

WHO Prequalification Programme / Vector Control Product Assessment

WHO Public Assessment Report: WHOPAR Part 3

Optica ULV

(Clarke International)

P-11637

Quality Assessment





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1 Chemical and physical data

Optica ULV Space Spray is an insecticide for indoor and outdoor use that controls adult *Aedes aegypti* and *Aedes albopictus* mosquito species. It is assessed for application as an ultralow volume (ULV) non-thermal cold aerosol mist for indoor and outdoor urban, residential, institutional, industrial, and recreational areas to control adult mosquitoes. It is packaged in 1L, 10L, and 208L ready-to-use containers.

Data on the chemical and physical properties of the active ingredient and the product OPTICA ULV Space Spray were provided. These data were obtained from studies conducted according to established standards and/or Good Laboratory Practices (GLP) and are considered complete. Three batches were tested and five samples were measured from each batch in accordance with WHO requirements for physical/chemical properties. The results are presented in Table 1. These summary results are based on the analysis of batches 2108110009, 2204110001, and 2204140001.

Table 1. Chemical and physical properties for OPTICA ULV Space Spray				
Data requirement	Study number	Test method ID	Results	
Physical state (the physical state was tested in four different test sample packaging: 1. Kortrax container 2. Non-FI HDPE 3. SS304 Coupon 4. SS316 Coupon	AN1110 Accelerated Storage Stability and Corrosion Characteristics of CMP132-022 (GLP Study)	OPPTS 830.6303, Clarke SOP-C007 Revision 3	Three batches and five samples/batch were tested: Batch No.2108110009: Pale yellow liquid Batch No.2204110001: Pale yellow liquid Batch No.2204140001: Pale yellow liquid After storage stability test, 2 weeks at 54 °C ±2°C, stored in four different packaging/transport materials, there were no significant changes in the physical state of the samples Batch No.2108110009: Pale yellow liquid Batch No.2204110001: Pale yellow liquid Batch No.2204140001: Pale yellow liquid	
Colour (the colour was tested in four different test sample packaging: 1. Kortrax container 2. Non-FI HDPE 3. SS304 Coupon 4. SS316 Coupon	AN1110 Accelerated Storage Stability and Corrosion Characteristics of CMP132-022 (GLP Study)	OPPTS 830.6302, Clarke SOP-C006 Revision 5	Three batches and five samples/batch were tested: Batch No.2108110009: Gardner Liquid Colour Standard 1 Batch No.2204110001: Gardner Liquid Colour Standard 1 Batch No.2204140001: Gardner Liquid Colour Standard 1 After storage stability test, 2 weeks at 54 °C ±2°C, stored in four different packaging/transport materials, there were no significant changes in the colour of the samples Batch No.2108110009: Gardner Liquid Colour Standard 1 Batch No.2204110001: Gardner Liquid Colour Standard 1 Batch No.2204140001: Gardner Liquid Colour Standard 1	
Odour (the odour was tested in four different test sample packaging: 1. Kortrax container 2. Non-FL HDPF	AN1110 Accelerated Storage Stability and Corrosion Characteristics of CMP132-022 (GLP Study)	OPPTS 830.6304, Clarke SOP-C005 Revision 3	Three batches and five samples/batch were tested: Batch No.2108110009: slightly sweet odour Batch No.2204110001: slightly sweet odour Batch No.2204140001: slightly sweet odour	



Table 1. Chemical and physical properties for OPTICA ULV Space Spray				
Data requirement	Study number	Test method ID	Results	
3. SS304 Coupon 4. SS316 Coupon			After storage stability test, 2 weeks at 54 °C ±2°C, stored in four different packaging/transport materials, there were no significant changes in the odour of the samples Batch No.2108110009: slightly sweet odour Batch No.2204110001: slightly sweet odour	
			Batch No.2204140001: slightly sweet odour	
pH* (1 % w/v solution) (the pH was tested in four different test sample packaging: 1. Kortrax container 2. Non-FI HDPE 3. SS304 Coupon 4. SS316 Coupon	AN1110 Accelerated Storage Stability and Corrosion Characteristics of CMP132-022 (GLP Study)	CIPAC MT 75.3, CIPAC Handbook J, p. 131, 2000	Three batches and five samples/batch were tested: Batch No.2108110009: average pH=6.14 Batch No.2204110001: average pH=5.89 Batch No.2204140001: average pH=5.95 After storage stability test, 2 weeks at 54 °C ±2°C, stored in four different packaging/transport materials, there were no significant changes in the pH values. Batch No.2108110009: average pH=6.49 Batch No.2204110001: average pH=6.11	
			Batch No.2204140001: average pH=5.77	
Viscosity* (at 20 °C and 50 RPM) (the viscosity was tested in four different test sample packaging: 1. Kortrax container 2. Non-FI HDPE 3. SS304 Courson	AN1110 Accelerated Storage Stability and Corrosion Characteristics of CMP132-022 (GLP Study)	CIPAC MT 192 Handbook M, page 210, 2009	Three batches and five samples/batch were tested: Batch No.2108110009: average initial viscosity 23.0 cP Batch No.2204110001: average initial viscosity 23.6 cP Batch No.2204140001: average initial viscosity 23.5 cP After storage stability test, 2 weeks at 54 °C ±2°C, stored in four different packaging/transport materials, there were no significant changes in the viscosity values. Batch No.2108110009: 23.2.cP	
4. SS316 Coupon			Batch No.2204110001: 23.9 cP Batch No.2204140001: 23.9 cP	
Viscosity* (at 20 °C and 60 RPM) (the viscosity was tested in four different test sample packaging: 1. Kortrax container 2. Non-FI HDPE 3. SS304 Coupon 4. SS316 Coupon	AN1110 Accelerated Storage Stability and Corrosion Characteristics of CMP132-022 (GLP Study)	CIPAC MT 192 Handbook M, page 210, 2009	Three batches and five samples/batch were tested: Batch No.2108110009: average initial viscosity 22.9 cP Batch No.2204110001: average initial viscosity 23.5 cP Batch No.2204140001: average initial viscosity 23.6 cP After storage stability test, 2 weeks at 54 °C ±2°C, stored in four different packaging/transport materials, there were no significant changes in the viscosity values. Batch No.2108110009: 23.1.cP Batch No.2204110001: 23.5 cP Batch No.2204110001: 23.8 cP	
Viscosity* (at 40 °C and 60 RPM) (the viscosity was tested in four different test sample packaging:	AN1110 Accelerated Storage Stability and Corrosion Characteristics of CMP132-022 (GLP Study)	CIPAC MT 192 Handbook M, page 210, 2009	Three batches and five samples/batch were tested: Batch No.2108110009: average initial viscosity 11.1 cP Batch No.2204110001: average initial viscosity 11.5 cP Batch No.2204140001: average initial viscosity 11.4 cP	



Table 1. Chemical and physical properties for OPTICA ULV Space Spray				
Data requirement	Study number	Test method ID	Results	
 Kortrax container Non-Fl HDPE SS304 Coupon SS316 Coupon 			After storage stability test, 2 weeks at 54 °C ±2°C, stored in four different packaging/transport materials, there were no significant changes in the viscosity values. Batch No.2108110009: 11.2.cP Batch No.2204110001: 11.3 cP Batch No.2204140001: 11.4 cP	
Specific gravity* (the specific gravity was tested in four different test sample packaging: 1. Kortrax container 2. Non-FI HDPE 3. SS304 Coupon 4. SS316 Coupon	AN1110 Accelerated Storage Stability and Corrosion Characteristics of CMP132-022 (GLP Study)	CIPAC MT 3 Handbook F, pqge 13, 1994.	Three batches and five samples/batch were tested: Batch No.2108110009: average specific gravity 1.0879 Batch No.2204110001: average specific gravity 1.0869 Batch No.2204140001: average specific gravity 1.0866 After storage stability test, 2 weeks at 54 °C ±2°C, stored in four different packaging/transport materials, there were no significant changes in the specific gravity values. Batch No.2108110009: average specific gravity 1.0877 Batch No.2204110001: average specific gravity 1.0845 Batch No.2204140001: average specific gravity 1.0834	
Broflanilide content (test item stored at room temperature)	AN1110 Accelerated Storage Stability and Corrosion Characteristics of CMP132-022 (GLP Study)	BROF-001 Broflanilide reverse phase HPLC method fully validated (Validation Study No. AN 1102). Equivalent to CIPAC 994/UL/M/3 (CIPAC MT 46.3 Handbook J, page 128, 2000)	Measured values: Three batches and five samples/batch were tested: Mean value Batch No.2108110009: 0.98 % w/w Mean value Batch No.2204110001: 0.98 % w/w Mean value Batch No.2204140001: 0.98 % w/w Mean value of three batches: 0.98 % w/w	
Broflanilide content (after accelerated storage stability, 2 weeks at 54 °C ±2°C. Four different test sample packaging were tested: 1. Kortrax container 2. Non-FI HDPE 3. SS304 Coupon 4. SS316 Coupon	AN1110 Accelerated Storage Stability and Corrosion Characteristics of CMP132-022 (GLP Study)	BROF-001 Broflanilide reverse phase HPLC method fully validated (Validation Study No. AN 1102). Equivalent to CIPAC 994/UL/M/3 (CIPAC MT 46.3 Handbook J, page 128, 2000)	Measured values:Three batches and five samples/batch were tested for eachtype of test sample:Mean values Batch No.2108110009Kortrax:0.99 % w/w (average of five samples results)Non-FI-HDPE:0.99 % w/w (average of five samples results)SS304:0.99 % w/w (average of five samples results)SS316:0.99 % w/w (average of five samples results)Mean value Batch No.2204110001Kortrax:0.98 % w/w (average of five samples results)Non-FI-HDPE:0.99 % w/w (average of five samples results)SS304:0.99 % w/w (average of five samples results)SS304:0.99 % w/w (average of five samples results)SS316:0.99 % w/w (average of five samples results)SS316:0.99 % w/w (average of five samples results)Mean value Batch No.2204140001Kortrax:0.97 % w/w (average of five samples results)	
			Mean value Batch No.2204140001 Kortrax: 0.97 % w/w (average of five samples result Non-FI-HDPE: 0.97 % w/w (average of five samples result	



Table 1. Chemical and physical properties for OPTICA ULV Space Spray				
Data requirement	Study number	Test method ID	Results	
			SS304:0.98 % w/w (average of five samples results)SS316:0.99 % w/w (average of five samples results)	
			No significant differences between broflanilide concentration values before and after storage stability test.	
Low temperature storage stability (at 0 ± 2 °C for 7 days)	AN1111 Low temperature Storage stability of CMP132-022 (GLP Study)	CIPAC MT 39.3 Handbook J, page 126, 2000	Three batches and five samples/batch were tested: Batch No.2108110009: No separation observed Batch No.2204110001: No separation observed Batch No.2204140001: No separation observed No adverse effects were recorded on the product properties after storage at low temperature.	
Long term storage stability* (at 30 ± 2 °C for 12 months)	AN1105 Long term storage stability of CMP132-022 (GLP Study)	(CIPAC MT 46.3 Handbook P, page 232, 2021)	Three batches and five samples/batch were tested for the following parameters, colour, odour, physical state, container corrosion, specific gravity and active ingredient content: Batch No.2108110009: No significant differences were observed between parameters tested before and after long term storage stability test. Batch No.2204110001: No significant differences were observed between parameters tested before and after long term storage stability test. Batch No.2204110001: No significant differences were observed between parameters tested before and after long term storage stability test. Batch No.2204140001: No significant differences were observed between parameters tested before and after long term storage stability test.	
Corrosion Characteristics* (OPPTS 830.6320, Clarke SOP-C019 Revision 3	AN1110 Accelerated Storage Stability and Corrosion Characteristics of CMP132-022 (GLP Study)	OPPTS 830.6320	Measured values: Three batches and five samples/batch were tested for each type of test sample: Average% Weight Change Batch No.2108110009 Kortrax: 0.0 (average of five samples results) Non-FI-HDPE: 0.0 (average of five samples results) SS304: 0.0 (average of five samples results) SS316: 0.0 (average of five samples results) Average% Weight Change Batch No.2204110001 Kortrax: 0.0 (average of five samples results) Non-FI-HDPE: 0.0 (average of five samples results) Non-FI-HDPE: 0.0 (average of five samples results) SS304: 0.0 (average of five samples results) SS316: 0.0 (average of five samples results) SS316: 0.0 (average of five samples results) Average% Weight Change Batch No.2204140001 Kortrax: 0.0 (average of five samples results) Non-FI-HDPE: 0.0 (average of five samples results) Non-FI-HDPE: 0.0 (average of five samples results) SS304: 0.0 (average of five samples results) Non-FI-HDPE: 0.0 (average of five samples results) SS304: 0.0 (average of five samples results)	

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Table 1. Chemical and physical properties for OPTICA ULV Space Spray				
Data requirement	Study number	Test method ID	Results	
Flammability*	REF 3.1 AN1103 Product Properties of CMP132-022.pdf	OPPTS 830.6415	Measured values: One batch and two samples/batch were tested: Batch No.2108110009: Average flash point 211.0 °C	

* Parameters not requested in the manufacturing release specifications

1.1 Manufacturing, composition and formulant information

Data on the manufacturing process and product composition for OPTICA ULV have been provided and are adequate. A summary is presented in Table 2. Detailed information on the manufacturing process and product formulation is considered Confidential Business Information (CBI).

Table 2. Manufacturing process and product composition data submitted for OPTICA ULV				
Description of starting material	Broflanilide technical			
Declaration of product formulation	Included in the confidential business information.			
Production / formulation process	 Broflanilide technical active substance is mixed in a mixing vessel with the other formulation components such as solvents, surfactants until complete dissolution of broflanilide. The mixture is agitated until a homogenous solution is obtained. The product is packaged into non-fluorinated high-density polyethylene (HDPE) jugs or Kortrax jugs, heat sealed and packed in an outer corrugated cardboard shipping carton (if appropriate) on-site. Outer packaging is sealed before material is released for warehousing or shipment. The product is also packaged into stainless steel drums. 			
Discussion of impurities	No relevant impurities are present in the product.			
Certification of limits	Broflanilide: 1 % w/w, acceptable limits 0.9 to 1.1 %w/w			

1.2 Enforcement analytical method

Table 3. Details of the analytical method used to determine broflanilide in OPTICA ULV				
Quantification of broflanilide	CIPAC 994/UL/M/3			

The method is appropriate for the determination of the active ingredient content of the product.



2 Overall quality conclusions

Based on the studies and information provided, all data requirements for the prequalification assessment of product quality have been satisfied. These data have been relied upon to assess the formulation, manufacturing process, and physical/chemical characteristics of the proposed product for the purpose of establishing the identity of the product and assuring that the product can be produced consistently.

The methods for assessing the physical/chemical properties of the product were CIPAC methods and/or validated methods.

The quality component of the dossier is considered complete, and the assessment of the submitted information on quality supports prequalification of the product.

Table 4. List of studies related to quality submitted to WHO as part of the prequalification dossier					
	Studies that were relied upon for decision making				
Study number	Study title				
AN1110	Accelerated Storage Stability and Corrosion Characteristics of CMP132-022				
AN1111	Low temperature Storage stability of CMP132-022				
AN1105	Long-Term Storage Stability of CMP132-022				
AN1103	Product Properties of CMP132-022.pdf				
AN1102	Method Validation of BROF-001 Rev.0				
Studies that were not used to inform decision making					
Study number	Study title				

3 Manufacturing release specifications

3.1 Summary of manufacturing release specifications

Broflanilide content

Table 5. Summary of manufacturing release specifications Description: The material shall consist of technical Broflanilide, complying with the requirements of FAO/WHO specification 994/TC (current version), in the form of a slightly pale to light yellow organic liquid, together with any necessary formulants. It shall be in the form of a stable homogeneous liquid, free from visible suspended matter and sediment. ID Property Method Declared value 1 Broflanilide identity CIPAC 994/UL/M/2 1.00 % w/w (10 g/kg)

CIPAC 994/UL/M/3

Manufacturers are expected to rely on the information above as part of a QC management plan and for validation of product quality when released. To the extent required, Certificates of Analysis to support the release of products should present results for the attributes identified in the above table.

3.2 Storage

2

Accelerated storage stability data were generated as per CIPAC MT 46.3 and CIPAC MT 39.3 on Optica Space Spray. Test samples were stored for 2 weeks at 54 °C and 7 days at 0 ± 2 °C, respectively. No significant differences were observed and recorded among the properties of the product after accelerated storage stability test conditions.

Products should be stored and transported in accordance with the conditions recommended by the manufacturer.

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Appendix 1. Summary of available data considered in Module 3

Batches used to generate the physical/chemical data

Batch number	Date of production	Description
2108110009	11/08/2021	pale yellow organic liquid
2204110001	11/04/2022	pale yellow organic liquid
2204140001	14/04/2022	pale yellow organic liquid

STUDY AN1110: Accelerated Storage Stability and Corrosion Characteristics of Optica ULV

SUMMARY

This study was conducted at Clarke Mosquito Control Products, Inc. in St. Charles, Illinois, USA, to determine the storage stability of Optica ULV Space Spray at 54°C ±2°C, for 14 days.

Three batches of test substance were used in this study; each batch was used to prepare initial property test samples and final property test samples as described below:

Initial property test samples were used to determine the initial product properties of Colour, Physical State, Odour, pH, Viscosity, Specific gravity and Active ingredient content. Initial property test samples were stored at ambient room temperature when not in use for testing.

Final property test samples were used to determine the final product properties of Colour, Physical State, Odour, pH, Viscosity, Specific gravity and Active ingredient content as well as Corrosion characteristics after storage for 14 days at 54°C ±2°C. Final property test samples consisted of 4 different test sample types:

- i. Kortrax Container Test Samples
- ii. Non-FI HDPE Container Test Samples
- iii. SS304 Coupon Test Samples
- iv. SS316 Coupon Test Samples

Storage stability was determined by comparing the initial vs. final product properties of colour, physical state, odour, pH, viscosity, specific gravity and active ingredient content before and after storage at 54°C \pm 2°C for 14 days.

Corrosion characteristics were determined by monitoring both the test substance and the containers/coupons for evidence of degradation and loss of material integrity.



Container corrosion:

Storage at 54°C ±2°C for 14 days had no effect on the material integrity of Optica ULV Space Spray or the proposed packaging/transport materials.

Batch number	Test Material	Average% Weight Change
	Kortrax	0.0
2108110009	Non-FI HDPE	0.0
	SS304	0.0
	SS316	0.0
	Kortrax	0.0
2204110001	Non-FI HDPE	0.0
	SS304	0.0
	SS316	0.0
	Kortrax	0.0
2204140001	Non-FI HDPE	0.0
	SS304	0.0
	SS316	0.0

Average % Weight Change per Batch

Colour:

Exposure to container/transport materials at $54^{\circ}C \pm 2^{\circ}C$ for 14 days had no effect on the colour characteristics of Optica ULV Space Spray.

Physical state:

Exposure to container/transport materials at 54°C \pm 2°C for 14 days had no effect on the physical state characteristics of Optica ULV Space Spray.

Odour:

Exposure to container/transport materials at $54^{\circ}C \pm 2^{\circ}C$ for 14 days had no effect on the odour characteristics of Optica ULV Space Spray.

pH:

Exposure to container/transport materials at 54°C ±2°C for 14 days had negligible effect on the pH characteristics of Optica ULV Space Spray.

Batch Number	Test sample type	Average pH	Shift in pH
	-	-	-
2108110009	Kortrax	5.77	-0.37
	Non-FI HDPE	6.67	0.53
	SS304	6.44	0.30
	SS316	7.11	0.97

Average Initial pH vs. Average Final pH



	Initial	5.89	-
	Kortrax	6.88	0.99
220/110001	Non-FI HDPE	6.00	0.11
2204110001	SS304	5.85	-0.04
	SS316	5.69	-0.20
	Initial	5.95	-
	Kortrax	5.63	-0.32
2204140001	Non-FI HDPE	5.70	-0.26
2201110001	SS304	5.95	-0.00
	SS316	5.78	-0.17

Viscosity:

Exposure to container/transport materials at 54°C ±2°C for 14 days had negligible effect on the viscosity characteristics of Optica ULV Space Spray.

Batch Number	Test sample type	Average Initial Viscosity	Shift in Final Viscosity
	Initial	23.0	-
	Kortrax	23.3	0.2
2108110009	Non-FI HDPE	23.2	0.2
2100110005	SS304	23.3	0.3
	SS316	23.3	0.3
	Inital	23.6	-
	Kortrax	23.8	0.1
2204110001	Non-FI HDPE	23.7	0.1
	SS304	23.7	0.2
	SS316	23.7	0.1
	Initial	23.5	-
	Kortrax	23.9	0.4
2204140001	Non-FI HDPE	24.0	0.4
	SS304	23.9	0.3
	SS316	23.9	0.4

Average Initial Viscosity vs. Average Final Viscosity at 20°C and 50RPM



Batch Number	Test sample type	Average Initial Viscosity	Shift in Final Viscosity
	Initial	22.9	-
	Kortrax	23.1	0.2
2108110009	Non-FI HDPE	23.1	0.2
2100110005	SS304	23.2	0.3
	SS316	23.1	0.2
	Initial	23.5	-
	Kortrax	23.6	0.1
2204110001	Non-FI HDPE	23.5	0.0
2201110001	SS304	23.5	0.0
	SS316	23.5	0.0
	Initial	23.6	-
	Kortrax	23.8	0.3
2204140001	Non-FI HDPE	23.8	0.3
	SS304	23.8	0.2
	SS316	23.8	0.2

Average Initial Viscosity vs. Average Final Viscosity at 20°C and 60RPM

Average Initial Viscosity vs. Average Final Viscosity at 40°C and 60RPM

Batch Number	Test sample type	Average Initial Viscosity	Shift in Final Viscosity
	Initial	11.1	-
	Kortrax	11.2	0.1
2108110009	Non-FI HDPE	11.2	0.1
2100110005	SS304	11.3	0.2
	SS316	11.2	0.1
	Inital	11.5	-
	Kortrax	11.4	-0.1
2204110001	Non-FI HDPE	11.3	-0.2
2201110001	SS304	11.3	-0.2
	SS316	11.3	-0.2
	Initial	11.4	-
	Kortrax	11.4	0.1
2204140001	Non-FI HDPE	11.4	0.1
	SS304	11.4	0.1
	SS316	11.5	0.1

Specific gravity:

Exposure to container/transport materials at 54°C ±2°C for 14 days had negligible effect on the specific gravity characteristics of Optica ULV Space Spray.

Overall Ave. Initial Specific Gravity vs. Overall Ave. Final Specific Gravity

Packaging/ Transport Material	Initial Overall Average Specific Gravity	Final Overall Average Specific Gravity	Shift in Overall Average Specific Gravity
Kortrax		1.0841	-0.0030
Non-Fl HDPE		1.0843	-0.0028
SS304	1.0871	1.0840	-0.0031
SS316		1.0843	-0.0028

Overall Average Densities

Test Sample Tvoe	Overall Average Density
Initial	1.0852
Kortrax	1.0822
Non-FI HDPE	1.0823
SS304	1.0821
SS316	1.0823

Active ingredient content:

Exposure to container/transport materials at 54°C \pm 2°C for 14 days had slight effect on the active ingredient content of Optica ULV Space Spray.

The average active ingredient content was not lower than 95 % of the average content found before storage.

Batch 2108110009	Batch 2108110009 Final Al Results And% Change vs Average Initial Al Summary			
Test Sample	% Broflanilide	% Change Broflanilide		
Kortrax 1	0.99	1.2		
Kortrax 2	1.00	1.4		
Kortrax 3	0.99	1.0		
Kortrax 4	0.99	1.1		
Kortrax 5	0.99	0.3		
Average Kortrax Al	0.99	1.0		

Batch 2108110009 Final AI Results And% Change vs Average Initial AI Summary



Non-Fl HDPE 1	1.00	1.7
Non-FL HDPE 2	0.98	-0.7
Non-Fl HDPE 3	0.99	0.5
Non-Fl HDPE 4	0.98	0.1
Non-Fl HDPE 5	0.98	0.1
Average Non-FI HDPE AI	0.99	0.3
SS304 1	1.00	1.6
SS304 2	0.99	1.0
SS304 3	0.98	-0.8
SS304 4	0.99	0.8
SS304 5	0.99	1.0
Average SS304 AI	0.99	0.7
SS316 1	1.00	1.4
SS316 2	0.99	0.4
SS316 3	0.99	0.6
SS316 4	0.99	0.8
SS316 5	0.99	0.8
Average SS316 AI	0.99	0.8

Batch 2204110001 Final AI Results And% Change vs Average Initial AI Summary

Test Sample	% Broflanilide	% Change Broflanilide
Kortrax 1	0.99	0.2
Kortrax 2	0.98	-0.1
Kortrax 3	0.97	-1.1
Kortrax 4	0.99	0.0
Kortrax 5	0.98	-0.4
Average Kortrax Al	0.98	-0.3
Non-FI HDPE 1	1.00	1.1
Non-FL HDPE 2	0.99	0.1
Non-Fl HDPE 3	0.99	0.2
Non-Fl HDPE 4	0.98	-0.1
Non-Fl HDPE 5	0.99	0.0
Average Non-Fl HDPE AI	0.99	0.3
SS304 1	0.99	0.0
SS304 2	0.99	0.9
SS304 3	0.98	-0.3
SS304 4	0.99	0.6

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SS304 5	1.00	1.2
Average SS304 AI	0.99	0.5
SS316 1	0.99	0.9
SS316 2	0.99	0.2
SS316 3	0.99	0.5
SS316 4	0.99	0.6
SS316 5	0.97	-1.2
Average SS316 AI	0.99	0.2

Batch 2204140001 Final AI Results And% Change vs Average Initial AI Summary

Test Sample	% Broflanilide	% Change Broflanilide
Kortrax 1	0.97	-0.6
Kortrax 2	0.98	-0.2
Kortrax 3	0.98	-0.1
Kortrax 4	0.97	-0.7
Kortrax 5	0.97	-1.2
Average Kortrax Al	0.97	-0.6
Non-Fl HDPE 1	0.97	-0.9
Non-FL HDPE 2	0.97	-0.6
Non-Fl HDPE 3	0.97	-0.8
Non-Fl HDPE 4	0.97	-0.7
Non-Fl HDPE 5	0.97	-0.9
Average Non-FI HDPE AI	0.97	-0.8
SS304 1	0.99	1.4
SS304 2	0.99	0.6
SS304 3	0.99	0.7
SS304 4	0.97	-0.6
SS304 5	0.97	-0.6
Average SS304 AI	0.98	0.3
SS316 1	0.98	0.3
SS316 2	0.99	0.7
SS316 3	0.99	0.7
SS316 4	0.98	-0.2
SS316 5	1.00	2.3
Average SS316 AI	0.99	0.8



STUDY AN1111: Low Temperature Storage Stability of Optica ULV

SUMMARY

This study was conducted at Clarke Mosquito Control Products, Inc. in St. Charles, Illinois, USA, to determine the low temperature storage stability of Optica ULV Space Spray formulation.

Three batches of test substance were used in this study; each batch was used to prepare initial property test samples and final property test samples as described below:

Initial property test samples were used to determine the initial product properties of Colour, Physical state, Odour, pH, Viscosity, Specific gravity and Active ingredient content. Initial property test samples were stored at ambient room temperature when not in use for testing.

Final property test samples were used to determine the final product properties of Colour, Physical state, Odour, pH, Viscosity, Specific gravity and Active ingredient content after storage for 7 days at 0°C \pm 2°C.

Low temperature stability was evaluated per CIPAC MT 39.3 after the storage period.

Physical state:

Storage at 0°C \pm 2°C for 7 days had no effect on the physical stability of the Optica ULV Space Spray product.

The volume of solid and/or liquid which separates is not more than 0.3 ml.

Colour:

Storage at 0°C \pm 2°C for 7 days had no effect on the colour characteristics of the Optica ULV Space Spray product.

Odour

Storage at 0°C \pm 2°C for 7 days had no effect on the odor characteristics of the Optica ULV Space Spray product.

pH:

Storage at 0°C ±2°C for 7 days had negligible effect on the pH characteristics of the Optica ULV Space Spray product.

Initial vs. Final Overall Average pH

Batch Number	Initial Overall Average PH	Final Overall Average pH	Shift in Overall Average pH
2108110009	6.14	5.59	-0.55
2204110001	5.89	5.84	-0.04
2204140001	5.95	6.18	0.23

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Viscosity:

Storage at 0°C ±2°C for 7 days had negligible effect on the viscosity characteristics of the Optica ULV Space Spray product.

Batch Number	Initial Overall Average Viscosity	Final Overall Average Viscosity	Shift in Overall Average Viscosity
2108110009	23.0	23.2	0.2
2204110001	23.6	23.4	-0.2
2204140001	23.5	23.7	0.2

Initial vs. Final Overall Average Viscosity (cP) at 20°C and 50RPM

Initial vs. Final Overall Average Viscosity (cP) at 20°C and 60RPM

Batch Number	Initial Overall Average Viscosity	Final Overall Average Viscosity	Shift in Overall Average Viscosity
2108110009	22.9	23.2	0.3
2204110001	23.5	23.5	0.0
2204140001	23.6	23.7	0.1

Initial vs. Final Overall Average Viscosity (cP) at 40°C and 60RPM

Batch Number	Initial Overall Average Viscosity	Final Overall Average Viscosity	Shift in Overall Average Viscosity
2108110009	11.1	11.2	0.1
2204110001	11.5	11.3	-0.2
2204140001	11.4	11.3	-0.1

Specific gravity:

Storage at 0°C ±2°C for 7 days had negligible effect on the specific gravity characteristics of the Optica ULV Space Spray product.

Initial vs. Final Overall Average Specific Gravity

Batch Number	Initial Overall Average Specific Gravity	Final Overall Average Specific Gravity	Shift in Overall Average Specific Gravity
2108110009	1.0879	1.0858	-0.0020
2204110001	1.0869	1.0839	-0.0030
2204140001	1.0866	1.0838	-0.0028

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Overall Average Densities

Test Sample Type	Overall Average Density	
Initial	1.0852	
Final	1.0826	

Active ingredient content:

Storage at 0°C \pm 2°C for 7 days had negligible effect on the active ingredient content of the Optica ULV Space Spray product.

Batch 2108110009 AI Results Summary and% Change vs Initial AI

Test sample	% Broflanilide	% Change Broflanilide
Initial Product Property – 1	0.98	
Initial Product Property – 2	0.98	
Initial Product Property – 3	0.98	
Initial Product Property – 4	0.98	
Initial Product Property – 5	0.98	
Overall Initial Product Property Average	0.98	
Final Product Property – 1	0.99	0.6
Final Product Property – 2	0.99	0.5
Final Product Property – 3	0.99	0.5
Final Product Property – 4	0.97	-1.1
Final Product Property - 5	0.97	-1.2
Overall Final Product Property Average	0.98	-0.1

Batch 2204110001 AI Results Summary and% Change vs Initial AI

Test sample	% Broflanilide	% Change Broflanilide
Initial Product Property – 1	0.98	
Initial Product Property – 2	0.98	
Initial Product Property – 3	0.99	
Initial Product Property – 4	0.99	
Initial Product Property – 5	0.99	
Overall Initial Product Property Average	0.99	
Final Product Property – 1	0.97	-1.2
Final Product Property – 2	0.99	0.6

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Final Product Property – 3	0.98	-0.2
Final Product Property – 4	0.99	0.1
Final Product Property - 5	0.98	-0.5
Overall Final Product Property Average	0.98	-0.2

Batch 2204140001 AI Results Summary and% Change vs Initial AI

Test sample	% Broflanilide	% Change Broflanilide
Initial Product Property – 1	0.97	
Initial Product Property – 2	0.99	
Initial Product Property – 3	0.98	
Initial Product Property – 4	0.98	
Initial Product Property – 5	0.98	
Overall Initial Product Property Average	0.98	
Final Product Property – 1	0.98	-0.1
Final Product Property – 2	0.96	-1.9
Final Product Property – 3	0.97	-1.3
Final Product Property – 4	0.97	-1.0
Final Product Property - 5	0.97	-0.6
Overall Final Product Property Average	0.97	-1.0

STUDY AN1105: Long-Term Storage Stability of Optica ULV (12 Month Interim Report) SUMMARY

This study was conducted at Clarke Mosquito Control Products, Inc. in St. Charles, Illinois, USA, to determine the storage stability of Optica ULV Space Spray formulation at $30^{\circ}C \pm 2^{\circ}C$ for 12 months.

Three batches of test substance were used in this study; each batch was used to prepare initial property test samples and final property test samples as described below:

Initial property test samples were used to determine the initial product properties of Colour, Physical state, Odour, Container corrosion, Specific gravity and Active ingredient content. Initial property test samples were stored at ambient room temperature when not in use for testing.

Final property test samples were used to determine the final product properties of Colour, Physical state, Odour, Container corrosion, Specific gravity and Active ingredient content as well as Corrosion characteristics after storage for 12 months at 30° ±2°C.



Long term stability was evaluated after the storage period of 12 months.

Physical state:

Storage at 30°C ±2°C for 12 months had no effect on the physical stability of the Optica ULV Space Spray product.

Colour:

Storage at 30°C ±2°C for 12 months had no effect on the colour characteristics of the Optica ULV Space Spray product.

Odour:

Storage at 30°C ±2°C for 12 months had no effect on the odour characteristics of the Optica ULV Space Spray product.

Container corrosion:

Storage at 30°C ±2°C for 12 months had no effect on the material integrity of packaging materials of the Optica ULV Space Spray product.

Average% Weight Change per batch

Batch number		Average% Weight Change	
	2108110009	0.0	
	2204110001	0.0	
	2204140001	0.0	

Specific gravity:

Storage at 30°C \pm 2°C for 12 months had negligible effect on the specific gravity characteristics of the Optica ULV Space Spray product.

Overall Average Initial Specific Gravity vs. Overall Average Final Specific Gravity

Packaging/ Transport Material	Initial Overall Average Specific Gravity	Final Overall Average Specific Gravity	Shift in Overall Average Specific Gravity
12Month	1.0846	1.0830	-0.0016

Overall Average Densities

Test Sample Type	Overall Average Density
Initial	1.0826
12Month	1.0810



Active ingredient content:

Storage at 30°C \pm 2°C for 12 months had negligible effect on the active ingredient content of the Optica ULV Space Spray product.

Average 3 Month Final Property Results and % Change by batch

Batch	Average % Broflanilide	% Change vs Initial
2108110009	1.01	3.5
2204110001	1.01	3.6
2204140001	1.00	4.3
% Change must be between ≤ 10.0 %→PASS		

Average 6 Month Final Property Results and % Change by batch

Batch	Average % Broflanilide	% Change vs Initial
2108110009	0.97	-1.2
2204110001	0.97	-0.7
2204140001	0.97	1.1
% Change must be between $\leq 10.0 \% \rightarrow PASS$		

Average 9 Month Final Property Results and % Change by batch

Batch	Average % Broflanilide	% Change vs Initial	
2108110009	0.99	0.6	
2204110001	0.98	0.1	
2204140001	0.97	1.7	
% Change must be between \leq 10.0 % \rightarrow PASS			

Average 12 Month Final Property Results and % Change by batch

Batch	Average % Broflanilide	% Change vs Initial	
2108110009	0.98	0.4	
2204110001	0.98	0.7	
2204140001	0.97	1.6	
% Change must be between $\leq 10.0 \% \rightarrow PASS$			

Appendix 2. Manufacturing release specifications: Methods and notes

Attribute 2: Broflanilide content

The extension of the reversed phase HPLC method 994/TC/M3 (CIPAC/5388) for the determination of broflanilide in UL formulations was accepted as provisional CIPAC method in 2024.

If the buyer requires both g/kg and g/l at 20°C, then in case of dispute the analytical results shall be calculated as g/kg.

Samples of the formulation taken before and after the storage stability test may be analysed concurrently after the test in order to reduce the analytical error.