World Health Organization

WHO Prequalification Programme / Vector Control Product Assessment

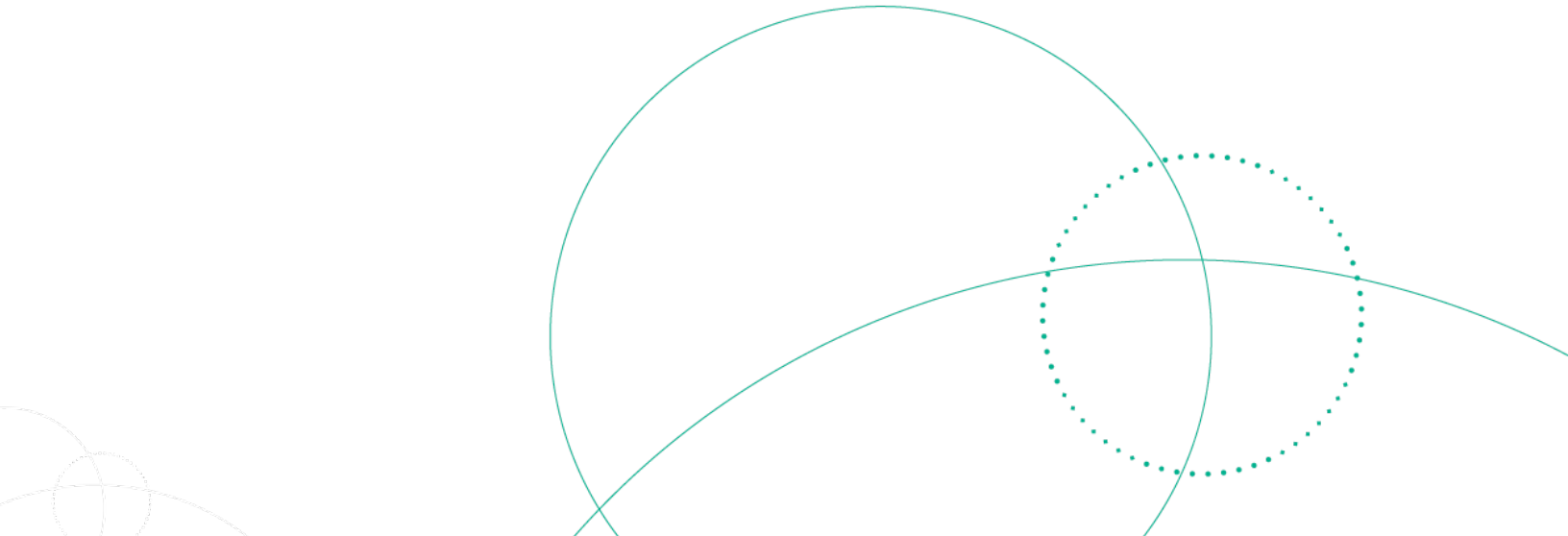
WHO Public Assessment Report: WHOPAR Part 3

Lambda-cyhalothrin 10% WP

(BR Agrotech Limited)

P-09306

Quality Assessment



Contents

1 Chemical and physical data

1.1 Chemical and physical properties

Lambda-cyhalothrin 10% WP having lambda-cyhalothrin is formulated as a wettable powder (WP) intended for use as indoor residual spray. It is packaged in 62.5g water-soluble bags. Several water-soluble bags are then packed in a LDPE bag/ tri-laminated sachet, which are further packed in the HDPE drums / corrugated boxes as per the customer requirement.

Data on the chemical and physical properties of the active ingredient and the product Lambda-cyhalothrin 10% WP were provided. These data were obtained from studies conducted according to established standards and/or Good Laboratory Practices (GLP) and are considered complete. Five batches were used for testing physical/chemical properties. The results are presented in Table 1. These summary results are based on the analysis of batches: PLMH210155; PLMH210164; PLMH220007; PLMH220016; PLMH220028.

Table 1. Chemical and physical properties for Lambda-cyhalothrin 10% WP

Data requirement	Study number	Test method ID	Results
Lambda-cyhalothrin content (test item stored at room temperature)	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	Lambda-cyhalothrin 463/WP/M CIPAC Handbook E, p.50-56, 1993	Five batches (PLMH210155; PLMH210164; PLMH220007; PLMH220016; PLMH220028) were tested in five replicates measured mean values, % w/w: 10.28; 10.26; 10.31; 10.15; 10.23 mean value of batches: 10.25
Lambda-cyhalothrin content (after accelerated storage stability test, 18 weeks at 30 °C)	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	Lambda-cyhalothrin 463/WP/M CIPAC Handbook E, p.50-56, 1993	Five batches (PLMH210155; PLMH210164; PLMH220007; PLMH220016; PLMH220028) were tested in five replicates measured mean values, % w/w: 10.16; 10.12; 10.18; 10.06; 10.14 mean value of batches: 10.13
Physical state	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	visual inspection	Fine powder Same physical state before and after accelerated storage stability test.
Colour	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	visual inspection	Off white Same colour before and after accelerated storage stability test.
Odour	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	physical examination	No characteristic odour. Same odour before and after accelerated storage stability test.

Table 1. Chemical and physical properties for Lambda-cyhalothrin 10% WP

Data requirement	Study number	Test method ID	Results
pH (1% w/v aqueous dilution, test item stored at room temperature)	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	MT 75.3, CIPAC Handbook J, p. 131, 2000	Five batches (PLMH210155; PLMH210164; PLMH220007; PLMH220016; PLMH220028) were tested in five replicates measured mean values: 6.69; 6.52; 6.65; 6.46; 6.61 mean pH value of batches: 6.59
pH (1% w/v aqueous dilution, (After accelerated storage stability test, 18 weeks at 30 °C)	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	MT 75.3, CIPAC Handbook J, p. 131, 2000	Five batches (PLMH210155; PLMH210164; PLMH220007; PLMH220016; PLMH220028) were tested. measured values: 6.42; 6.39; 6.45; 6.29; 6.42 mean pH value: 6.39
Wettability (Test items stored at room temperature)	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	MT 53.3.1, CIPAC Handbook F, p.165, 1995	Five batches (PLMH210155; PLMH210164; PLMH220007; PLMH220016; PLMH220028) were tested in five replicates. Measured mean values in seconds: 38; 36; 41; 32; 39 mean value of batches: 37.2 sec
Wettability (After accelerated storage stability test, 18 weeks at 30 °C)	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	MT 53.3.1, CIPAC Handbook F, p.165, 1995	Five batches (PLMH210155; PLMH210164; PLMH220007; PLMH220016; PLMH220028) were tested. Measured values in seconds: 41; 38; 44; 33; 42 mean value: 39.6 sec
Wet sieve test (Test item stored at room temperature)	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	MT 59.3, CIPAC Handbook F, p.179, 1994	Five batches (PLMH210155; PLMH210164; PLMH220007; PLMH220016; PLMH220028) were tested in five replicates. Measured mean values % retained: 0.45; 0.61; 0.52; 0.37; 0.42 mean value of batches: 0.47 %
Wet sieve test (After accelerated storage stability test, 18 weeks at 30 °C)	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	MT 59.3, CIPAC Handbook F, p.179, 1994	Five batches (PLMH210155; PLMH210164; PLMH220007; PLMH220016; PLMH220028) were tested. Measured values % retained: 0.52; 0.65; 0.58; 0.42; 0.48 mean value: 0.53 %
Suspensibility for lambda-cyhalothrin (Test items stored at room temperature)	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	MT 184, CIPAC Handbook K, p.142, 2003	Five batches (PLMH210155; PLMH210164; PLMH220007; PLMH220016; PLMH220028) were tested in two replicates at two concentration levels (low dose 0.75 % and high dose 1.5%) Measured suspensibility values %: low dose: 87.26; 86.59; 88.02; 86.91; 86.38 mean value: 87.03 % high dose: 84.19; 83.91; 84.01; 83.66; 82.94 mean value: 83.74 %

Table 1. Chemical and physical properties for Lambda-cyhalothrin 10% WP			
Data requirement	**Study number**	**Test method ID**	**Results**
Suspensibility for lambda-cyhalothrin (After accelerated storage stability test, 18 weeks at 30 °C)	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	MT 184, CIPAC Handbook K, p.142, 2003	Five batches (PLMH210155; PLMH210164; PLMH220007; PLMH220016; PLMH220028) were tested at two concentration levels (low dose 0.75 % and high dose 1.5%) measured suspensibility values %: low dose: 85.22; 84.24; 85.37; 83.66; 84.15 mean value: 84.53 % high dose: 82.34; 81.66; 82.21; 80.46; 80.06 mean value: 81.35 %
Persistent foam (Test items stored at room temperature)	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	MT 47.2, CIPAC Handbook F, p.152, 1994	Five batches (PLMH210155; PLMH210164; PLMH220007; PLMH220016; PLMH220028) were tested in five replicates. Measured mean values, ml: 45.2; 52.4; 48.2; 50.0; 53.2 mean value of batches: 49.8 ml
Persistent foam (After accelerated storage stability test, 18 weeks at 30 °C)	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	MT 47.2, CIPAC Handbook F, p.152, 1994	Measured values: Five batches (PLMH210155; PLMH210164; PLMH220007; PLMH220016; PLMH220028) were tested. measured values, ml: 47.5; 53.0; 50.5; 51.5; 53.5 mean value: 51.2 ml
Dissolution rate of water-soluble bags (Test item stored at room temperature)	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	CIPAC MT 176, CIPAC Handbook F, 1995	Five batches (PLMH210155; PLMH210164; PLMH220007; PLMH220016; PLMH220028) were tested in five replicates. Measured mean values in seconds: 12.0; 13.4; 12.8; 13.8; 13.4 mean value of batches: 13.1 sec
Dissolution rate of water-soluble bags (After accelerated storage stability test, 18 weeks at 30 °C)	RCC 4458 GLP study and "Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10 % WP (CYRON 25)"	CIPAC MT 176, CIPAC Handbook F, 1995	Five batches (PLMH210155; PLMH210164; PLMH220007; PLMH220016; PLMH220028) were tested. Measured values in seconds: 13.5; 14.0; 13.0; 14.5; 14.0 mean value: 13.8 sec

No significant differences were recorded among the properties of the product kept at ambient temperature and after accelerated storage stability test conditions (18 weeks at 30 °C).

1.2 Manufacturing, composition and formulant information

Data on the manufacturing process and product composition for Lambda-cyhalothrin 10% WP 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 Lambda-cyhalothrin 10% WP

Description of starting material	Lambda-cyhalothrin technical, lambda-cyhalothrin content ≥970 g/kg
Declaration of product formulation	Included in the confidential business information.
Production / formulation process	Lambda-cyhalothrin technical grade active ingredient is mixed with the other formulation components such as solvents, dispersing agents, wetting agents, antifoaming agents and carriers. The mixture is milled to the desired particle size. After this step the obtained material is packed into containers with approved labels. The packed products are organized and arranged for delivery.
Packaging	Lambda-cyhalothrin 10% WP is packed in the water-soluble bag. Several water-soluble bags are then packed in a LDPE bag / tri-laminated sachet, which are further packed in the HDPE drums / corrugated boxes as per the customer requirement.
Discussion of impurities	There are no known impurities in the technical material and inert ingredients of the product.
Certification of limits	Lambda-cyhalothrin: 10.0 % w/w, acceptable limits 9.0 to 11.0 % w/w

1.3 Enforcement analytical method

Table 3. Details of the analytical method used to determine lambda-cyhalothrin in Lambda-cyhalothrin 10% WP

Quantification of lambda-cyhalothrin	CIPAC GC method for lambda-cyhalothrin: 463/WP/M, CIPAC Handbook E, p.50-56, 1993 The analytical method is a GC method suitable for determination of lambda-cyhalothrin content in the formulation.

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

2 Entomological characterisation

Laboratory studies to characterize the effect of the active ingredient in Lambda-cyhalothrin 10% WP on Anopheline mosquito species and the residual efficacy on wall surface substrates were submitted to WHO as part of the prequalification dossier.

2.1 Laboratory Studies

Data on the residual efficacy of the formulated product Lambda-cyhalothrin 10% WP were provided for cement, wood, mud, glass and tile substrates. These data were obtained from studies conducted according to established standards and/or Good Laboratory Practices (GLP).

2.1.1 Optimum dosage selection and residual efficacy

One study was presented to characterize the residual efficacy of the product on test surfaces under laboratory conditions and to determine the LC_{50} and LC_{90} of the formulated product. The study contained two sub-studies, a range finding study and a residual efficacy study. In the range finding study, prepared substrate blocks of cement, wood, mud, glass and tile were treated with 20 mg AI/m^2, 22.5 mg AI/m^2, 25 mg AI/m^2, 27.5 mg AI/m^2 and 30 mg AI/m^2 test item concentration; in the residual efficacy study, the treatment concentrations used were 20 mg AI/m^2, 25 mg AI/m^2, and 30 mg AI/m^2. The selection of concentrations in the range finding and residual efficacy studies were aligned with the labelled application rates for the product to which the applicant was claiming equivalence.

The WHO cone test was the experimental method used in bioavailability studies. The negative control in each sub-study were prepared blocks of each substrate sprayed with distilled water and the positive control was a prequalified wettable powder product containing 10% lambda-cyhalothrin, to which the product, Lambda-cyhalothrin 10% WP, was claiming equivalence, hereafter referred to as PC1. The endpoint used to evaluate bioavailability was 24-hour mortality, with a threshold of ≥80% mortality. The residual efficacy criterion for establishing equivalence was the number of months during which mortality was ≥80.

The mosquito test system was *Anopheles stephensi.* Susceptibility to the diagnostic doses of alpha-cypermethrin (0.05%), bendiocarb (0.1%), and malathion (5.0%) was confirmed in testing conducted in September 2021.

The results for the range finding and residual efficacy studies are presented in Tables 4 and 5. In the range finding study, greater than 80% mortality was observed on all substrates and concentrations at each timepoint from 0 to two weeks. In the residual efficacy study, at the recommended concentration of 25 mg AI/m^2, greater than 80% mortality was observed on cement, wood and mud surfaces to 12 weeks, and on glass and tile surfaces to 14 weeks, using the insecticide susceptible test system.

LC_{50} and LC_{90} values from the residual efficacy study were calculated using probit-plane regression analyses. These results are presented in Table 6.

Table 4. 24-hour mortality (%) for WHO cone tests conducted on prepared substrate blocks treated with Lambda-cyhalothrin 10% WP

Dose (mg AI/m²)	Week			Week		
	0	1	2	0	1	2
	Cement			Wood		
20	100	100	100	100	100	100
22.5	100	100	100	100	100	100
25	100	100	100	100	100	100
27.5	100	100	100	100	100	100
30	100	100	100	100	100	100
	Mud			Glass		
20	100	100	95 (90 – 100)	100	100	100
22.5	100	100	100	100	100	100
25	100	100	100	100	100	100
27.5	100	100	100	100	100	100
30	100	100	100	100	100	100
	Tile					
20	100	100	100			
22.5	100	100	100			
25	100	100	100			
27.5	100	100	100			
30	100	100	100			

Table 5. 24-hour mortality (%, 95% CI*) for WHO cone tests conducted on prepared substrate blocks treated with Lambda-cyhalothrin 10% WP against insecticide susceptible *An. stephensi*

Dose (mg AI/m²)	Week										
	0	1	2	4	6	8	10	12	14	16	18
	Cement										
20	100	100	100	100	92.5 (90-95)	87.5 (85-90)	82.5 (80-85)	77.5 (75-80)	70 (66-74)	62.5 (60-65)	35 (32-38)
25	100	100	100	100	95 (92-98)	90 (88-94)	85 (82-88)	82.5 (80-85)	75 (72-78)	67.5 (65-70)	45 (42-48)
30	100	100	100	100	97.5 (95-100)	95 (92-98)	90 (86-94)	85 (82-88)	80 (76-84)	72.5 (70-75)	52.5 (50-55)
PC1 (25)	100	100	100	100	95 (92-98)	90 (90-90)	85 (82-88)	82.5 (80-85)	75 (72-78)	65 (62-68)	42.5 (40-45)
	Wood										
20	100	100	100	100	92.5 (90-95)	90 (90-90)	85 (82-88)	80 (76-84)	72.5 (70-75)	65 (62-68)	40 (40-40)
25	100	100	100	100	97.5 (95-100)	92.5 (90-95)	87.5 (85-90)	85 (82-88)	77.5 (75-80)	70 (66-74)	47.5 (45-50)
30	100	100	100	100	100	95 (92-98)	92.5 (90-95)	87.5 (85-90)	82.5 (80-85)	75 (70-75)	55 (52-58)
PC1 (25)	100	100	100	100	95 (92-98)	92.5 (90-95)	85 (82-88)	85 (82-88)	77.5 (75-80)	70 (66-74)	45 (42-48)
	Mud										
20	100	100	97.5 (95-100)	92.5 (90-95)	90 (90-90)	82.5 (80-85)	80 (76-84)	75 (70-75)	67.5 (65-70)	60 (62-68)	32.5 (30-35)
25	100	100	100	97.5	92.5	87.5	82.5	80	72.5	65	40

Table 5. 24-hour mortality (%, 95% CI*) for WHO cone tests conducted on prepared substrate blocks treated with Lambda-cyhalothrin 10% WP against insecticide susceptible *An. stephensi*

Dose (mg AI/m²)	Week										
	0	1	2	4	6	8	10	12	14	16	18
				(95-100)	(90-95)	(85-90)	(80-85)	(76-84)	(70-75)	(62-68)	(36-44)
30	100	100	100	100	97.5 (95-100)	92.5 (90-95)	87.5 (85-90)	82.5 (80-85)	77.5 (75-80)	70 (66-74)	50 (46-54)
PC1 (25)	100	100	100	95 (92-98)	92.5 (90-95)	87.5 (85-90)	82.5 (80-85)	80 (76-84)	72.5 (70-75)	65 (62-68)	40 (36-44)
	Glass										
20	100	100	100	100	95 (92-98)	92.5 (90-95)	87.5 (85-90)	82.5 (80-85)	75 (72-78)	67.5 (65-70)	42.5 (40-45)
25	100	100	100	100	100	97.5 (95-100)	90 (90-90)	87.5 (85-90)	80 (76-84)	72.5 (70-75)	55 (52-58)
30	100	100	100	100	100	100	92.5 (90-95)	90 (86-94)	85 (82-88)	77.5 (73-82)	60 (56-64)
PC1 (25)	100	100	100	100	97.5 (95-100)	95 (92-98)	90 (86-94)	85 (82-88)	82.5 (80-85)	75 (72-78)	55 (52-58)
	Tile										
20	100	100	100	100	100	97.5 (95-100)	90 (86-94)	85 (82-88)	77.5 (73-82)	70 (66-74)	50 (46-54)
25	100	100	100	100	100	100	92.5 (90-95)	87.5 (85-90)	82.5 (80-85)	75 (72-78)	57.5 (55-60)
30	100	100	100	100	100	100	95 (92-98)	90 (86-94)	87.5 (85-90)	80 (76-84)	65 (62-68)
PC1 (25)	100	100	100	100	100	97.5 (95-100)	92.5 (90-95)	87.5 (85-90)	82.5 (80-85)	75 (72-78)	57.5 (53-62)

*Confidence Intervals (expressed in parenthesis) have been provided by the applicant and not evaluated as part of the WHO Prequalification process

Table 6. Time series LC_{50} and LC_{90} for Lambda-cyhalothrin 10% WP determined using WHO cone tests conducted on prepared substrate blocks against insecticide susceptible *An. stephensi*

Parameter µg/ml (95% CI)	Week										
	0	1	2	4	6	8	10	12	14	16	18
	Cement										
LC_{50}	-	-	-	-	0.124 (0.00-0.453)	0.149 (0.00-0.453)	0.183 (0.00-0.494)	0.134 (0.00-0.536)	0.205 (0.00-0.557)	0.253 (0.00-0.615)	0.564 (0.414-0.715)
LC_{90}	-	-	-	-	0.356 (0.130-0.583)	0.462 (0.328-0.597)	0.612 (0.220-1.037)	0.839 (0.00-1.937)	1.071 (0.00-2.744)	1.647 (0.00-5.88)	2.197 (0.00-4.754)
	Wood										
LC_{50}	-	-	-	-	0.040 (0.00-0.394)	0.093 (0.00-0.457)	0.137 (0.00-0.472)	0.133 (0.00-0.509)	0.195 (0.00-0.535)	0.234 (0.00-0.598)	0.504 (0.388-0.669)
LC_{90}	-	-	-	-	0.278 (0.00-0.843)	0.404 (0.178-0.632)	0.534 (0.000-0.736)	0.702 (0.086-1.318)	0.927 (0.00-2.084)	1.429 (0.00-4.615)	2.034 0.00- 6.610)
	Mud										
LC_{50}	-	-	-	0.040 (0.00-0.394)	0.172 (0.00-0.435)	0.187 (0.00-0.452)	0.184 (0.00-0.519)	0.139 (0.00-0.564)	0.218 (0.00-0.578)	0.275 (0.00-0.629)	0.609 (0.406-0.813)
LC_{90}	-	-	-	0.278 (0.00-0.843)	0.412 (0.284-0.541)	0.539 (0.376-0.702)	0.700 (0.00-1.530)	1.009 (0.00-2.824)	1.238 (0.00-3.579)	1.893 (0.00-7.399)	2.331 (0.00-5.257)
	Glass										
LC_{50}	-	-	-	-	-	0.040 (0.00-0.394)	0.079 (0.00-0.464)	0.131 (0.00-0.486)	0.187 (0.00-0.513)	0.218 (0.00-0.578)	0.465 (0.363-0.568)
LC_{90}	-	-	-	-	-	0.278 (0.00-0.843)	0.487 (0.270-0.705)	0.628 (0.278-0.908)	0.804 (0.038-1.570)	1.238 (0.00-3.579)	1.686 (0.00-3.582)
	Tile										
LC_{50}	-	-	-	-	-	-	0.019	0.071	0.183	0.205	0.402

Parameter µg/ml (95% CI)	Week										
	0	**1**	**2**	**4**	**6**	**8**	**10**	**12**	**14**	**16**	**18**
							(0.00-0.457)	(0.00-0.478)	(0.00-0.492)	(0.00-0.557)	(0.249-0.557)
LC_{90}	-	-	-	-	-	-	0.304 (0.178-0.632)	0.608 (0.104-1.113)	0.699 (0.218-1.181)	1.071 (0.00-2.744)	1.562 (0.00- 4.259)

2.2 Entomological characterisation conclusions

The submitted laboratory studies characterize the residual efficacy of the formulated product on prepared substrate blocks treated with a single application of Lambda-cyhalothrin 10% WP against one strain of *An. stephensi* mosquitoes. Following an application of 25 mg AI/m^2, the laboratory results demonstrate the bioavailability of Lambda-cyhalothrin 10% WP for up to twelve weeks on cement, wood, and mud blocks against insecticide susceptible *An. stephensi.* Cross-resistance between Lambda-cyhalothrin 10% WP and other insecticides used for indoor residual spraying was not assessed.

3 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, physical/chemical characteristics and bioavailability 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 7. List of studies submitted to WHO as part of the prequalification dossier

Studies that were relied upon for decision making	
Study number	**Study title**
9669/2021	Comparative insecticidal efficacy and residual activity of Lambda-cyhalothrin 10% WP against Malarial Vector (*Anopheles stephensi*) on selected substrates.
4458	Determination of Stability at elevated temperature before and after storage of Lambda-cyhalothrin 10% WP
Study Report 31.08.2022	Quality Control Analysis of Five Batches of Lambda-cyhalothrin 10% WP
Studies that were not used to inform decision making	
Study number	**Study title**
	None

4 Manufacturing release specifications

4.1 Summary of manufacturing release specifications

Table 8. Summary of manufacturing release specifications

Description: The material shall consist of a homogeneous mixture in the form of powder, together with filler and any other necessary formulants. It shall be in the form of an off-white, very fine and slightly dusty powder, free from visible extraneous matter and hard lumps.

ID	Property	Method	Declared value
1*	Sub-sampling	See Appendix	
2	Lambda-cyhalothrin identity	Lambda-cyhalothrin 463/WP/M CIPAC Handbook E, p.50-56, 1993)	
3	Lambda-cyhalothrin content	Lambda-cyhalothrin 463/WP/M CIPAC Handbook E, p.50-56, 1993	100 g/kg (equivalent to 10% w/w) (± 10% of the declared content)
4	Relevant impurities	Not applicable	No relevant impurities
5	pH range	CIPAC MT 75.3, CIPAC Handbook J, p.131, 2000	5.5 to 9
6	Wet sieve test	CIPAC MT 185, CIPAC Handbook K, p.149, 2003	Maximum: 2% retained on a 75 µm test sieve
7*	Suspensibility	CIPAC MT 184, CIPAC Handbook K, p.142, 2003	The suspensibility (chemical assay) should be minimum 50% in CIPAC Standard Water D, after 30 min
8*	Persistent foam	CIPAC MT 47.3 CIPAC Handbook O, p.177, 2017	Maximum: 60 ml after 1 min
9	Wettability	CIPAC MT 53.3, CIPAC Handbook F, p.165, 1995	The formulation shall be completely wetted in 60 seconds without swirling
10*	Dissolution of the bag	CIPAC MT 176, CIPAC Handbook F, p. 444, 1995	Flow time of the suspension: maximum 30 sec.

*Indicates that additional information is available in Appendix 2.

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.

4.2 Storage

Accelerated storage stability data were generated as per CIPAC MT 46.4 on Lambda-cyhalothrin 10% WP. Test samples were stored for 18 weeks at 30 °C. 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. Products which have been stored in accordance with these recommendations are expected to maintain their declared physical/chemical properties for up to 2 years.

Where products that have been subjected to prolonged storage (>2 years), adverse conditions, or in opened/damaged packaging/containers, product testing is recommended to assess its suitability for use.

Appendix 1. Summary of available data considered in Module 3

Batches used to generate the physical/chemical data

Batch number	Date	Formulation	Uses
PLMH210155	17/08/2021	Off white solid	storage stability
PLMH210164	13/10/2021	Off white solid	storage stability
PLMH220007	14/01/2022	Off white solid	storage stability
PLMH220016	18/02/2022	Off white solid	storage stability
PLMH220028	14/03/2022	Off white solid	storage stability

Appendix 2. Manufacturing release specifications: Methods and notes

Sub-sampling

Lay the bag on a bench and carefully open one side of the bag with a cutter, taking care not to damage the seals. Transfer the contents of the bag into a suitable flask. This material shall be used to carry out the tests for:

- active ingredient identity
- active ingredient content
- pH range
- wettability
- wet sieve test
- suspensibility
- persistent foam
- dissolution of the bag

The bag is then opened on three sides, completely cleaned from adhering powder by brushing or suction and weighed to the nearest 0.01 g. Aliquots of an aqueous solution of the bag material shall be used in the suspensibility and persistent foam tests.
In the case of delay of the above tests, the bag shall be stored in a watertight container (glass bottle or equivalent) to avoid any change in its properties.

Attribute 7: Suspensibility

The formulation should be tested at the highest and lowest rates of use recommended by the supplier, provided this does not exceed the conditions given in method MT 184.

Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric and solvent extraction determination may be used on a routine basis provided that these methods have been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".

Attributes 7 and 8: Suspensibility and Persistent foam

The procedure for adding the bag material to the solution for the suspensibility and persistent foam tests should be as follows:
Prepare a stock solution of the bag material (1 mg/ml) by weighing approximately a sample (100 mg) of the bag (excluding sealed parts) to the nearest mg. Dissolve this sample by stirring in the standard water used for the tests to give a final volume of 100 ml. Store the stock solution in a stoppered bottle before use.
Calculate the volume (V ml) of the stock solution of the bag to be added to the test suspension of the wettable powder according to the following equation:
V(ml) = X *x* 1000B/W
Where: B (g) = weight of the emptied and cleaned bag
W (g) = nominal weight of the WP contained in the bag
X (g) = weight of the WP sample used in the test

Attribute 9: Persistent foam

The mass of sample to be used in the test should be specified at the highest rate recommended for Lambda-cyhalothrin 10 WP (1.5% or 1.5 g test item in 100 ml). The test is to be conducted in CIPAC standard water D.

Attribute 10: Dissolution of the bag

The sampling of the bag for the dissolution test should be as follows:
Lay the empty cleaned bag in its original configuration (double layer). Delineate and then cut up a test sample including part of the upper seal (5 cm) and symmetrically including the vertical seal (10 cm). If the size of the bag is less than this dimension, use the whole bag.
Carry out the dissolution test immediately to avoid any modification of the sample.