

NUTREL/SIC

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

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

Table of Contents

CP 2	PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT	4
CP 2.1	Appearance.....	6
CP 2.2	Explosive and oxidising properties	6
CP 2.3	Flammability and self-heating.....	6
CP 2.4	Acidity/alkalinity and pH value.....	6
CP 2.5	Viscosity and surface tension.....	7
CP 2.6	Relative density and bulk density	7
CP 2.7	Storage Stability and shelf-life: effects of temperature on technical characteristics of the plant protection product	8
CP 2.8.1	Wettability	9
CP 2.8.2	Persistence of foaming.....	9
CP 2.8.3	Suspensibility, spontaneity and dispersion stability	9
CP 2.8.4	Degree of dissolution and dilution stability.....	9
CP 2.8.5.1	Particle size distribution	9
CP 2.8.5.2	Dust content	10
CP 2.8.5.3	Attrition	10
CP 2.8.5.4	Hardness and integrity.....	10
CP 2.8.6	Emulsifiability, re-emulsifiability, emulsion stability	10
CP 2.8.7	Flowability, pourability and dustability	10
CP 2.9	Physical and chemical compatibility with other products including other plant protection products with which its use is to be authorised	11
CP 2.10	Adherence and distribution to seeds	11
CP 2.11	Other studies	11

CP 2 PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

The specific weight of hydrolysed proteins ranges from 1.2 to 1.3 kg/dm³ (g/cm³), and the purity applied to the technical is equal to 99%.

It is derived that the active substance coincides with the formulated product.

The RR for the two leader formulates have been developed with material having a specific weight equal to 1.26 kg/dm³. The correspondence between active and technical is shown in the tables here below.

The formulated product with specific weight equal to 1.17 kg/dm³ has not been re-registered.

NUTREL (reg. 11502 re-registered on 15/05/2017)

% a.s.(pure)	Specific weight.	g/L	g/kg
30	1.26	378	300
Technical (w/w)	purity	g/L	
381.8	99%	378	

AMADENE (reg. 03411, re-registered on 13/03/2017)

% a.s. (pura)	p.sp.	g/L	g/kg
36	1.26	454	360
Technical (w/w)	purity	g/L	
458.2	99%	454	

NUTREL 30 (reg. 11728, 31/07/2003)

% a.s.(pure)	Specific weight	g/L	g/kg
36	1.17	421	360
Tecnico (w/w)	pureness	g/L	
425.5	99%	421	

DAR considers a material having a specific weight of 1.23 kg/dm³. The chemical- physical characterization of NUTREL has been developed based on this.

DAR

% a.s. (technical)	purity	% a.s. (pure)	
24.24	99%	24	

% a.s. (pure)	Specific weight.	g/L	g/kg
24	1.23	297	240
Technical (w/w)	purity	g/L	
300.1	99%	297	

DIACHEM SpA, having access to the LoA of SICIT 2000 S.p.A, produced studies on AMADENE on analytical methods for the determination of hydrolyzed proteins in the formulated product (Study 13052-01C conducted by Renolab, 14th January 2014), determination of the physico-chemical properties before and after accelerated storage stability at 54°C for 14 days and low temperature storage of 0 °C for 7 days (Study 13052-02C conducted by Renolab, 15th January 2014) and the determination of the two years storage stability and shelf life data (Study 13052-03C conducted by Renolab, 23rd April 2014)

Considering the purity of the technical (99%) and the specific weight (1.26) of NUTREL and AMADENE, it is considered possible to extrapolate the data from studies conducted on AMADENE. The formulated products is identified to the active substance.

The studies were conducted by Renolab on AMADENE batch n. 1201033901 in compliance with GLP.

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.1 Appearance	Visual assessment.	AMADENE. Batch 1201033901. 36% hydrolysed proteins. Purity: 99%	Brown liquid, average viscosity, undefined smell		Study13052-02C conducted by Renolab
CP 2.2 Explosive and oxidising properties	EEC A.14	AMADENE. Batch 1201033901. 36% hydrolysed proteins. Purity: 99%	The product has no explosive properties		Study13052-02C conducted by Renolab
CP 2.3 Flammability and self-heating			Flammability point > 100°C. The formulated product is not flammable (water based)		
CP 2.4 Acidity/alkalinity and pH value	CIPAC MT75.3	AMADENE. Batch 1201033901. 36% hydrolysed proteins. Purity: 99%	Neat form. pH= 6.83 1% dil. pH= 6.66		Study13052-02C conducted by Renolab

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.5 Viscosity and surface tension	EEC method A.5	AMADENE. Batch 1201033901. 36% hydrolysed proteins. Purity: 99%	Pure: 37.9 mN/m 1g/L: 53.5 mN/m		Study13052-02C conducted by Renolab
CP 2.6 Relative density and bulk density	CIPAC MT 3.1 EEC A3	AMADENE. Batch 1201033901. 36% hydrolysed proteins. Purity: 99%	Relative density: 20°C 1.245 g/mL Relative density: 40°C: 1.235g /mL		Study13052-02C conducted by Renolab

CP 2.7 Storage Stability and shelf-life: effects of temperature on technical characteristics of the plant protection product			<p>The physical-chemical properties investigated before and after accelerated storage and after low temperature storage stability tests are comparable.</p> <p>The physical-chemical properties investigated before and after 1 year of storage stability test are comparable.</p>		<p>Study13052-02C conducted by Renolab</p> <p>Study13052-03C</p>
---	--	--	--	--	--

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.8.1 Wettability			Not applicable		
CP 2.8.2 Persistence of foaming	CIPAC MT 47.2	AMADENE. Batch 1201033901. 36% hydrolysed proteins. Purity: 99%	After 10'': 70 mL After 1': 24 mL After 3': 4 ml After 12': 0 ml		Study13052-02C conducted by Renolab
CP 2.8.3 Suspending ability, spontaneity and dispersion stability			Not applicable		
CP 2.8.4 Degree of dissolution and dilution stability			Not applicable		
CP 2.8.5.1 Particle size distribution			Not applicable as NUTREL is a soluble liquid.		

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.8.5.2 Dust content			Not applicable as NUTREL is a soluble liquid.		
CP 2.8.5.3 Attrition			Not applicable		
CP 2.8.5.4 Hardne ss and integrity			Not applicable		
CP 2.8.6 Emulsifi ability, re- emulsifiability, emulsion stability			Not applicable		
CP 2.8.7 Flowabil ity, pourability and dustability			Not applicable		

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			The product is compatible with the majority of insecticides and plant protection products, with the exclusion of mineral oils and nitro-derivatives		
CP 2.10 Adhere nce and distribution to seeds			Not applicable		
CP 2.11 Other studies			Not available		

Data summary relative to stability after accelerated storage Procedure at 54°C, 14 days (CIPAC MT 46/GIFAP Monograph 17) for the product AMADENE

Source: Study 13052-02C conducted by Renolab

Test	Method	Result pre storage assay	Result post storage assay	Conclusion
Appearance, colour and odour	Visual assessment	Brown liquid, average viscosity, undefined smell.	Unchanged.	No remarks.
Stability of packaging	Visual assessment and weighing of bottles	External packaging, polyethylene bottles 5L capacity were correctly sealed, not damaged or collapsed without any leaks.	The bottle was unchanged, not damaged and without any leaks.	No remarks.
Relative Density	CIPAC MT 3.1 EEC A3	20°C: Density= 1.245 g/mL 40°C: Density=1.235 g/mL	Not required.	
Surface tension	EEC method A.5	Pure: 37.9 mN/m 1 g/L: 53.54 mN/m	Not required.	
Persistent foam at the highest rate of use	CIPAC MT 47.2	After 10'' = 70 mL After 1' = 24 mL After 3' = 4 mL After 12' = 0 mL	Not required.	
Viscosity	CIPAC MT 22/OECD 114	20°C Kinematic: 40.0 mm ² /s	Not required.	

		Dynamic: 49.8 mPa s 40°C Kinematic: 20.2 mm ² /s Dynamic: 25.0 mPa s		
Statement of explosive properties	EEC A.14	The test item has no explosive properties.	Not required.	
pH of 1% and of undiluted product	CIPAC MT 75.3	Undiluted product: pH=6.,78 1 % diluted product: pH=6.57	Undiluted product: pH=6.,83 1 % diluted product: pH=6.66	Values are comparable and in compliance with the requirement of the appropriate clauses.
Acidity or alkalinity	CIPAC MT 191	-	-	Required if pH is < 4 or > 10
Solution stability	CIPAC MT 41	About 0.5mL of cream of top. Colour unchanged.	About 0.5mL of cream of top. Colour unchanged.	No remarks.
Active ingredient content	Internal method MACCF 155-1	36,17 % w/w 450.3 g/L	36,52 % w/w 454.7 g/L	Values determined according the study SP13052-01C, are comparable and in compliance with the requirement of the appropriate clauses. .

Data summary relative to stability after ambient storage for the product AMADENE

Source: Study 13052-03C conducted by Renolab

Test	Method	Result pre storage assay	Result after 1 year storage assay	Result after 2 year storage assay	Conclusion
Appearance, colour and odour	Visual assessment	Brown liquid, average viscosity, undefined smell.	Unchanged.	Unchanged.	No remarks.
Stability of packaging	Visual assessment and weighing of bottles	External packaging, polyethylene bottles 5L capacity were correctly sealed, not damaged or collapsed without any leaks.	The bottle was unchanged, not damaged and without any leaks.	The bottle was unchanged, not damaged and without any leaks.	No remarks.
pH of 1% diluted product	CIPAC MT 75.3	pH=6.57	pH=6.67	pH=6.73	Values are comparable and in compliance with the requirement of the appropriate clauses.
pH of undiluted product		pH=6.78	pH=6.90	pH=6.84	
Solution stability	CIPAC MT 41	About 0.5mL of cream of top. Colour unchanged.	Transparent, no deposits.	Transparent, no deposits.	No remarks.

Acidity or alkalinity	CIPAC MT 191	-	-	-	Required if pH is < 4 or > 10
Active ingredient content	Internal method MACCF 155-1	36,17 % w/w 450.3 g/L	35,87 % w/w 446.5 g/L	36,10 % w/w 449.4 g/L	Values determined according the study SP13052-01C, are comparable and in compliance with the requirement of the appropriate clauses. .

Data summary relative to accelerated stability CIPAC 46.1.3 for the product NUTREL

Source: Study n.19/2004 conducted by Chelab

Test	Method	Result	Result	Result	Conclusion
		No thermal treatment	after storage for 14 days at 4°C	after storage for 14 days at 54°C	

pH of 1% diluted product	Internal method MP-0436-rev.3	4.22	4.21	3.95	Values in accordance with the specifications were pH 1% w/w solution=3,5-4,5.
Protein nitrogen content	ISTISAN96/34#13	4.79 g/100g	4.79 g/100g	4.81 g/100g	Values in accordance with the specifications were Organic Nitrogen content(x6,25) = 24-33 % w/w.
Ammonium nitrogen content	ISTISAN96/34#15	0.23 g/100g	0.23 g/100g	0.23 g/100g	Values in accordance with the specifications were Ammonia Nitrogen = 0,15-0,6 % w/w.
Relative Density	CIPAC MT 3.2	1.234 g/mL	1.234 g/mL	1.234 g/mL	Values in accordance with the specifications were relative density = 1.2-1.3 g/mL.
Viscosity	OECD 114	20°C Kinematic: 22.0 mm ² /s Dynamic: 24.9 mPa s 25°C Kinematic: 17.6 mm ² /s Dynamic: 20.2 mPa s	20°C Kinematic: 22.0 mm ² /s Dynamic: 24.9 mPa s 25°C Kinematic: 17.6 mm ² /s Dynamic: 20.1 mPa s	20°C Kinematic: 23.4 mm ² /s Dynamic: 27.8 mPa s 25°C Kinematic: 18.7 mm ² /s Dynamic: 23.2 mPa s	Values in accordance with the specifications were Kinematic viscosity at 20-25 °C =17-50 mm ² /s dynamic viscosity at 20-25 °C =17-50 mPa*s
Dilution stability	CIPAC 41	No precipitation. No turbidity.	No precipitation. No turbidity.	No precipitation. No turbidity.	Values in accordance with the specifications were dilution stability(clarity) =

					limpid(absence of precipitations or turbidity).
--	--	--	--	--	---