

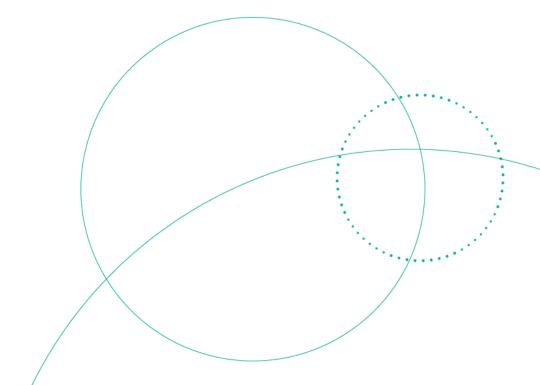
WHO Prequalification Programme / Vector Control Product Assessment

WHO Public Assessment Report: WHOPAR Part 3

Vector Guard (Disease Control Technologies LLC)

P-09284

Quality Assessment





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1 Chemical and physical data

1.1 Chemical and physical properties

Data on the chemical and physical properties of the active ingredient and the product Vector Guard were provided. These data were obtained from studies conducted according to established standards and/or Good Laboratory Practices (GLP) and are considered complete. Product specific properties are summarized in Table 1. Numerical results are presented as: mean (range). These summary results are based on the analysis of batches: RS120W-APBO120R, RS121W-APBO121R, RS122W-APBO122R.

Complete results from the Studies 25238 and 18037 are available in Appendix 1.

Table 1. Chemical and physical properties fo	r Vector Guard fabric (roof)	
Data requirement	Test method ID	Result
Identification of Alpha-cypermethrin and Piperonyl butoxide (PBO)	Alpha-cypermethrin CIPAC 454/LN/M/3.2 Piperonyl butoxide CIPAC 33/LN/M/3	The active ingredients each comply with an identity test
Alpha-cypermethrin content Accelerated Storage Alpha-cypermethrin content Retention	CIPAC 454/LN/M/3.2	5.65 g/kg (5.59 - 5.71 g/kg)* (5.57 - 5.73 g/kg)** 99.0% (97.9-99.8%)*
Piperonyl butoxide content Accelerated storage piperonyl butoxide retention	CIPAC 33/LN/M/3	18.59 g/kg (18.40-18.71 g/kg)* (18.12 - 18.90 g/kg)** 98.93% (96.7-100.5%)*
Wash resistance index (Alpha-cypermethrin) Accelerated Storage Alpha-cypermethrin WRI	CIPAC MT195	98.13% (97.80-98.70%)* 97.03% (96.10-97.80%)*
Wash resistance index (Piperonyl butoxide) Accelerated Storage Piperonyl butoxide WRI	CIPAC MT195	96.67% (95.60-97.90%)* 94.77% (93.70-95.50%)*
Mesh size (mean)	See Appendix 2	Average (21-22)* holes/cm ² Minimum (20-21)** holes/cm ²
Fabric weight	ISO 3801	36.5 g/m ² (36.0-36.8 g/m ²)*
Dimensional stability of netting to washing	ISO 5077/6330	Length: -4.9% (-7.6% to -2.6%)* Width: -4.7% (-6.7% to -3.2%)*
Accelerated storage dimensional stability	150 5077/6330	Length: -1.5% (-1.8% to -1.3%)* Width: -7.4% (-8.3% to -6.9%)*
Bursting strength Accelerated storage bursting strength	ISO 13938-2	336 kPa (328-346 kPa)* (295-360 kPa)*
	13230-7	375 kPa (355-387 kPa)* (323-408 kPa)*

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Seam bursting strength	ISO 13938-2	499 kPa (465-522 kPa)* (402-605 kPa)*
Flammability	EN 1102	No ignition or propagation. Maximum hole dimension 100 mm length.

* range of means

** range of individual measurements in samples

Data requirement	Test method ID	Result
Identification of Alpha-cypermethrin	CIPAC 454/LN/M/3.2	The active ingredient complies with an identity test
Alpha-cypermethrin content Accelerated Storage Alpha-cypermethrin content retention	CIPAC 454/LN/M/3.2	5.31 g/kg (5.12 - 5.47 g/kg)* (5.10 - 5.50 g/kg)** 98.3% (95.1-100.2%)*
Alpha-cypermethrin wash resistance index	CIPAC MT195	98.67% (98.3-98.9%)*
Fabric weight	ISO 3801	38.0 g/m ² (37.5 -38.3 g/m ²)* (37.1 - 38.5 g/m ²)**

Table 1 and Table 2 include details of the alpha-cypermethrin + piperonyl butoxide fabric which is to be used for the roofs of nets with Royal Sentry 2.0 fabric (alpha-cypermethrin only) as sides. The new fabric (used in roof) is referred to as Vector Guard. The finished product with the new fabric for the roof and the Royal Sentry 2.0 fabric for the sides is referred to as Vector Guard.

The data provided for the net sides corresponds to the one compiled in Vector Guard dossier. For full information see Decision document 003-002.

No significant differences were recorded among the properties of the product kept at ambient temperature and after accelerated storage stability test conditions.

1.2 Manufacturing, composition and formulant information

Data on the manufacturing process and product composition for Vector Guard 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 proc	ess and product composition data submitted for Vector Guard
Description of starting material	The starting material is alpha-cypermethrin active ingredient masterbatch (for roof and sides), piperonyl butoxide synergist masterbatch (for roof), colour masterbatch (for roof and sides) and HDPE (for roof and sides). All masterbatches (Al/synergist as well as colour) are obtained from third-party suppliers.
	The sources of active ingredients are supported by a current evaluation report confirming compliance of the materials with the established WHO specification.
Declaration of product formulation	Included in the confidential business information.



Table 2. Manufacturing proc	ess and product composition data submitted for Vector Guard
	Rectangular nets are constructed from separate roof and wall polyethylene fabrics with yarn deniers of 120 D for the roof and 120 D for the walls, with a fabric weight of 35 g/m ² .
Production / formulation process	The manufacturing process includes blending of the raw materials (mixture of HDPE granules, alpha-cypermethrin masterbatch - for roof and sides fabrics, piperonyl butoxide masterbatch - for roof fabric), extrusion of the mixture for yarn spinning, beam winding, warping, warp knitting, and heat setting.
	The finished product is manufactured by cutting and sewing of the fabric (roof and sides), addition of label tag, folding prior to packaging, packing, and baling.
Packaging	Nets may be packed into individual polyethylene bags with printed labels. Either packed or loose nets are compressed and baled, with a quantity of 50 nets/bale, and the bale is covered with an outer bag. Nets are pressed by a hydraulic press to the desired height then strapped.
Discussion of impurities	There are no relevant impurities of toxicological concern.
Certification of limits	Roof: Alpha-cypermethrin: 5.8 g/kg, acceptable limits 4.35-7.25 g/kg Piperonyl butoxide: 20.3 g/kg (roof), acceptable limits 15.23-25.38 g/kg
	Sides: Alpha-cypermethrin: 5.8 g/kg, acceptable limits 4.35-7.25 g/kg

1.3 Enforcement analytical method

Table 3. Details of the analytical method used to determine Alpha-cypermethrin and Piperonyl Butoxide in Vector Guard					
Quantification of alpha- Alpha-cypermethrin: 454/LN/M/3.2, CIPAC Handbook M, p. 41, 2009.					
cypermethrin and piperonyl					
butoxide	Piperonyl butoxide: 33/LN/M/3, CIPAC Handbook N, p.111, 2012.				

These methods are appropriate for the determination of the active ingredient content of the product.



2 Chemical and entomological fabric characterisation

Laboratory studies to characterize the availability of the active ingredient and synergist and the insecticidal effect of the fabric of Vector Guard on Anopheline mosquito species were submitted to WHO as part of the prequalification dossier. Sampled pieces of ITNs used in the biological laboratory studies were characterized for their alpha-cypermethrin and piperonyl butoxide content using GC.

2.1 Laboratory studies

2.1.1 Entomological characterisation

Data on the wash regeneration and wash resistance properties of the Vector Guard product were provided. These data were obtained from studies conducted according to established standards and/or Good Laboratory Practices (GLP). These summary results are based on ITNs drawn from batch numbers RS120W-APBO120R, RS121W-APBO121R, RS122W-APBO122R.

One laboratory study was submitted to characterise the Vector Guard fabric. Bioavailability was evaluated in wash regeneration and wash resistance studies. The endpoint(s) used to evaluate bioavailability were knockdown at 60-minutes post-exposure and 24-hour control corrected mortality (M24). Demonstration of bioavailability post-wash was used to determine the wash interval that was selected for use in the wash resistance study. Thresholds of \geq 95% knockdown and/or \geq 80% mortality in WHO cone tests were used to determine wash resistance. Results from pyrethroid mosquitoes were used to select the wash interval and evaluate the wash resistance results.

The bioavailability of alpha-cypermethrin and piperonyl butoxide on the surface of the ITN was characterized using the insecticide susceptible test system *Anopheles gambiae* s.s. Ifakara strain and the pyrethroid resistant test system *Anopheles arabiensis* Kingani strain, with pyrethroid resistance mediated by the over-expression of cytochrome P450 enzymes and an observed mortality to the diagnostic dose of alpha-cypermethrin of 17% in WHO cylinder tests conducted in March 2022 (Table 4).

WHO cone tests were the experimental method used in bioavailability studies. The wash interval was determined to be two days. Using this wash interval, and the KD results for the pyrethroid resistant *An. arabiensis* Kingani test system, Vector Guard was wash resistant to 20 washes. These results are summarized in Tables 4-6.

Table 4. Insecticide resistance profile of laboratory reared An. gambiae s.s. Ifakara and An. arabiensis Kingani test systems using WHO cylinder tests in March 2022						
M24 (%)						Alpha-cypermethrin (0.05%) + PBO (4%)
<i>An. gambiae</i> s.s. Ifakara	100	100	100	100	100	100
An. arabiensis Kingani	11	22	17	99	100	100



Table 5. Wash regeneration study results for Vector Guard roof and sides using the insecticide susceptible *An. gambiae* s.s. Ifakara test system and the pyrethroid resistant *An. arabiensis* Kingani strain in WHO cone tests to characterize the bioavailability of alpha-cypermethrin and PBO

Dave neet week		An. gambiae Ifa	kara	An. arabiensis Kingani			
Days post-wash	n	%KD (95% CI) %M24 (95% CI)		n	%KD (95% CI)	%M24 (95% CI)	
Vector Guard roof							
UW	200	100	100	200	100	100	
1	200	96.5 (94.1-98.9)	96.5 (94.1-98.9)	200	100	75.0 (67.7-82.3)	
2	200	100	100	200	100	95.5 (92.9-98.1)	
3	200	100	100	200	100	93.5 (90.2-96.8)	
5	200	100	100	200	100	99.0 (97.0-101.0)	
7 200		100	100	200	100	93.5 (89.7-97.3)	
Vector Guard sides (120D)							
UW	200	100	99.5 (98.5-100)	200	100	99.5 (98.5-100)	
1	200	100	100	200	100	59.0 (47.9-70.1)	
2	2 200 100 100 200 100		94.5 (90.8-98.2)				
3	3 200 100		100	200	100	93.0 (88.4-97.6)	
5	5 200 100 <u>99.0</u> (97.0-100) 200 100		94.5 (90.8-98.2)				
7			100	200	100	100	



5.0

(1.9 - 8.1)

1.0

(0.0-2.4)

4.5

(1.2-7.8)

Table 6. Wash resistance study results for Vector Guard using the insecticide susceptible *An. gambiae* Ifakara test system and the pyrethroid resistant *An. arabiensis* Kingani strain in WHO cone tests to characterize the bioavailability of alphacypermethrin and PBO

Vector Guard roof								
Wash No.		An. gambiae Ifa	Ikara		An. arabiensis Kingani			
wash No.	n	%KD (95% CI)	%M24 (95% CI)	n	%KD (95% CI)	%M24 (95% CI)		
0	200	100	100	200	100	100		
1	200	100	100	200	100	27.5 (21.8-33.2)		
3	200	100	100	200	100	6.5 (3.0-10.0)		
5	200	100	100	200	100	5.0 (2.3-7.7)		
10	200	100	100	200	100	16.0 (10.7-21.3)		
15	200 100 100 200		97.0 (93.4-100)	5.5 (2.4-8.6)				
20	200	100	100 100 200		97.0 (94.8-99.2)	7.5 (3.1-11.9)		
25	200	100	100	200	98.5 (96.8-100)	5.0 (1.4-8.6)		
/ector Guard sides (120	(סו							
Wash No.	An. gambiae Ifakara				An. arabiensis Kingani			
wash no.	n	%KD (95% CI)	%M24 (95% CI)	n	%KD (95% CI)	%M24 (95% CI)		
0	200	100	100	200	100	100		
1	200	100	94.0 (90.0-98.0) 200		100	55.5 (47.1-63.9)		
3	200	100	100 200		100	15.0 (7.7-22.3)		
5	5 200 100 <u>99.5</u> (98.5-100)		99.5 (98.5-100)	200	96.5 (93.7-99.3)	8.0 (4.3-11.7)		
10 200 100		78.0 (70.7-85.3)	200	100	11.0 (6.1-15.9)			
			. ,			· · · /		

2.1.1.1 Chemical characterisation

200

200

200

100

99.0

(97.6-100)

100

15

20

25

Data on the alpha-cypermethrin and piperonyl butoxide content of sampled pieces of the Vector Guard product used in the entomological laboratory wash resistance study and the supplemental laboratory study were provided. These data were obtained from studies conducted according to established standards and/or Good Laboratory Practices (GLP). These summary results are based on ITNs drawn from batches RS120W-APBO120R, RS121W-APBO121R, and RS122W-APBO122R. The results are summarized in Tables 7 and 8.

100

91.5

(87.1-95.9)

37.5

(28.4-46.6)

200

200

200

100

98.0

(96.1 - 99.9)

56.5

(44.3-68.7)



Table 7. AI content and retention of sampled pieces of Vector Guard used in the entomological wash resistance study (batch numbers RS120W-APBO120R, RS121W-APBO121R, and RS122W-APBO122R)

Wash No.	Mean Alpha- cypermethrin content (g/kg)	RSD (%)	Alpha- cypermethrin retention	Alpha- cypermethrin retention per wash	Mean piperonyl butoxide content (g/kg)	RSD (%)	Piperonyl butoxide retention	Piperonyl butoxide retention per wash
Vector 0	Guard roof							
0	5.75 (5.55-5.94)	1.3	-	-	18.7 (17.6-19.3)	2.2	-	-
1	5.37 (5.26-5.48)	1.7	93.39%	100.0%	16.6 (16.2-16.8)	1.7	88.77%	88.5%
3	5.40 (5.22-5.57)	2.7	93.91%	100.2%	16.9 (16.6-17.3)	1.7	90.37%	96.6%
5	5.38 (5.14-5.49)	3.0	93.57%	100.0%	16.0 (15.4-16.4)	2.7	85.56%	96.9%
10	5.37 (5.24-5.44)	1.6	93.39%	100.0%	15.7 (15.5-15.8)	0.8	83.96%	98.3%
15	5.40 (5.34-5.45)	1.0	93.91%	100.0%	15.0 (14.8-15.3)	1.6	80.21%	98.5%
20	5.34 (5.14-5.45)	2.6	92.87%	100.0%	14.6 (14.0-15.3)	4.5	78.07%	98.8%
25	5.36 (5.13-5.47)	3.0	93.22%	100.0%	14.8 (13.5-15.7)	6.6	79.14%	99.1%
Vector C	Guard sides (120D)				· · · · · ·			
0	5.37 (5.16-5.75)	3.2	-	-	-	-	-	-
1	5.16 (4.68-5.47)	6.6	96.09%	96.0%	-	-	-	-
3	4.91 (4.55-5.32)	6.9	91.43%	97.1%	-	-	-	-
5	5.32 (5.10-5.49)	3.4	99.07%	99.8%	-	-	-	-
10	4.96 (4.72-5.41)	6.2	92.36%	99.2%	-	-	-	-
15	4.89 (4.41-5.27)	7.6	91.06%	99.4%	-	-	-	-
20	5.07 (4.61-5.45)	7.1	94.41%	99.7%	-	-	-	-
25	4.87 (4.60-5.32)	6.7	90.69%	99.6%	-	-	-	-

The mean AI content presented in Table 7 was determined based on 12 net samples (for sides) and 9 net samples (for roof) for Wash No. 0 and 4 net samples (for sides and roof) for all other Wash Nos. belonging to three batches (RS120W-APBO120R, RS121W-APBO121R, and RS122W-APBO122R), indicating ranges to the AI content in parenthesis.

Al retention per wash in Table 7 (ranges in parenthesis) is calculated as:

• Al retention per wash = $100 \text{ x} \text{ }^{\text{n}}\text{V}(t_{n}/t_{0})$ where:

 t_n = total active ingredient content after n washing cycles

t₀ = total active ingredient content before washing

n = number of washes.

2.2 Chemical and entomological fabric characterisation conclusions

The submitted laboratory studies characterize the fabric of Vector Guard against two strains of *An. gambiae* complex mosquitoes. Following three washes intended to deplete the surface of the fabric of bioavailable insecticide, the laboratory results demonstrate that sufficient bioavailable insecticide to induce mortality in insecticide susceptible and pyrethroid resistant test systems was present two days after washing.

Wash resistance to 20 washes using standardised washing methods was demonstrated against two *An. gambiae* complex test systems, one which was insecticide susceptible and one pyrethroid resistant system carrying metabolic resistance mechanisms. Based on the submitted studies, Vector Guard is wash resistant to 20 washes using a two-day wash interval against pyrethroid susceptible *An. gambiae* Ifakara



and against pyrethroid resistant *An. arabiensis* Kingani which carries metabolic resistance mediated by the over-expression of cytochrome P450 enyzmes.

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, biological regeneration time, and bioavailability using products prepared with a defined wash interval 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 9. List of studies related to chemistry submitted to WHO as part of the prequalification dossier							
	Studies that were relied upon for decision making						
Study number	Study Title						
25238	Physical-chemical properties and accelerated storage stability of 3 batches of Vector Guard [®] [alpha- cypermethrin 5.8 g/kg (roof and sides) + piperonyl butoxide 20.3 g/kg (roof) long-lasting (incorporated into polyethylene) insecticidal net (LN)]						
18037/2020 - 1	CITEVE Physical Testing of Vector Guard Batch RS120W-APBO120R						
18034/2020 - 1	CITEVE Physical Testing of Vector Guard Batch RS121W-APBO121R						
18033/2020 - 1	CITEVE Physical Testing of Vector Guard Batch RS122W-APBO122R						
7853/2021 – 1	CITEVE Physical Testing - After storage at 54C for two (2) weeks on the roof panel fabric of Vector Guard Batches RS120W-APBO120R, RS121W-APBO121R, RS122W-APBO122R						
BIT063	Laboratory and experimental hut evaluation of Vector Guard [®] Insecticide Treated Net (ITN) in comparison with Olyset [®] Plus ITN and Royal Sentry [®] 2.0 ITN against strongly pyrethroid-resistant Anopheles arabiensis and fully susceptible Anopheles gambiae s.s. in Tanzania						
25516	Chemical analysis of net samples from the Phase I laboratory study of Vector Guard [®] compared to Olyset [®] Plus and Royal Sentry [®] 2.0 in Tanzania						
	Studies that were not used to inform decision making						
	None						

4 Manufacturing release specifications

4.1 Summary of manufacturing release specifications

Table 10. Summary of manufacturing release specifications

Description

The material shall be in the form of netting, consisting of 120 denier* for the roof and 120 denier* for the walls monofilament high density polyethylene (HDPE) yarn, incorporating technical alpha-cypermethrin complying with the requirements of WHO specification 454/LN (current version) and technical piperonyl butoxide complying with the requirements of WHO specification 33/LN (current version) together with any necessary other formulants. The product shall appear clean and shall be suitable for use as an insecticidal net.

ID	Property	Method	Declared value
Vector Gu	ard roof		
1*	Sampling Plan	See <u>Appendix 2</u>	
2	Alpha-cypermethrin content	454/LN/M/3.2, CIPAC Handbook M, p. 41, 2009	5.8 g/kg ± 25%
3	Piperonyl butoxide content	33/LN/M/3, CIPAC Handbook N, p.111, 2012	20.3 g/kg ± 25%
4	Alpha-cypermethrin wash resistance index	MT195	≥ 90%
5	Piperonyl butoxide wash resistance index	MT195	≥ 90%
6	Fabric weight	ISO 3801 / EN 12127	35 g/m ² ± 10%
7*	Bursting strength – fabric	ISO 13938/2: 1999	≥ 300 kPa
8*	Bursting strength – seam	ISO 13938/2: 1999	The average bursting strength of seams shall be not less than the measured average for the weaker fabric of the two (when considering a seam connecting two different nettings), or not less than the stated value for the fabric (when considering a seam connecting a given fabric to itself)
9*	Netting mesh size	See <u>Appendix 2</u>	Average not less than 17 holes/cm ² Min. not less than 16 holes/cm ²
10*	Dimensional stability	ISO 3759 / ISO 6330 / ISO 5077	Extension <5% Shrinkage <10%
DCT Roya	l Sentry 2.0 (sides - 120D) – WHO specif	ication 454/LN/4 (September 2020)	
1*	Sampling Plan	See <u>Appendix 2</u>	
2	Alpha-cypermethrin content	CIPAC 454/LN/M/3.2	5.8 g/kg ± 25%
4	Alpha-cypermethrin wash resistance index	MT195, CIPAC Handbook O, p. 205, 2017	Within the range 90% to 100%
6	Fabric weight	ISO 3801 / EN 12127	35 g/m² ± 10%
7*	Bursting strength – fabric	ISO 13938:2	≥ 350 kPa



8*	Bursting strength – seam	ISO 13938:2	Not less than the measured average for the fabric
9*	Netting mesh size	See <u>Appendix 2</u>	Average not less than 17 holes/cm ² Min. not less than 16 holes/cm ²
10*	Dimensional stability	ISO 3759 / ISO 6330 / ISO 5077	Extension in both directions <5% Shrinkage in both directions <10%

* 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. Test samples were stored for 14 days at 54°C. No significant differences were recorded among the properties of the product kept at ambient temperature and after accelerated storage stability test conditions.

Products should be stored and transported in appropriate conditions in accordance with the recommendations of the manufacturer.

Where products have been subjected to prolonged storage or adverse conditions during storage, analysis and testing are recommended to assess changes in characteristics and their suitability for use.

Appendix 1. Summary of available data considered in Module 3

E	Batches used to generate the physical/chemical data					
	Batch Number	Date	Formulation			
	RS120W-APBO120R	July 2021	White (sides)	Storage stability		

0	• • •		
Batch Number	Date	Formulation	Uses
RS120W-APBO120R	July 2021	White (sides)	Storage stability, in-use stability (laboratory), in-
		Light blue (roof)	use stability (semi-field)
RS121W-APBO121R	July 2021	White (sides)	Storage stability, in-use stability (laboratory), in-
		Light blue (roof)	use stability (semi-field)
RS122W-APBO122R	July 2021	White (sides)	Storage stability, in-use stability (laboratory), in-
		Light blue (roof)	use stability (semi-field)

Product characteristics

Study 25238

Property	Batch ID	Test Method	Results		
Roof					
Alpha-cypermethrin content (mean of 3 samples) Alpha-cypermethrin distribution (range for 3 samples)	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R RS120W-APBO120R RS121W-APBO121R	CIPAC 454/LN/M/3.2	5.65 g/kg (RSD 0.4%) 5.59 g/kg (RSD 0.4%) 5.71 g/kg (RSD 0.5%) 5.63-5.68 g/kg (97.1-97.9%) 5.57-5.61 g/kg (96.0-96.7%)		
(Numbers in parenthesis indicate percentage of target dose)	RS122W-APBO122R		5.68-5.73 g/kg (97.9-98.8%)		
PBO content (mean of 3 samples)	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	CIPAC 33/LN/M/3	18.66 g/kg (RSD 0.9%) 18.71 g/kg (RSD 1.4%) 18.40 g/kg (RSD 2.1%)		
PBO distribution (range for 3 samples) (Numbers in parenthesis indicate percentage of target dose)	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	CIFAC 35/LIV/W/3	18.53-18.85 g/kg (91.3-92.9%) 18.43-18.90 g/kg (90.8-93.1%) 18.12-18.85 g/kg (89.3-92.9%)		
Alpha-cypermethrin wash resistance index	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	CIPAC MT195	98.7% 97.9% 97.8%		
PBO wash resistance index	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	CIPAC MT195	97.9% 95.6% 96.5%		
Fabric weight	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	ISO 3801	36.0 g/m ² 36.7 g/m ² 36.8 g/m ²		
Sides (120D)					
Alpha-cypermethrin content (mean of 3 samples)	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R		5.12 g/kg (RSD 0.6%) 5.47 g/kg (RSD 0.5%) 5.35 g/kg (RSD 0.6%)		
Alpha-cypermethrin distribution (range for 3 samples)	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	CIPAC 454/LN/M/3.2	5.10-5.15 g/kg (87.9-88.8%) 5.44-5.50 g/kg (93.8-94.8%) 5.31-5.38 g/kg (91.6-92.8%)		
(Numbers in parenthesis indicate percentage of target dose)					

WHO Prequalification of Vector Control Products 1211 Geneva 27

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Property	Batch ID	Test Method	Results			
	Roof					
Alpha-cypermethrin wash resistance index	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	CIPAC MT195	98.3% 98.8% 98.9%			
Fabric weight	RS120W-APBO120R RS121W- APBO121R RS122W- APBO122R	ISO 3801	37.5 g/m ² 38.1 g/m ² 38.3 g/m ²			

Study 18037

Property	Batch ID	Test Method	Results
Fabric weight	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	EN 12127	35.4 g/m ² 35.7 g/m ² 36.0 g/m ²
Dimensional stability	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	ISO 5077/6330	-4.4%, -3.2% -2.6%, -4.2% -7.6%, -6.7%
Mesh size (average/minimum)	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	In-house	22/21 holes/cm ² 21/20 holes/cm ² 22/21 holes/cm ²
Bursting strength (fabric)	RS120W-APBO120R RS121W-APBO121R RS122W-APBO122R	ISO 13938-2	333 kPa 346 kPa 328 kPa
Bursting strength (seam)	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	ISO 13938-2	465 kPa 522 kPa 511 kPa
Flammability	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	EN 1102	No ignition or propagation. Maximum hole dimension 100 mm length.
Fabric weight	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R		36.0 g/m ² 36.7 g/m ² 36.8 g/m ²



Storage stability

Studies 25238 and 18037:

Property	Batch ID	Before	After	Change	
Roof					
Alpha-cypermethrin content (mean)	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	5.65 g/kg 5.59 g/kg 5.71 g/kg	5.64 g/kg 5.55 g/kg 5.59 g/kg	-0.01 g/kg (-0.2%) -0.04 g/kg (-0.7%) -0.22 g/kg (-2.1%)	
PBO content (mean)	RS120W-APBO120R RS121W- APBO121R RS122W- APBO122R	18.66 g/kg 18.71 g/kg 18.40 g/kg	18.59 g/kg 18.09 g/kg 18.49 g/kg	-0.07 g/kg (-0.4%) -0.62 g/kg (-3.3%) +0.09 g/kg (+0.5%)	
Alpha-cypermethrin wash resistance index	RS120W-APBO120R RS121W- APBO121R RS122W- APBO122R	98.7% 97.9% 97.8%	97.2% 97.8% 96.1%	-1.5% -0.1% -1.7%	
PBO wash resistance index	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	97.9% 95.6% 96.5%	95.1% 95.5% 93.7%	-2.8% -0.1% -2.8%	
Dimensional stability	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	-4.4%, -3.2% -2.6%, -4.2% -7.6%, -6.7%	-1.3%, -6.9% -1.5%, -8.3% -1.8%, -6.9%		
Bursting strength (fabric)	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	333 kPa 346 kPa 328 kPa	355 kPa 383 kPa 387 kPa	+22 kPa +37 kPa +59 kPa	
Sides (120D)					
Alpha-cypermethrin content (mean)	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	5.12 g/kg 5.47 g/kg 5.35 g/kg	5.13 g/kg 5.20 g/kg 5.33 g/kg	+0.01 g/kg (+0.2%) -0.27 g/kg (-4.9%) -0.02 g/kg (-0.4%)	
Alpha-cypermethrin wash resistance index	RS120W- APBO120R RS121W- APBO121R RS122W- APBO122R	98.3% 98.8% 98.9%	96.2% 93.3% 97.1%	-2.1% -5.5% -2.8%	



Appendix 2. Manufacturing release specifications: methods and notes

Description

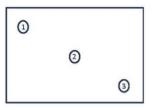
- The linear density (denier) of the yarn cannot be measured in the netting or the manufactured bed net but it should be identified on the packaging.
- DCT's Vector Guard netting fabric is intended to be used as a roof panel in a finished LLIN product assembled with DCT Royal Sentry 2.0 (120D) – WHO specification 454/LN/4 (September 2020) wall panel.

Sampling Plan – Applicable to all attributes for which samples are to be taken from various parts of the constructed ITN.

- Sampling should be taken as Figure 1:
 - Figure 1 General method for sampling rectangular shaped mosaic ITNs with different fabric specifications for the roof and wall panels.

Recommended positions from which 3 pieces of netting (minimum size 25×25 cm each) should be taken from the roof panel of the ITN.

Roof panel



Recommended positions from which 3 pieces of netting (minimum size 25×25 cm each) should be taken from the wall panel of the ITN.

Wall Panel

		3
	0	
3		

Roof panel and wall panel samples must not be mixed. Each subset of samples must be tested independently.



Attribute 8: Bursting strength – seam

Five repeated bursting strength measurements shall be made, and with the seam well centered on the test head.

If there are fewer than five seams available for sampling, repeat measurements shall be made on the available seams (1 to 4), enough to provide a required total of 5 measurements.

Attribute 9: Mesh size

In the absence of a simple or standard method to determine the size of holes, which may have complex shapes, in highly flexible fabrics, mesh size is determined by counting the number of holes in a square of the fabric. Counting may be done directly on the fabric or indirectly by taking a picture/photocopy of the fabric. Indirect methods may ease counting and provide a permanent record. The number of holes per measured area is converted in holes/cm2. Before counting, the fabric should be conditioned according to ISO 139 (4 h, 20°C, 65% relative humidity). Use a template to define the square of netting, taking care not to stretch or distort the fabric. The template should be a 1-2 mm thick rigid sheet, in/on which an accurately calibrated (±1% in each dimension) square (e.g., 1 x 1 in or 5 x 5 cm) has been cut/marked. If a template is not available and a ruler must be used, great care is required to ensure that the area counted is square. Where practicable, one edge of the square to be counted should be aligned with a row of complete holes in the fabric. Incomplete holes $\geq \frac{1}{2}$ are counted as complete holes, whereas those $< \frac{1}{2}$ are not counted. Count 5 replicate squares selected according to the above-mentioned sampling plan, calculate the average and note the lowest value. Another suitable method is the use of a stereomicroscope with an image analyser software, where the number of holes in a defined area is counted. In case of discrepancy between the netting mesh size using stereomicroscopic method and direct or indirect counting method, the stereomicroscopic method shall be the referee method.

Attribute 10: Dimensional Stability

Method of preparation, marking and measuring: ISO 3759. Method of washing: ISO 6330. Method of calculation: ISO 5077. Size of test portions: 500 mm x 500 mm; mark off 350 mm x 350 mm within each test portion. Test a total of 4 replicate portions, 2 washed in each of 2 separate loads. Type of washing machine: ISO type A (front loading). Washing programme: 30°C Mild programme. Fill the washer with fabrics and ballast Type III (polyester ballast) up to 2 kg (according to the ISO 6330 standard). Drying: flat drying.