

BIOCEBO/BIO

DOCUMENT M-CP, Section 2

PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

Version history¹

Date	Data points containing amendments or additions and brief description	Document identifier and version number
2005-26-06	Initial Document M version, submitted for application of approval of the active substance.	M-Hydr.Protein-AnnexIII
2018-01-09	<p>Addition of new product characterisation data:</p> <p>Finished report: 12-3638-01: Physico-chemical characterisation of BIOCEBO (hydrolysed proteins 30% w/v). Laboratorios Munuera, S.L.U. (Murcia, Spain). 2013.</p> <p>Finished report: 12-3638-03: Storage stability for two years at room temperature of BIOCEBO (hydrolysed proteins 30% w/v). Laboratorios Munuera, S.L.U. (Murcia, Spain). 2015.</p>	DOCUMENT M-CP, Section 2

¹ It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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CP 2 PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

GLP-certified laboratories have performed all tests using batch Batch 12/0001, containing 30 g/l active substance (*12-3638-01, 12-3638-03*)

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.1 Appearance	Not applicable, visual	Hydrolysed proteins 300 g/l SL formulation	Soluble concentrate (Dark brown liquid)		12-3638-01
CP 2.2 Explosive and oxidising properties	EEC A.14 and EEC A.17	Hydrolysed proteins 300 g/l SL formulation	Not explosive Not applicable		
CP 2.3 Flammability and self-heating	Not applicable	Hydrolysed proteins 300 g/l SL formulation	Not flammable Not a solid or gas		
CP 2.4 Acidity/alkalinity and pH value	CIPAC MT 75.3	Hydrolysed proteins 300 g/l SL formulation	pH = 5.01	Y	12-3638-01
CP 2.5 Viscosity and surface tension	Not applicable CEE A.5	Hydrolysed proteins 300 g/l SL formulation	Not applicable 36.5 nM/m	N Y	12-3638-01
CP 2.6 Relative density and bulk density	CIPAC MT 3.3.2. Not applicable	Hydrolysed proteins 300 g/l SL formulation	1.14 g/ml (20 °C) Not a powder or granule	Y	12-3638-01

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.7 Storage Stability and shelf-life: effects of temperature on technical characteristics of the plant protection product	Storage Stability after 14 days at 54° C CIPAC MT 46.3	Hydrolysed proteins 300 g/l SL formulation	No variation of active ingredient was observed after 14 days at 54°C.	Y	12-3638-01
	Stability after storage for other periods and/or temperatures CIPAC MT 39.1	Hydrolysed proteins 300 g/l SL formulation	After storage at 0°C ±2 for 7 days, the volume of solid and/or liquid which separates was not more than 0.3 mL.	Y	12-3638-01
CP 2.8.1 Wettability	Not applicable	Hydrolysed proteins 300 g/l SL formulation	Not applicable: Biocebo is not a solid formulation		
CP 2.8.2 Persistence of foaming	CIPAC MT 47.1	Hydrolysed proteins 300 g/l SL formulation	The maximum volume of foam was of 11 mL after 12 minutes of the test item at room temperature	Y	12-3638-01
CP 2.8.3 Suspensibility, spontaneity and dispersion stability	Suspensibility: CIPAC MT 15, 161 or 168 Spontaneity and dispersion: CIPAC MT 160 or 174	Hydrolysed proteins 300 g/l SL formulation	Not applicable: Biocebo is not a solid formulation Not applicable: Biocebo is not a solid formulation		
CP 2.8.4 Degree of dissolution and dilution stability	CIPAC MT 41.1	Hydrolysed proteins 300 g/l SL formulation	30 min. Clear solution, not separated material 24 h. Clear solution, not separated material	Y	12-3638-01

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.8.5.1 Particle size distribution	OECD 110	Hydrolysed proteins 300 g/l SL formulation	Not applicable: Biocebo is not a solid formulation		
CP 2.8.5.2 Dust content	CIPAC MT 58.3 or 170	Hydrolysed proteins 300 g/l SL formulation	Not applicable: Biocebo is not a solid formulation		
CP 2.8.5.3 Attrition	OECD 110	Hydrolysed proteins 300 g/l SL formulation	Not applicable: Biocebo is not a solid formulation		
CP 2.8.5.4 Hardness and integrity	Not applicable	Hydrolysed proteins 300 g/l SL formulation	Not applicable: Biocebo is not a solid formulation		
CP 2.8.6 Emulsifiability, re-emulsifiability, emulsion stability	Not applicable	Hydrolysed proteins 300 g/l SL formulation	Not applicable: Biocebo is not a solid formulation		
CP 2.8.7 Flowability, pourability and dustability	CIPAC MT 20 or 173	Hydrolysed proteins 300 g/l SL formulation	Not applicable: Biocebo is not a solid formulation		

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.9 Physical and chemical compatibility with other products including other plant protection products with which its use is to be authorised	Not applicable	Hydrolysed proteins 300 g/l SL formulation	BIOCEBO is compatible with insecticides regularly used for the control of olive and fruit flies, such as dimethoate.		
CP 2.10 Adherence and distribution to seeds	Not applicable	Hydrolysed proteins 300 g/l SL formulation	Not applicable: Biocebo is not intended to be applied as a seed dressing		
CP 2.11 Other studies					12-3638-03. Storage stability for two years at room temperature

12-3638-01: Physico-chemical characterisation of BIOCEBO (hydrolysed proteins 30% w/v). Laboratorios Munuera, S.L.U. (Murcia, Spain). 2013.

12-3638-03: Storage stability for two years at room temperature of BIOCEBO (hydrolysed proteins 30% w/v). Laboratorios Munuera, S.L.U. (Murcia, Spain). 2015.