP 2.5/02 KCP 2.6/01 KCP 2.7/01 KCP 2.7/02 KCP 2.8.2/01 KCP 2.8.4/02	Gao, J.	2017	CHEMICAL AND PHYSICAL CHARACTERIZATION OF EPIBRASSINOLIDE 0.01 % SL: COLOR, PHYSICAL STATE, ODOR, pH, DENSITY, SURFACE TENSION, CORROSION, ACCELERATED STORAGE STABILITY, FLASH POINT, VISCOSITY, PERSISTENT FOAM, [...] Report No.: NC-2015-034 (219-001) Nutrichem Laboratory Co., Ltd., Beijing, China GLP, unpublished	N	Y	New study necessary for the approval of 24- Epibrassinoli de	Sunergist Co., Ltd. Suntton Co., Ltd.	N
KCP 2.2/01 KCP 2.2/02	Feyrer, A.; Goerg, J.	2017	STATEMENT RELATED TO THE EXPLOSIVE AND OXIDISING PROPERTIES OF THE PLANT PROTECTION PRODUCT SUNERGIST Report No.: PP309-00002-17/02 (281- 001) Scientific Consulting Company, Bad Kreuznach, Germany Not GLP, unpublished	N	Y	New study necessary for the approval of 24- Epibrassinoli de	Sunergist Co., Ltd. Suntton Co., Ltd.	N
KCP 2.7/03	Shao, D.	2018	AMENDED FINAL REPORT: STORAGE STABILITY STUDY OF EPIBRASSINOLIDE 0.01% SL Report No.: BGS-2015-001 (245-002) Bioguide Technologies Co., Ltd., Beijing, China GLP, unpublished	N	Y	New study necessary for the approval of 24- Epibrassinoli de	Sunergist Co., Ltd. Suntton Co., Ltd.	N