

ENTOMELA 50SL/ENT50

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
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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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of dark brown liquid, with a characteristic odour. It is not anticipated to have explosive or oxidising properties. The pH of the neat formulation is increased over time. The stability data indicate a shelf life of at least 2 years at ambient temperature. Its technical characteristics are acceptable for a soluble concentrate formulation.

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.1 Appearance	Macroscopic examination	ENTOMELA 50SL Batch No 5013011 Batch No 5013012 Batch No 5013013 Batch No 5013014 Batch No 5013015	<i>Dark Brown Liquid with characteristic odour</i>	N	HELLASCHEM 5 BATCHES ANALYSIS OF ENTOMELA 50SL Iliopulos N. 2013 Certificate of analysis, 1320.130731/309 Iliopulos N. 2013 Certificate of analysis, 1321.130731/309 Iliopulos N. 2013 Certificate of analysis, 1322.130731/309 Iliopulos N. 2013 Certificate of analysis, 1323.130731/309 Iliopulos N. 2013 Certificate of analysis, 1324.130731/309

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	Scientifically justified statement. –	ENTOMELA 50SL Batch No 5014016	All known information on ingredients (urea, beet molasses and water) proving that the preparation ENTOMELA 50SL cannot be explosive. The formulation is not anticipated to have explosive or oxidizing properties.	N	JUSTIFIED STATEMENT FOR SAFETY PROPERTIES OF BEET MOLASSES UREA HYDROLYSATES Iliopulos N. 2014 Certificate of analysis, 2342(1).140903/309
CP 2.3 Flammability and self-heating	Scientifically justified statement. – Preliminary tests A preliminary test was performed in correspondence with the Pendky-Martens closed tester method. The temperature of the sample was gradually increased up to boiling point.	ENTOMELA 50SL Batch No 5014016	All known information on flammability of the ingredients (urea, beet molasses and water) and preliminary test proving that the preparation ENTOMELA 50SL can not be flammable and flash point cannot be determined. No indication of ignition was observed.	N	JUSTIFIED STATEMENT FOR SAFETY PROPERTIES OF BEET MOLASSES UREA HYDROLYSATES Iliopulos N. 2014 Certificate of analysis, 2342(1).140903/309

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.4 Acidity/alkalinity and pH value N.G.Stavrakis – 26/02/2018	CIPAC MT 75.3	ENTOMELA 50SL Batch No 5013011 Batch No 5013012 Batch No 5013013 Batch No 5013014 Batch No 5013015 Batch No 5013016 Batch No 5014016 ENTOMELA 75SL (similar product) Batch number 073610 Batch number 063610 Batch number 023610 Batch number 033610	- Test conditions: Neat formulation 25° C. - Normal pH value is 6.75 - 5 batch - analysis results gives pH range 6.48-6.70. pH range: 6.20-8.00(7.3) (undiluted 25° C). pH maximum value 7.3 may appear after 1 year of storage. The maximum pH value 8.0 may appear after two years of storage with no other effect on specifications and no significant effect on application as when diluted in application rates gives lower pH. The pH of the formulation in its initial, unopened packaging is increased over time The maximum pH value for the “fresh” formulation (within one month) is 7,10. The range in this case is 6.20-7.10. pH is max 7.3 after 1 year from its production date, and pH max 8.0 after 2 years from its production date. The pH (initial) of the two accelerated studies of 2013 and 2014 were pH=6.72 and pH=6.68. After 20& 23 months pH: 7.75-7.78 After 26 months pH: 7.94	N	HELLASCHEM 5 BATCHES ANALYSIS OF ENTOMELA 50SL Iliopulos N. 2013 Certificate of analysis, 1320.130731/309 Iliopulos N. 2013 Certificate of analysis, 1321.130731/309 Iliopulos N. 2013 Certificate of analysis, 1322.130731/309 Iliopulos N. 2013 Certificate of analysis, 1323.130731/309 Iliopulos N. 2013 Certificate of analysis, 1324.130731/309 Iliopulos N. 2013 Certificate of analysis, 1367.130905/309 Iliopulos N. 2014 Certificate of analysis, 2342(1) 140903/309 TEST REPORTS AFTER 20 AND 23 MONTHS. G. Bekiaropoulos –Agrolab 2012 – Test report 2810 G. Bekiaropoulos –Agrolab 2012 – Test report 2811 G. Bekiaropoulos – Agrolab 2012 – Test report 2812 G. Bekiaropoulos – Agrolab 2012 – Test report 2813 M-CP Section 2 - ENT50

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
	CIPAC MT 191	ENTOMELA 75SL (similar product) Batch no 014012	After 26 months pH:7.94	N	NEW (2014) SHELF LIFE STUDY Iliopulos N. 2014 Certificate of analysis, 2353.140906/309
		ENTOMELA 50SL Batch No 5014016	We tested the used dilution on application rates of the product (2%, 6% w/w and 10% w/w in water). In all cases the dilution gives a pH value (pH 6.67, 6.57 and 6.48 respectively) lower than the value of the product itself (without dilution, pH 6.68). It was used deionized water (pH 5.8-6.2).		NEW (2014) PHYSICOCHEMICAL DATA ABOUT ENTOMELA 50SL Iliopulos N. 2014 Certificate of analysis, 2342(1).140903/309
		ENTOMELA 50SL Batch No 5014016	After 6 weeks at 45° pH of the product was 7.38 and pH of dilution 2%, 6%, 10% was 7.12, 7.10, 7.08 respectively.		NEW (2014) STORAGE STABILITY Iliopulos N. 2014 Certificate of analysis, 2342-1.140903/309
		ENTOMELA 75SL(similar product) Batch no 014012	Even in case of aged products of 26 months pH was 7.94 and pH of dilution 2%, 6%, 10% was 7.65, 7.61, 7.56 respectively. These values are near normal pH value and cannot have any negative effect on bait.		NEW (2014) SHELF LIFE STUDY Iliopulos N. 2014 Certificate of analysis, 2353.140906/309

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	Kinematic Viscosity OECD Test guideline 114 Surface tension A5. EC reg. 440/2008	ENTOMELA 50SL Batch No 5014016	1148 cSt (=mm ² /sec), Cannon-Fenske 500 Viscometer, 40°C 70.6 (mN/m), 20o C, 1g/L Deionized water was used.	N	NEW (2014) PHYSICOCHEMICAL DATA ABOUT ENTOMELA 50SL Iliopulos N. 2014 Certificate of analysis, 2342(1).140903/309

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.6 Relative density and bulk density	Relative density CIPAC 3.3.2	ENTOMELA 50SL Batch No 5013011 Batch No 5013012 Batch No 5013013 Batch No 5013014 Batch No 5013015 Batch No 5013016 Batch No 5014016	Normal density value: 1.35 gr/ml at 20° C 5 batch analysis results: min 1.357-max 1.369 gr/ml at 20° C Density specifications: 1.31-1.39 gr/ml at 20° C The initial density of the two accelerated studies were 1.356gr/ml and 1.346gr/ml at 20°C	N	HELLASCHEM 5 BATCHES ANALYSIS OF ENTOMELA 50SL Iliopulos N. 2013 Certificate of analysis, 1320.130731/309 Iliopulos N. 2013 Certificate of analysis, 1321.130731/309 Iliopulos N. 2013 Certificate of analysis, 1322.130731/309 Iliopulos N. 2013 Certificate of analysis, 1323.130731/309 Iliopulos N. 2013 Certificate of analysis, 1324.130731/309 Iliopulos N. 2013 Certificate of analysis, 1367.130905/309 Iliopulos N. 2014 Certificate of analysis, 2342(1) 140903/309
	Bulk density		Not applicable		

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 6 weeks at 45° C CIPAC MT 46.3	ENTOMELA 50SL Batch No 5013016	<p>According to CIPAC MT46.3 the equivalent accelerated test of 45° C for 6 weeks preferred as it is more near to normal temperatures and the product is used as odour emitter.</p> <p>The product is not heat sensitive, only pH may rise if we use temperatures over 50° C. But these temperatures are not inside the normal conditions of storage. The test preformed in original HDPE packing .</p> <p>At elevated temperature stability test (MT 46.3) the analysis data before and after incubation for 45 days at 45° C shows insignificant value difference between the two cases, the values after incubation are inside the limits and this prove the stability of the product during this test. At the end of this table there are the analytical results.</p>	N	<p>STORAGE STABILITY REPORT 2013</p> <p>Iliopulos N. 2013 Certificate of analysis, 1367.130905/309</p> <p>Iliopulos N. 2013 Certificate of analysis, 1367.130905/309* (filename 1367-1 entomela 50_en)</p>

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
	CIPAC MT 46.3, CIPAC MT41.1, CIPAC MT47.1 CIPAC MT191 ASTM E 1518-05	ENTOMELA 50SL Batch No 5014016	<p>The same test was performed again in 2014 and all above mentioned parameters tested found inside limits in case of metallic specimen inside glass bottle.</p> <p>Only pH in case of 45o C for 6 weeks was 7.38. This cannot have any significant effect on application as when diluted in application rates 2%-10% gives lower pH near to normal pH value.</p> <p>The test was performed also to examine the packing material durability:</p> <ol style="list-style-type: none"> 1) in commercial packing of 1 lt plastic bottle HDPE. 2) In a glass bottle with a small metallic surface inside - similar with the material made the 200lt steel drums used for packing. <p>In both cases no deterioration to packing material observed after the heat stability test.</p> <p>Except the previous quality parameters mentioned above we have tested pH of dilutions, persistent foaming, Dilution stability, and Physical compatibility:</p> <ol style="list-style-type: none"> a) The foam was always less than 1ml. b) No material separate for 24h at 30oC. c) The product is compatible with the four insecticides tested. <p>At the end of this table there are the analytical results.</p>	N	<p>NEW (2014) STORAGE STABILITY REPORT</p> <p>Iliopulos N. 2014 Certificate of analysis, 2342(1) 140903/309</p> <p>Iliopulos N. 2014 Certificate of analysis, 2342-1. 140903/309</p>
		ENTOMELA 75SL (Similar product) Batch No 7514007	<p>The same test was performed also to examine durability of the packing material for ENTOMELA 75SL:</p> <ol style="list-style-type: none"> 1) in commercial packing of 1 lt plastic bottle HDPE. 2) In a glass bottle with a small metallic surface inside - similar with the material made the 200lt steel drums used for packing. <p>All parameters tested found inside limits in case of HDPE packing</p> <p>In both cases no deterioration of packing material observed after the heat stability test</p> <p>At the end of this table there are the analytical results.</p>		<p>Iliopulos N. 2014 Certificate of analysis, 2343(2).140903/309</p> <p>Iliopulos N. 2014 Certificate of analysis, 2343-3.140903/309</p>

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
	Minimum content after heat stability testing CIPAC MT 46.3	ENTOMELA 50SL	<p>At elevated temperature stability test (MT 46.3) the analysis data before and after incubation for 45 days at 45° C shows insignificant value difference between the two cases (see 2.7.2)</p> <p>The relative degradation of each of the a.s. is less than 5%.</p>	N	<p>STORAGE STABILITY REPORT 2013</p> <p>NEW (2014) STORAGE STABILITY REPORT</p>
	Effect of low temperatures on stability CIPAC 39.3	ENTOMELA 50SL Batch No 5013016	<p>At low temperature stability test (MT 39.3) no separation or sedimentation was recorded. The analysis data before and after storage for 7 days at 0o C shows insignificant value difference between the two cases, the values after storage are inside the limits and this prove the stability of the product during this test.</p>	N	<p>STORAGE STABILITY REPORT 2013</p> <p>Iliopulos N. 2013 Certificate of analysis, 1367.130905/309</p> <p>Iliopulos N. 2013 Certificate of analysis, 1367.130905/309*(filename 1367-2 entomela 50_en)</p> <p>NEW (2014) STORAGE STABILITY REPORT</p> <p>Iliopulos N. 2014 Certificate of analysis, 2342(1) 140903/309</p> <p>Iliopulos N. 2014 Certificate of analysis, 2342-2. 140903/309</p>
		Batch No 5014016	At the end of this table there are the analytical results for the two storage studies.		

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
N.G.Stavrakis – 26/02/2018	Ambient temperature shelf life	ENTOMELA 75SL (similar product) Batch number 073610 Batch number 063610 Batch number 023610 Batch number 033610	The product stored for 20 & 23 months in ambient temperature inside his original HDPE packing. No initial results (before storage) are available but the product was inside limits of specifications when stored. Determination of total nitrogen and physicochemical properties of the product show that the product is stable after this period of time with only some rising of pH The pH is in the range 7.75-7.78 but this rising near pH normal value is not affecting the attractiveness of the product in use.All other results are inside limits of technical specifications of the product. At the end of this table there are the analytical results.	N	TEST REPORTS AFTER 20 AND 23 MONTHS. G. Bekiaropoulos –Agrolab 2012 – Test report 2810 G. Bekiaropoulos –Agrolab 2012 – Test report 2811 G. Bekiaropoulos –Agrolab 2012 – Test report 2812 G. Bekiaropoulos –Agrolab 2012 – Test report 2813
	CIPAC MT41.1, CIPAC MT47.1 CIPAC MT191 ASTM E 1518-05	ENTOMELA 75SL (similar product) Batch number 014012	The product stored for 26 months in ambient temperature inside his original HDPE packing. No initial results (before storage) are available but the product was inside limits of specifications when stored. All tested parameters Urea, Total Nitrogen, Ammoniacal Nitrogen, Aminoacids index e.t.c. are inside technical specifications limits. Only pH value is raised to 7.94. Tests for dilution stability show that no material has separated after standing for 24h at 30° C. Tests for persistent foaming show again that the foam was less than 1ml all the times tested. Tests on pH on solutions of 2%, 6% and 10% shows that the product after dilution with water gives a lower pH of 7.56-7.65 Tests for physical compatibility show that the product is compatible with all the insecticides tested. At the end of this table there are the analytical results. The stability data indicate a shelf life of at least 2 years when stored in its original unopened container at normal ambient temperature 1- 40°		NEW (2014) SHELF LIFE STUDY Iliopulos N. 2014 Certificate of analysis, 2353.140906/309
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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	<p>ENTOMELA 50SL</p> <p>Batch No 5014016</p> <p>ENTOMELA 75SL (similar product)</p> <p>Batch number 014012</p>	<p>5.0g sample was weighed and added to CIPAC standard water C (5% w/v), at 25°C</p> <p>The foam after 1 min was less than 1ml.</p> <p>After incubation for 6 weeks in 45°C and for 7 days at 0°C (storage stability tests) 5.0g sample was weighed and added to CIPAC standard water C (5% w/v), at 25°C</p> <p>The foam after 1 min was less than 1ml.</p> <p>After storage for 26 months (shelf life test) according to CIPAC MT47.2 5.0g sample was weighed and added to CIPAC standard water C (5% w/v), at 25°C</p> <p>The foam after 1 min was less than 1ml.</p>	N	<p>NEW (2014) PHYSICO-CHEMICAL DATA ABOUT ENTOMELA 50SL</p> <p>Iliopulos N. 2014 Certificate of analysis, 2342(1).140903/309</p> <p>NEW (2014) STORAGE STABILITY REPORT</p> <p>Iliopulos N. 2014 Certificate of analysis, 2342-1. 140903/309</p> <p>Iliopulos N. 2014 Certificate of analysis, 2342-2. 140903/309</p> <p>NEW (2014) SHELF LIFE STUDY</p> <p>Iliopulos N. 2014 Certificate of analysis, 2353.140906/309</p>
CP 2.8.3 Suspensibility, spontaneity and dispersion stability			Not applicable		

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.8.4 Degree of dissolution and dilution stability	Dilution stability CIPAC MT 41	ENTOMELA 50SL Batch No 5014016 ENTOMELA 75SL (similar product) Batch number 014012	CIPAC standard water C was used (25% w/v), at 30°C Dilution factor: 4 No material has separated after standing for 24 h at 30°C After incubation for 6 weeks in 45°C and for 7days at 0° C (storage stability tests) no material has been separated after standing for 24 h at 30°C according to CIPAC MT41. After storage for 26 months (shelf life test) no material has been separated after standing for 24 h at 30°C according to CIPAC MT41	N	NEW (2014) PHYSICOCHEMICAL DATA ABOUT ENTOMELA 50SL Iliopulos N. 2014 Certificate of analysis, 2342(1).140903/309 NEW (2014) STORAGE STABILITY REPORT Iliopulos N. 2014 Certificate of analysis, 2342-1. 140903/309 Iliopulos N. 2014 Certificate of analysis, 2342-2. 140903/309 NEW (2014) SHELF LIFE STUDY Iliopulos N. 2014 Certificate of analysis, 2353.140906/309
CP 2.8.5.1 Particle size distribution			Not applicable		
CP 2.8.5.2 Dust content			Not applicable		

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.8.5.3 Attrition			Not applicable		
CP 2.8.5.4 Hardness and integrity			Not applicable		
CP 2.8.6 Emulsifiability, re-emulsifiability, emulsion stability			Not applicable		
CP 2.8.7 Flowability, 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	Physical compatibility of tank mixes ASTM E1518 – 05	ENTOMELA 50SL Batch No 5014016	<p>The product is always used in tank mix with an insecticide formulation.</p> <p>In compatibility tests the following formulations of insecticides were tested according to ASTM E1518 – 05 with ENTOMELA 50SL.</p> <ol style="list-style-type: none"> 1) Perfekthion 40 EC /BASF (Dimethoate 40% w/v) 2) Fastac 10 SC / BASF (Alphacypermethrin 10% w/v) 3) Decis 2,5 EC / Bayer (deltamethrin 2,5% w/v) 4) Karate 10 CS / Syngenta(L-cyhalothrin 9,43% w/w) <p>The application rates for the insecticides are:</p> <ol style="list-style-type: none"> 1)Perfekthion 40EC 625cc/100lt 2)Karate 10CS 125cc/100lt 3)Fastac 10SC 300cc/100lt 5)Decis 2,5EC 50cc/100lt <p>Deionized water (pH 5.8-6.2) and application rate 2gr/100ml used for ENTOMELA 50SL. In all cases the product found compatible to insecticides used.</p>	N	<p>NEW (2014) PHYSICOCHEMICAL DATA ABOUT ENTOMELA 50SL</p> <p>Iliopoulos N. 2014 Certificate of analysis, 2342(1).140903/309</p>

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference																	
		ENTOMELA 50SL Batch No 5014016	<p>In next table given the pH of tank mix before and after the addition of each insecticide.</p> <table><tr><th rowspan="2">ENTOMELA 50SL 2% Tank mix with</th><th colspan="2">pH</th></tr><tr><th>Before insectic. added</th><th>After Insectic. added</th></tr><tr><td>Perfection</td><td>6.88</td><td>5.15</td></tr><tr><td>Karate</td><td>6.87</td><td>6.86</td></tr><tr><td>Fastac</td><td>6.85</td><td>6.85</td></tr><tr><td>Decis</td><td>6.85</td><td>6.85</td></tr></table>	ENTOMELA 50SL 2% Tank mix with	pH		Before insectic. added	After Insectic. added	Perfection	6.88	5.15	Karate	6.87	6.86	Fastac	6.85	6.85	Decis	6.85	6.85		Iliopulos N. 2014 Physical compatibility test - pH of samples. 4781/27.12.2014
		ENTOMELA 50SL 2% Tank mix with	pH																			
			Before insectic. added	After Insectic. added																		
		Perfection	6.88	5.15																		
Karate	6.87	6.86																				
Fastac	6.85	6.85																				
Decis	6.85	6.85																				
ENTOMELA 50SL Batch No 5014016	<p>pH remains stable before and after the addition of pesticide product, except the case of product Perfection-Dimethoate 40%w/v) where a significant pH reduction occurs</p> <p>The test was performed also at storage stability tests and the product found compatible to same insecticides after incubation for 6 weeks in 45oC and for 7days at 0o C.</p>	NEW (2014) STORAGE STABILITY REPORT Iliopulos N. 2014 Certificate of analysis, 2342-1. 140903/309 Iliopulos N. 2014 Certificate of analysis, 2342-2.																				
ENTOMELA 75SL Batch number 014012	<p>In a new shelf life study after storage for 26 months in ambient temperature inside his original HDPE packing the product found compatible to same insecticides.</p> <p>The use of ENTOMELA attractants for more than 20 years in agricultural practice with different insecticides registered and used in Greece for bait sprays in national scale proving his compatibility</p>	NEW (2014) SHELF LIFE STUDY Iliopulos N. 2014 Certificate of analysis, 2353.140906/309																				
		CONFIRMATION OF GREEK MINISTRY																				

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
	Chemical compatibility of tank mixes	<p>ENTOMELA 50SL Batch No 5014016</p> <p>ENTOMELA 75SL</p>	<p>In physical compatibility tests. The pH of tank mix with the 4 insecticides remains stable before and after the addition of pesticide product, except the case of product Perfekthion-Dimethoate 40% w/v) where a significant pH reduction occurs. pH of tank mix is not alkaline.</p> <p>After 1 year the pH of ENTOMELA 75SL is not more than 7.3 and after 2 years not more than 8.0.</p> <ul style="list-style-type: none"> - After 2 years the solutions 2-10% of ENTOMELA 75SL gave a pH value: 7.56-7.65 which is close to normal pH value. - The beet molasses-urea hydrolysates like ENTOMELA 75SL after a lot of time (3-4 years) may reach alkaline pH of 8.5 but this have not a negative effect e.g. on dimethoate content as the mixture changes to acidic after preparation. - Although pH increasing by time a shelf life time of two years is acceptable because active substance and physicochemical properties are inside limits and there is no evidence for negative effect in application even with Dimethoate, which is well known that is not very stable in alkaline solutions. <p>The use of ENTOMELA attractants for more than 20 years in agricultural practice with different insecticides registered and used in Greece for bait sprays in national scale proving his compatibility.</p>		<p>Iliopulos N. 2014 Physical compatibility test - pH of samples. 4781/27.12.2014</p> <p>“The pH increasing of Beet Molasses -Urea Hydrolysates, the possible influence on bait applications with insecticide, and the effect on shelf life time” - Stavrakis N. 2014.</p> <p>CONFIRMATION OF GREEK MINISTRY</p>
CP 2.10 Adherence and distribution to seeds			Not applicable		

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
CP 2.11 Other studies	<p>1) Modified EN 15475:2009 Similar method to 2.6.2 section 7.5 EC Reg. 2003/2003.</p> <p>2) ISO 457/1983</p> <p>3) Modified AOAC 965.31</p> <p>4) ISO 2920:2004 at 105°C.</p> <p>5) Modified CIPAC MT.10.2</p>	<p>ENTOMELA 50SL</p> <p>Batch No 5013011</p> <p>Batch No 5013012</p> <p>Batch No 5013013</p> <p>Batch No 5013014</p> <p>Batch No 5013015</p>	<p>Other parameters, included in the Product Specifications have been tested.</p> <p>1) Ammonium salts (as NH₄Cl): max 5.30 % w/w</p> <p>2) Chlorine salts (as NaCl): max 2.0 % w/w</p> <p>3) Amino-acids index: max 2.0 (meq/10gr)</p> <p>4) Dry matter: app. 74-82 % w/w</p> <p>5) Insoluble in water: max 0,7% w/w</p> <p>Please see the new Table added below (before and after storage results). See also the 5 batches analysis.</p>	N	<p>HELLASCHEM 5 BATCHES ANALYSIS OF ENTOMELA 50SL</p> <p>Iliopulos N. 2013 Certificate of analysis, 1320.130731/309</p> <p>Iliopulos N. 2013 Certificate of analysis, 1321.130731/309</p> <p>Iliopulos N. 2013 Certificate of analysis, 1322.130731/309</p> <p>Iliopulos N. 2013 Certificate of analysis, 1323.130731/309</p> <p>Iliopulos N. 2013 Certificate of analysis, 1324.130731/309</p>

STORAGE STABILITY REPORTS 2013						
Storage Stability test after 6 weeks at 45° C – ENTOMELA 50SL (inside HDPE packing)						
Method	Parameter tested	Before storage 1367.130905/309	After storage 1367.130905/309*	Value difference	Product specifications	
					Normal value	Limits
AOAC 2001.11	Total nitrogen (% w/w)	8.64	8.61	0.03	8.40	8.00-9.24
	Protein equivalent (% w/w)	54.0	53.8	0.02	52.5	50.00-57.75
Modified AOAC 959.03	Urea nitrogen (% w/w)	8.20	8.18	0.02	7.93	7.46-8.41
	Urea equivalent (% w/w)	17.6	17.5	0,01	17.00	15.98-18.02
Modified EN 15475:2009 - Similar method to 2.6.2 section 7.5 EC Reg. 2003/2003	Ammoniacal Nitrogen (% w/w)	0.40	0.38	0.02		Max 1.38
	Equivalent ammonium salts as NH ₄ Cl (% w/w)	1.50	1.50	-		Max 5.30
In house ISO 457/1983	Chlorine salts as NaCl (% w/w)	1.40	1.40	-		Max 2.00
Modified AOAC 965.31	Aminoacid index	0.8	0.8	-		Max 2.00
In house ISO 2920 at 105°C	Dry matter (% w/w)	77.7	77.7	-	78.0	74.0-82.0
Modified CIPAC MT.10.2	Insoluble in water (% w/w)	0.18	0.18	-		Max 0.7
CIPAC 75.3	pH (25° C)	6.72	6.69	0.03	6.75	6.2-8.0 (7.3)*
CIPAC 3.3.2	Density 20° C (g/ml)	1.356	1.358	0.002	1.35	1.31-1.39
Macroscopic examination	Form	Surupy liquid	Surupy liquid	-	Surupy liquid	
Macroscopic examination	Color	Deep reddish brown	Deep reddish brown	-	Deep reddish brown	
Sensory evaluation	Odor	Characteristic	Characteristic	-	Characteristic	
Storage Stability test after 7 days at 0° C - ENTOMELA 50SL (inside HDPE packing)						
Method	Parameter tested	Before storage 1367.130905/309	After storage 1367.130905/309*	Value difference	Product specifications	
					Normal value	Limits

AOAC 2001.11	Total nitrogen (% w/w)	8.64	8.63	0.01	8.40	8.00-9.24
	Protein equivalent (% w/w)	54.0	53.9	0.01	52.5	50.00-57.75
Modified AOAC 959.03	Urea nitrogen (% w/w)	8.20	8.20	-	7.93	7.46-8.41
	Urea equivalent (% w/w)	17.6	17.6	-	17.00	15.98-18.02
Modified EN 15475:2009 - Similar method to 2.6.2 section 7.5 EC Reg. 2003/2003	Ammoniacal Nitrogen (% w/w)	0.40	0.39	0.01		Max 1.38
	Equivalent ammonium salts as NH ₄ Cl (% w/w)	1.50	1.50	-		Max 5.30
In house ISO 457/1983	Chlorine salts as NaCl (% w/w)	1.40	1.40	-		Max 2.00
Modified AOAC 965.31	Aminoacid index	0.8	0.8	-		Max 2.00
In house ISO 2920 at 105°C	Dry matter (% w/w)	77.7	77.8	0.01	78.0	74.0-82.0
Modified CIPAC MT.10.2	Insoluble in water (% w/w)	0.18	0.18	-		Max 0.7
CIPAC 75.3	pH (25° C)	6.72	6.73	0.01	6.75	6.2-8.0 (7.3)*
CIPAC 3.3.2	Density 20° C (g/ml)	1.356	1.352	0.004	1.35	1.31-1.39
Macroscopic examination	Form	Surupy liquid	Surupy liquid	-	Surupy liquid	
Macroscopic examination	Color	Deep reddish brown	Deep reddish brown	-	Deep reddish brown	
Sensory evaluation	Odor	Characteristic	Characteristic	-	Characteristic	
Storage stability after 20 months – ENTOMELA 75SL (HDPE packing)						
Method	Parameter tested	Batch no 073610 Report 2810	Batch no 063610 Report 2811	Comment	Product specifications	
					Normal value	Limits
Kjedahl	Protein equivalent (% w/w)	76.9	77.6	Both Inside limits	76.87	75.00-81.50
Volumetric	Equivalent ammonium salts as NH ₄ Cl (% w/w)	1.30	4.00	Both Inside limits		Max 5.30
Volumetric	Chlorine salts as NaCl	1.60	1.50	Both Inside limits		Max 2.00

	(% w/w)					
Gravimetric	Dry matter (% w/w)	78.2	78.2	Both Inside limits	78.0	74.0-82.0
Gravimetric	Insoluble in water (% w/w)	0.08	0.09	Both Inside limits		Max 0.7
-	pH (25° C)	7.75	7.78	Both Inside limits	6.75	6.2-8.0 (7.3)*
Gravimetric	Density 20° C (g/ml)	1.31	1.32	Both Inside limits	1.35	1.31-1.39
Storage stability after 23 months – ENTOMELA 75SL (HDPE packing)						
Method	Parameter tested	Batch no 023610 Report 2812	Batch no 033610 Report 2813	Comment	Product specifications	
					Normal value	Limits
Kjedahl	Protein equivalent (% w/w)	76.20	75.70	Both Inside limits	76.87	75.00-81.50
Volumetric	Equivalent ammonium salts as NH ₄ Cl (% w/w)	4.00	4.40	Both Inside limits		Max 5.30
Volumetric	Chlorine salts as NaCl (% w/w)	0.69	0.52	Both Inside limits		Max 2.00
Gravimetric	Dry matter (% w/w)	76.9	78.0	Both Inside limits	78.0	74.0-82.0
Gravimetric	Insoluble in water (% w/w)	0.55	0.65	Both Inside limits		Max 0.7
-	pH (25° C)	7.75	7.78	Both Inside limits	6.75	6.2-8.0 (7.3)*
Gravimetric	Density 20° C (g/ml)	1.31	1.31	Both Inside limits	1.35	1.31-1.39

* pH maximum value 7.3 may appear after 1 year of storage. The maximum pH value 8.0 may appear after two years of storage with no other effect on specifications and no significant effect on application as when diluted in application rates gives lower pH.

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Storage Stability test after 6 weeks at 45° C – ENTOMELA 50SL (inside glass bottle with metallic specimen)						
Method	Parameter tested	Before storage 2342(1).140903/309	After storage 2342-1.140903/309	Value difference	Product specifications	
					Normal value	Limits
AOAC 2001.11	Total nitrogen (% w/w)	8.61	8.56	0.05	8.40	8.00-9.24
	Protein equivalent (% w/w)	53.8	53.5	0.3	52.5	50.00-57.75
Modified AOAC 959.03	Urea nitrogen (% w/w)	8.15	8.05	0.10	7.93	7.46-8.41
	Urea equivalent (% w/w)	17.50	17.30	0.20	17.00	15.98-18.02
Modified EN 15475:2009 - Similar method to 2.6.2 section 7.5 EC Reg. 2003/2003	Ammoniacal Nitrogen (% w/w)	0.42	0.46	0.04		Max 1.38
	Equivalent ammonium salts as NH ₄ Cl (% w/w)	1.57	1.72	0.15		Max 5.30
In house ISO 457/1983	Chlorine salts as NaCl (% w/w)	1.20	1.10	0.10		Max 2.00
Modified AOAC 965.31	Aminoacid index	0.9	0.7	0.2		Max 2.00
In house ISO 2920 at 105°C	Dry matter (% w/w)	78.4	79.6	1.2	78.0	74.0-82.0
Modified CIPAC MT.10.2	Insoluble in water (% w/w)	0.17	0.18	0.01		Max 0.7
CIPAC 75.3	pH (25° C)	6.68	7.38	0.70	6.75	6.2-8.0 (7.3)*
CIPAC 3.3.2	Density 20° C (g/ml)	1.346	1.372	0.026	1.35	1.31-1.39
Macroscopic examination	Form	Surupy liquid	Surupy liquid		Surupy liquid	
Macroscopic examination	Color	Deep reddish brown	Deep reddish brown		Deep reddish brown	
Sensory evaluation	Odor	Characteristic	Characteristic		Characteristic	
CIPAC MT47.1	Persistent Foaming	<1ml	<1ml		<1ml	-
OECD Test guideline 114	Viscosity (cSt)	1148	1260	112	1200	<2000
EC Reg. 440/2008	Surface tension	70.6	70.0	0.06		-

	(mN/m), 20° C 1g/L					
CIPAC MT 41.1	Dilution Stability	No material separated for 24h at 30°C	No material separated for 24h at 30°C		No material separate for 24h at 30°C	No material separated for 24h at 30°C
CIPAC MT 191	pH/acidity (% w/w H ₂ SO ₄) Solution 2% Solution 6% Solution 10%	6.67/0.035 6.57/0.045 6.48/0.056	- - -			
	pH/alkalinity (% w/w NaOH) Solution 2% Solution 6% Solution 10%	- - -	7.12/0.006 7.10/0.008 7.08/0.005			
ASTM E1518 –05	Physical Compatibility with insecticides	Perfekthion 40 EC /BASF (Dimethoate 40% w/v) : Compatible Fastac 10 SC / BASF (Alphacypermethrin 10% w/v): Compatible Decis 2,5 EC / Bayer (deltametrin 2,5% w/v):Compatible Karate 10 CS / Syngenta(L-cyhalothrin 9,43% w/w):Compatible				
Storage Stability test after 7 days at 0° C ENTOMELA 50SL (HDPE packing)						
Method	Parameter tested	Before storage 2342(1).140903/309	After storage 2342-2.140903/309	Value difference	Product specifications	
					Normal value	Limits
AOAC 2001.11	Total nitrogen (% w/w)	8.61	8.60	0.01	8.40	8.00-9.24
	Protein equivalent (% w/w)	53.8	53.7	0.1	52.5	50.00-57.75
Modified AOAC 959.03	Urea nitrogen (% w/w)	8.15	8.15	-	7.93	7.46-8.41
	Urea equivalent (% w/w)	17.50	17.50	-	17.00	15.98-18.02
Modified EN	Ammoniacal Nitrogen	0.42	0.44	0.02		Max 1.38

15475:2009 - Similar method to 2.6.2 section 7.5 EC Reg. 2003/2003	(% w/w) Equivalent ammonium salts as NH ₄ Cl (% w/w)	1.57	1.64	0.07		Max 5.30
In house ISO 457/1983	Chlorine salts as NaCl (% w/w)	1.20	1.20	-		Max 2.00
Modified AOAC 965.31	Aminoacid index	0.9	0.8	0.1		Max 2.00
In house ISO 2920 at 105°C	Dry matter (% w/w)	78.4	78.8	0.4	78.0	74.0-82.0
Modified CIPAC MT.10.2	Insoluble in water (% w/w)	0.17	0.20	0.03		Max 0.7
CIPAC 75.3	pH (25° C)	6.68	6.80	0.12	6.75	6.2-8.0 (7.3)*
CIPAC 3.3.2	Density 20° C (g/ml)	1.346	1.352	0.006	1.35	1.31-1.39
Macroscopic examination	Form	Surupy liquid	Surupy liquid	-	Surupy liquid	
Macroscopic examination	Color	Deep reddish brown	Deep reddish brown	-	Deep reddish brown	
Sensory evaluation	Odor	Characteristic	Characteristic	-	Characteristic	
CIPAC MT47.1	Persistent Foaming	<1ml	<1ml	-	<1ml	-
OECD Test guideline 114	Viscosity (cSt)	1148	1115	33	1200	<2000
EC Reg. 440/2008	Surface tension (mN/m), 20° C 1g/L	70.6	71.0	0.04		-
CIPAC MT 41.1	Dilution Stability	No material separated for 24h at 30°C	No material separated for 24h at 30°C		No material separate for 24h at 30°C	No material separated for 24h at 30°C
CIPAC MT 191	pH/acidity (% w/w H ₂ SO ₄)					
	Solution 2%	6.67/0.035	6.70/0.038			
	Solution 6%	6.57/0.045	6.55/0.042			
	Solution 10%	6.48/0.056	6.50/0.058			
	pH/alkalinity (% w/w NaOH)					
	Solution 2%	-	-			
	Solution 6%	-	-			
	Solution 10%	-	-			
ASTM E1518 –05	Physical Compatibility with insecticides	Perfekthion 40 EC /BASF (Dimethoate				

		40% w/v) : Compatible Fastac 10 SC / BASF (Alphacypermethrin 10% w/v): Compatible Decis 2,5 EC / Bayer (deltametrin 2,5% w/v):Compatible Karate 10 CS / Syngenta(L-cyhalothrin 9,43% w/w):Compatible				
Storage Stability test after 6 weeks at 45° C – ENTOMELA 75SL (inside HDPE packing)						
Method	Parameter tested	Before storage 2343(2).140903/309	After storage 2343-3.140903/309	Value difference	Product specifications	
					Normal value	Limits
AOAC 2001.11	Total nitrogen (% w/w)	12.32	12.2	0.12	12.30	12.00-13.04
	Protein equivalent (% w/w)	77.00	75.70	1.30	76.87	75.00-81.50
Modified AOAC 959.03	Urea nitrogen (% w/w)	11.45	11.80	0.35	11.67	10.97-12.37
	Urea equivalent (% w/w)	24.50	25.20	0.70	25.00	23.50-26.50
Modified EN 15475:2009 - Similar method to 2.6.2 section 7.5 EC Reg. 2003/2003	Ammoniacal Nitrogen (% w/w)	0.65	0.37	0.28		Max 1.38
	Equivalent ammonium salts as NH4Cl (w/w)	2.52	1.38	1.14		Max 5.30
In house ISO 457/1983	Chlorine salts as NaCl (% w/w)	1.10	1.20	0.10		Max 2.00
Modified AOAC 965.31	Aminoacid index	1.30	0.70	0.60		Max 2.00
In house ISO 2920 at 105°C	Dry matter (% w/w)	78.80	79.80	1.00	78.0	74.0-82.0
Modified CIPAC MT.10.2	Insoluble in water (% w/w)	0.20	0.18	0.02		Max 0.7
CIPAC 75.3	pH (25° C)	7.14	7.68	0.54	6.75	6.2-8.0 (7.3)*
CIPAC 3.3.2	Density 20° C (g/ml)	1.368	1.370	0.002	1.35	1.31-1.39
Macroscopic	Form	Surupy liquid	Surupy liquid	-		

examination						
Macroscopic examination	Color	Deep reddish brown	Deep reddish brown	-		
Sensory evaluation	Odor	Characteristic	Characteristic	-		
CIPAC MT47.1	Persistent Foaming	<1ml	<1ml	-	<1ml	-
OECD Test guideline 114	Viscosity (cSt)	1280	1410	130	1300	<2000
EC Reg. 440/2008	Surface tension (mN/m), 20° C 1g/L	70.4	71.0	0.6		-
CIPAC MT 41.1	Dilution Stability	No material separated for 24h at 30°C	No material separated for 24h at 30°C		No material separate for 24h at 30°C	No material separated for 24h at 30°C
CIPAC MT 191	pH/acidity (% w/w H ₂ SO ₄)					
	Solution 2%	6.88/0.024	-			
	Solution 6%	6.80/0.028	-			
	Solution 10%	6.78/0.022	-			
	pH/alkalinity (% w/w NaOH)					
	Solution 2%	-	7.15/0.024			
	Solution 6%	-	7.10/0.028			
	Solution 10%	-	7.08/0.022			
ASTM E1518 –05	Physical Compatibility with insecticides	Perfekthion 40 EC /BASF (Dimethoate 40%w/v) : Compatible Fastac 10 SC / BASF (Alphacypermethrin 10% w/v): Compatible Decis 2,5 EC / Bayer (deltametrin 2,5% w/v):Compatible Karate 10 CS / Syngenta(L-cyhalothrin 9,43% w/w):Compatible				
Storage stability after 26 months - ENTOMELA 75SL (HDPE Packing)						
Method	Parameter tested	Batch number 014012 2353.140906/309	Comment	Product specifications		
				Normal value	Limits	
AOAC 2001.11	Total nitrogen (% w/w)	12.27	Inside specifications limits	12.30	12.00-13.04	

	Protein equivalent (% w/w)	76.70	Inside specifications limits	76.87	75.00-81.50
Modified AOAC 959.03	Urea nitrogen (% w/w)	11.05	Inside specifications limits	11.67	10.97-12.37
	Urea equivalent (% w/w)	23.60	Inside specifications limits	25.00	23.50-26.50
Modified EN 15475:2009 - Similar method to 2.6.2 section 7.5 EC Reg. 2003/2003	Ammoniacal Nitrogen (% w/w)	1.00	Inside specifications limits		Max 1.38
	Equivalent ammonium salts as NH ₄ Cl (% w/w)	3.88	Inside specifications limits		Max 5.30
In house ISO 457/1983	Chlorine salts as NaCl (% w/w)	1.20	Inside specifications limits		Max 2.00
Modified AOAC 965.31	Aminoacid index	1.00	Inside specifications limits		Max 2.00
In house ISO 2920 at 105°C	Dry matter (% w/w)	78.7	Inside specifications limits	78.0	74.0-82.0
Modified CIPAC MT.10.2	Insoluble in water (% w/w)	0.22	Inside specifications limits		Max 0.7
CIPAC 75.3	pH (25° C)	7.94	Inside specifications limits	6.75	6.2-8.0 (7.3)*
CIPAC 3.3.2	Density 20° C (g/ml)	1.358	Inside specifications limits	1.35	1.31-1.39
Macroscopic examination	Form	Surupy liquid	-		
Macroscopic examination	Color	Deep reddish brown	-		
Sensory evaluation	Odor	Characteristic	-		
CIPAC MT47.1	Persistent Foaming	<1ml		<1ml	-
OECD Test guideline 114	Viscosity (cSt)	1160cSt		1300	<2000
EC Reg. 440/2008	Surface tension (mN/m), 20° C 1g/L	70.4			-
CIPAC MT 41.1	Dilution Stability	No material separated for 24h at 30°C		No material separate for 24h at 30°C	No material separated for 24h at 30°C
CIPAC MT 191	pH/acidity (% w/w H ₂ SO ₄)	- -			

	Solution 2% Solution 6% Solution 10%	-			
	pH/alkalinity (% w/w NaOH) Solution 2% Solution 6% Solution 10%	7.65/0.049 7.61/0.046 7.56/0.042			
ASTM E1518 –05	Physical Compatibility with insecticides	Perfekthion 40 EC /BASF (Dimethoate 40% w/v) : Compatible Fastac 10 SC / BASF (Alphacypermethrin 10% w/v): Compatible Decis 2,5 EC / Bayer (deltametrin 2,5% w/v):Compatible Karate 10 CS / Syngenta(L-cyhalothrin 9,43% w/w):Compatible			

* pH maximum value 7.3 may appear after 1 year of storage. The maximum pH value 8.0 may appear after two years of storage with no other effect on specifications and no significant effect on application as when diluted in application rates gives lower pH.