SVMA14-004

DOCUMENT M-CP, Section 2

PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

Version history[1]

Date	Data points containing amendments or additions and brief description	Document identifier and version number
21/02/2020	Additional data on stability in HDPE packaging in CP 2.7.3 highlighted in yellow	SVMA14-004 document M-CP 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

It should be noted that grey script reflects studies already submitted and evaluated by Greece in 2017 in the context of the zonal registration of the product SVMA14-004. These studies were considered acceptable.
Black script reflects new studies not yet provided nor evaluated in Europe

GLP-certified laboratories have performed all tests using batches n° 141209LAB or n° 150708L or n° 201702001511, all containing 30 % w/v of pure hydrolysed proteins.

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.1 Appearance	Visual observations	Batch n° 141209LAB, contains 30 % w/v of pure hydrolysed proteins	It is a homogeneous brown opaque liquid.	Y	Demangel B., 2015 Defitraces, Report No. 15-919069-002

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.2 Explosive and oxidising properties	Exothermic reactions by DSC and statement	Batch n° 141209LAB, contains 30 % w/v of pure hydrolysed proteins	According to their composition and structural formula, proteins from animal proteins hydrolysate (30.0% w/v) are not expected to be explosive. Moreover, the product SVMA14-004 is an aqueous solution (Please refer to Document J for the composition). Water is an inert component. In addition the Differential Scanning Calorimetry (DSC) graphs show no exothermic effect; this confirms that the product SVMA14-004 is not expected to present a significant hazard for explosivity, and testing is considered as unnecessary. Explosive properties test should not be required. SVMA14-004 shall not be classified as explosive.	Y	Demangel B., 2015 Defitraces, Report No. 15-919069-001
	Statement		According to their composition and structural formula, proteins from animal proteins hydrolysate (30.0% w/v) are not expected to have oxidising properties. Moreover, the product SVMA14-004 is an aqueous solution (Please refer to Document J for the composition). Water is an inert component. Accordingly, the product SVMA14-004 is not expected to present a significant hazard for oxidising properties, and testing is considered as unnecessary. Oxidising properties test should not be required.	Y	Demangel B., 2015 Defitraces, Report No. 15-919069-001

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.3 Flammability and self-heating	EC A15 method	Batch n° 141209LAB, contains 30 % w/v of pure hydrolysed proteins	Only a preliminary test was performed: No auto-ignition temperature was observed up to 599 °C (corrected value).	Y	Demangel B., 2015 Defitraces, Report No. 15-919069-001
CP 2.4 Acidity/alkalinity and pH value	CIPAC MT 75.3	Batch n° 141209LAB, contains 30 % w/v of pure hydrolysed proteins	The mean pH value of the pure test item was: 4.89 at 21.1 °C after 1 min. 4.87 at 21.1 °C after 2 min.	Y	Demangel B., 2015 Defitraces, Report No. 15-919069-002

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	OECD No. 114 and SIO Standard 3219	Batch n° 141209LAB, contains 30 % w/v of pure hydrolysed proteins	Taking into account the results obtained at 20.0 °C and 40.0 °C, SVMA14-004 was considered to have newtonian properties in the experimental conditions used. The mean dynamic viscosity of SVMA14-004 was 9.35 mPa.s at 20.0 °C ± 0.2 °C 5.28 mPa.s at 40.0 °C ± 0.2 °C The mean kinematic viscosity of the test item was 8.05 x 10-6 m2.s-1 at 20.0 °C ± 0.2 °C and 4.55 x 10-6 m2.s-1 at 40.0 °C ± 0.2 °C.	Y	Demangel B., 2015 Defitraces, Report No. 15-919069-001
	EC A5 method and OECD No. 115	Batch n° 141209LAB, contains 30 % w/v of pure hydrolysed proteins	The formulation has a low kinematic viscosity but it should be noted that formulation does not contain any substances classified in Category 1 for aspiration toxicity. The mean surface tension of SVMA14-004 at 19.9 °C was 39.9 mN/m ± 0.4 mN/m. SVMA14-004 was considered as surface-active in the experimental conditions used.		Demangel B., 2015 Defitraces, Report No. 15-919069-001
CP 2.6 Relative density and bulk density	EC A3 method and OECD No. 109	Batch n° 141209LAB, contains 30 % w/v of pure hydrolysed proteins	The mean relative density of SVMA14-004 was D = 1.161 ± 0.001 at 20.6 °C.	Y	Demangel B., 2015 Defitraces, Report No. 15-919069-001

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					

<table>
<tr>
<td>CP 2.7.1Storage Stability after 14 days at 54º C</td>
<td>CIPAC MT 46.3</td>
<td>Batch n° 201702001511 contains 30 % w/v of hydrolysed proteins</td>
<td>
<table>
<tr><th>Test</th><th>Initial</th><th>After 14 days at 54 ºC</th></tr>
<tr><td>Appearance</td><td>Homogeneous brown opaque liquid</td><td>Homogeneous brown opaque liquid</td></tr>
<tr><td>Packaging</td><td>White opaque HDPE flask</td><td>White opaque HDPE flask. No sign of degradation or leak was observed.</td></tr>
<tr><td>Weight</td><td>1298.9 g</td><td>1298.1 g (-0.1 %)</td></tr>
<tr><td>Content of hydrolysed proteins</td><td>31.1 % w/v</td><td>31.2% w/v
Deviation from T0: +0.3%</td></tr>
<tr><td>Dilution stability</td><td>A homogeneous brown limpid liquid with particles in suspension was noted on SVMA14-004 solution at 1.5% v/v in standard water D after standing for 24 h at 30 °C ± 2 °C. After performing the wet sieving following a procedure adapted to CIPAC MT 185 method, the test item solution was considered to be stable.</td><td>A brown limpid liquid with a brown deposit was noted on the test item solution at 1.5% v/v in standard water D after standing for 24 h at 30 °C ± 2 °C. After performing the wet sieving following a procedure adapted from CIPAC MT 185 method, the test item solution was considered to be stable.</td></tr>
<tr><td>Persistante foaming</td><td>The mean volume of foam produced after several inversions of SVMA14-004 diluted at 1.5% v/v in standard water D at 20 °C ± 2 °C was more than 70 mL after 1 min of standing.</td><td>The mean volume of foam produced after several inversions of SVMA14-004 diluted at 1.5% v/v in standard water D at 20 °C ± 2 °C was more than 70 mL after 1 min of standing.</td></tr>
<tr><td>pH values</td><td>The mean pH value of the pure test item was:
4.80 at 20.3 °C after 1 min.
4.80 at 20.5 °C after 2 min.</td><td>The mean pH value of the pure test item was:
4.67 at 19.6 °C after 1 min.
4.67 at 19.5 °C after 2 min.</td></tr>
</table>
The aspect of the test item was considered to be stable after an accelerated storage procedure at 54 °C ± 2 °C for 14 days, no significant change of weight was observed.
The packaging material was considered to be stable after an accelerated storage procedure at 54 °C ± 2 °C for 14 days.
No significant change was observed in the content of the active substance after the accelerated storage procedure at 54 °C ± 2 °C for 14 days. The content of hydrolysed proteins of 312 g/L determined
</td>
<td>Y</td>
<td>Demangel B., 2017 Defitraces, Report No. 16-919069-004</td>
</tr>
</table>

<table>
<tr><th>Test or study & Data point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Findings</th><th>GLP Y/N</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>after storage is in agreement with the FAO limits.
The test item was considered to be stable.</td><td></td><td></td></tr>
<tr><td>CP 2.7.2 Effect of low temperatures on stability</td><td>CIPAC MT 39.3, CIPAC MT 185
Deviations:
For CIPAC MT 39.3, the temperature of the undisturb period was out of the range 23 °C ± 2 °C during 3 hours and 19 minutes with a minimal temperature at 19.0 °C and a maximal temperature at 22.1 °C with a mean temperature at 21.4 °C.
For CIPAC MT 185 test, the flow rate was not constant as the sieve was quickly saturated.
These deviations were not considered to have affected the quality or the interpretation of the results obtained</td><td>Batch n° 150708L, contains 30 % w/v of hydrolysed proteins</td><td>The aspect of the test item was not considered to be stable after a low temperature stability for 7 days at 0 ± 2 °C, deposit was observed after the undisturbed period and inverting the cones for the second test.
<table>
<tr><th>Observations</th><th>Cone 1</th><th>Cone 2</th></tr>
<tr><td>At the start of the test</td><td colspan="2">Homogeneous brown opaque liquid</td></tr>
<tr><td>After 7 days at 0 ± 2 °C</td><td colspan="2">Brown opaque liquid with brown/beige deposit in suspension</td></tr>
<tr><td>After the undisturbed period and inverting the cones</td><td colspan="2">Brown opaque liquid with brown/beige deposit in suspension</td></tr>
</table>
The test item should be shaken before use after being stored 7 days at 0 ± 2 °C following CIPAC MT 39.3 method.
The mean percentage retention of the test item issued from the CIPAC MT 39.3 test held on a 75-µm sieve was 0.1% of the total sieved test item.</td><td>Y</td><td>Demangel B., 2015 Defitraces, Report No. 15-919069-001</td></tr>
</table>

<table>
<tr>
<td>CP 2.7.3 Ambient temperature shelf life</td>
<td>Technical Monograph No. 17</td>
<td>Batch n° 141209LAB, contains 30 % w/v of hydrolysed proteins</td>
<td>
<table>
<tr><th>Test</th><th>Initial</th><th>After 24 months at 20°C</th></tr>
<tr><td>Appearance</td><td>Homogeneous brown opaque liquid</td><td>Homogeneous brown opaque liquid</td></tr>
<tr><td>Packaging</td><td>White opaque PET flask</td><td>White opaque PET flask</td></tr>
<tr><td>Weight</td><td>1247.0 g</td><td>1239.2 g (-0.6 %)</td></tr>
<tr><td>Content of hydrolysed proteins</td><td>31.3 % w/v</td><td>30.9% w/v
Deviation from T0: -1.3%</td></tr>
<tr><td>Dilution stability</td><td>A homogeneous brown limpid liquid with particles in suspension was noted on SVMA14-004 solution at 1.5% v/v in standard water D after standing for 24 h at 30 °C ± 2 °C. After performing the wet sieving following a procedure adapted to CIPAC MT 185 method, the test item solution was considered to be stable.</td><td>An orange limpid liquid with deposit and brown particles in suspension was noted on the test item solution at 1.5% v/v in standard water D after standing for 24 h at 30 °C ± 2 °C. After performing the wet sieving following a procedure adapted to CIPAC MT 185 method, the test item solution was considered to be stable.</td></tr>
<tr><td>Persistante foaming</td><td>The mean volume of foam produced after several inversions of SVMA14-004 diluted at 1.5% v/v in standard water D at 20 °C ± 2 °C was more than 70 mL after 1 min of standing.</td><td>The mean volume of foam produced after several inversions of SVMA14-004 diluted at 1.5% v/v in standard water D at 20 °C ± 2 °C was more than 70 mL after 1 min of standing.</td></tr>
<tr><td>pH values</td><td>The mean pH value of the pure test item was:
4.89 at 21.1 °C after 1 min.
4.87 at 21.1 °C after 2 min.</td><td>The mean pH value of the pure test item was:
4.82 at 21.0 °C after 1 min.
4.82 at 21.0 °C after 2 min.</td></tr>
</table>
The aspect of the test item was considered to be stable after 24 months of storage procedure at 20 °C ± 2 °C.
The packaging material was considered to be stable after 24 months of storage procedure at 20 °C ± 2 °C, no significant change of weight was observed.
No significant change was observed in the content of hydrolysed proteins after 24 months of storage procedure at 20 °C ± 2 °C. The content of hydrolysed proteins of 312 g/L determined after storage is in agreement with the FAO limits.
</td>
<td>Y</td>
<td>Demangel B., 2017 Defitraces, Report No. 15-919069-003</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td>Batch n° 201702001511, contains 30 % w/v of hydrolysed proteins</td>
<td>
The test item was considered to be stable.
<table>
<tr><th>Test</th><th>Initial</th><th>After 24 months at 20°C</th></tr>
<tr><td>Appearance</td><td>Homogeneous brown opaque liquid</td><td>Homogeneous brown opaque liquid</td></tr>
<tr><td>Packaging</td><td>White opaque HDPE flask</td><td>White opaque HDPE flask</td></tr>
<tr><td>Weight</td><td>1267.7 g</td><td>1264.8 g (-0.2 %)</td></tr>
<tr><td>Content of hydrolysed proteins</td><td>31.1 % w/v</td><td>30.0 % w/v
Deviation from T0: -3.5%</td></tr>
<tr><td>Dilution stability</td><td>A homogeneous amber limpid liquid with particles in suspension was noted on the test item solution at 1.5% v/v in standard water D after standing for 24 hours at 30 °C ± 2 °C. After performing the wet sieving following a procedure adapted from CIPAC MT 185 method, the test item solution was considered to be stable.</td><td>A homogeneous amber limpid liquid with particles in suspension was noted on the test item solution at 1.5% v/v in standard water D after standing for 24 hours at 30 °C ± 2 °C. After performing the wet sieving following a procedure adapted from CIPAC MT 185 method, the test item solution was considered to be stable.</td></tr>
<tr><td>Persistante foaming</td><td>The mean volume of foam produced after several inversions of</td><td>The mean volume of foam produced after several inversions of SVMA14-004</td></tr>
</table>
</td>
<td>Y</td>
<td>Demangel B., 2019

Defitraces, Report No. 16-919069-005</td>
</tr>
</table>

<table>
<tr><th>Test or study & Data point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Findings</th><th>GLP Y/N</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>SVMA14-004 diluted at 1.5% v/v in standard water D at 20 °C ± 2 °C was more than 70 mL after 1 min of standing.</td><td>diluted at 1.5% v/v in standard water D at 20 °C ± 2 °C was more than 70 mL after 1 min of standing.</td></tr>
<tr><td>pH values</td><td>The mean pH value of the pure test item was:
4.80 at 20.3 °C after 1 min.
4.80 at 20.5 °C after 2 min.</td><td>The mean pH value of the pure test item was:
4.70 at 20.5 °C after 1 min.
4.70 at 20.7 °C after 2 min.</td></tr>
</table>

The aspect of the test item was considered to be stable after 24 months of storage procedure at 20 °C ± 2 °C.
The packaging material was considered to be stable after 24 months of storage procedure at 20 °C ± 2 °C, no significant change of weight, degradation or leak was observed.
No significant change was observed in the content of hydrolysed proteins after 24 months of storage procedure at 20 °C ± 2 °C. The nominal concentration of hydrolysed proteins of 30% w/v determined after storage is in agreement with the FAO limits.
The test item was considered to be stable.</td><td></td><td></td></tr>
<tr><td colspan="6"></td></tr>
<tr><td>CP 2.8.1 Wettability</td><td>-</td><td>-</td><td>Not relevant for a SL formulation</td><td>-</td><td>-</td></tr>
</table>

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.8.2 Persistence of foaming	CIPAC MT 47.2	Batch n° 141209LAB, contains 30 % w/v of pure hydrolysed proteins	The mean volume of foam produced after several inversions of SVMA14-004 diluted at 1.5% v/v in standard water D at 20 °C ± 2 °C was more than 70 mL after 1 min of standing. Therefore, an additional test of mixtures preparation in practical conditions has been conducted. Please refer to point KCP 2.11.	Y	Demangel B., 2015 Defitraces, Report No. 15-919069-002
CP 2.8.3 Suspensibility, spontaneity and dispersion stability	-	-	Not relevant for a SL formulation	-	-
CP 2.8.4 Degree of dissolution and dilution stability	CIPAC MT 41.1	Batch n° 141209LAB, contains 30 % w/v of pure hydrolysed proteins	A homogeneous brown limpid liquid with particles in suspension was noted on SVMA14-004 solution at 1.5% v/v in standard water D after standing for 24 h at 30 °C ± 2 °C. After performing the wet sieving following a procedure adapted to CIPAC MT 185 method (75 µm sieve), the test item solution was considered to be stable.	Y	Demangel B., 2015 Defitraces, Report No. 15-919069-002
CP 2.8.5.1 Particle size distribution	-	-	Not relevant for a SL formulation	-	-
CP 2.8.5.2 Dust content	-	-	Not relevant for a SL formulation	-	-
CP 2.8.5.3 Attrition	-	-	Not relevant for a SL formulation	-	-

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.8.5.4 Hardness and integrity	-	-	Not relevant for a SL formulation	-	-
CP 2.8.6 Emulsifiability, re-emulsifiability, emulsion stability	-	-	Not relevant for a SL formulation	-	-
CP 2.8.7 Flowability, pourability and dustability	-	-	Not relevant for a SL 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	AFPP - Experimental general principles of adjuvants - General method No. MG08 - Revised March 2006	Batch n° 141209LAB, contains 30 % w/v of pure hydrolysed proteins	According to the assays performed (observation of the solution, pH value and residue on 150-µm test sieve), the following conclusions were drawn: - The mixture of SVMA14-004 at 1.5% v/v + REDLAN-E at 0.4% v/v was compatible. - The mixture of SVMA14-004 at 1.5% v/v + NUPRID at 0.075% v/v was compatible, but to be used immediately after stirring. - The mixture of SVMA14-004 at 1.5% v/v + KARATE ZEON+ at 0.13% v/v was compatible.	Y	Demangel B., 2015 Defitraces, Report No. 15-919069-005
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	ASTM E 1518-05 Method (dynamic shaker method)	Batch n° 150708L, contains 30 % w/v of pure hydrolysed proteins	The compatibility of the formulated product SVMA-14-004 was evaluated in terms of dispersion stability and wet sieve residue. The following conclusions were drawn: - The mixture of SVMA14-004 at 0.75% v/v + IMIDAN 50 WP at 0.05% w/v was compatible, but to be used immediately after stirring. - The mixture of SVMA14-004 at 0.15% v/v + DECIS 2.5 EC at 0.05% v/v was compatible. Note regarding the applied doses by applicant: “In the specific case of IMIDAN 50 WP and DECIS 2.5 EC, the maximum recommended concentration of use for the test item is 0.75% and 0.15% respectively, as it was done in this study. Therefore, the tests have been done at the maximum recommended concentration of use of SVMA-14-004 for these specific tank mixes.”	Y	M. Mori Vincenzo, BioSpheres, Report No. CPU-005-16

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.10 Adherence and distribution to seeds	-	-	Not relevant for a SL formulation	-	-
CP 2.11 Other studies	Practical conditions	SVMA14-004	The product mixed with no problem with water at a rate of 1.5L/ha in a volume of 100L of water/ha. The test was performed three times by filling half the tank, by filling 2/3 tank and in full tank. A very few foam lay could be seen but just after agitation, and diseapeared very quickly (15 minutes maximum). The height of formed foam was about 1 to 2 cm.This foam was not a problem to prepare the mixture in good conditions. During application, foliage was perfectly wet, covered by spray of SVMA14-004. Wetting was important, hydro paper was convered with high quality (class 3). It was concluded that there is no restriction to use SVMA14-004 in practical conditions.	Y	Perrin Estelle, 2015 SGS AGRI MIN, Report n° 15-00671-01