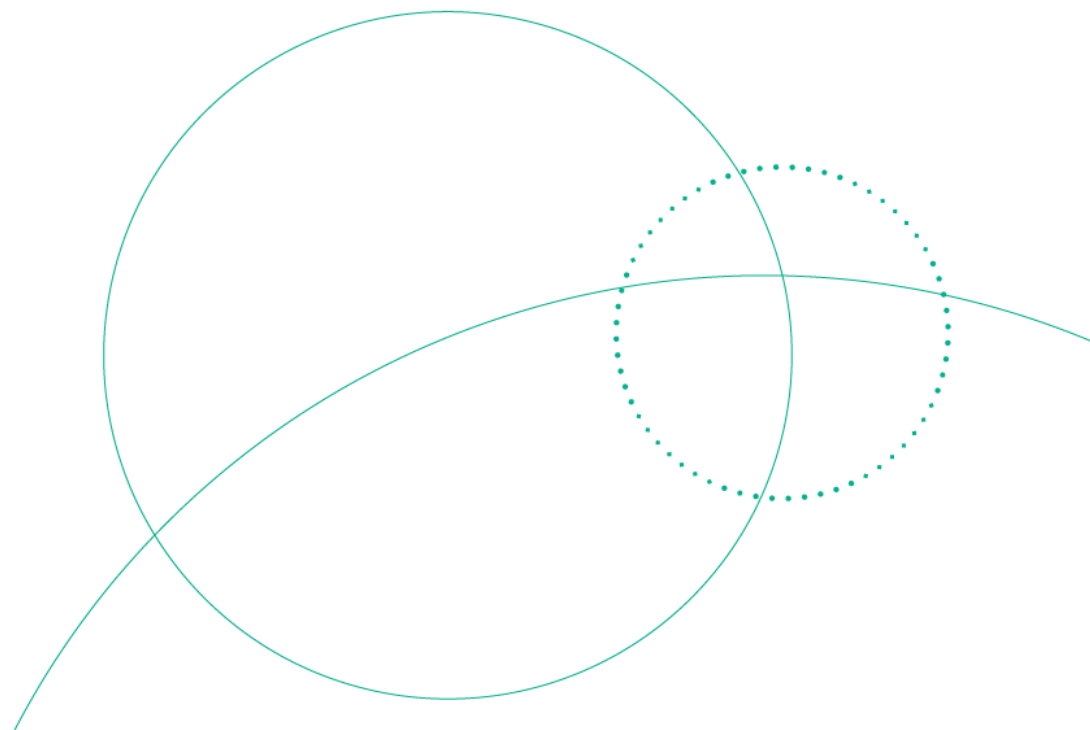


WHO Prequalification Programme / Vector Control Product Assessment

# WHO Public Assessment Report: WHOPAR Part 3

PermaNet Dual (Vestergaard Sàrl) P-03228

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 PermaNet Dual 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: 1 116 21, 1 178 20, 1 187 20, 1 188 20, 1 189 20.

Complete results from the Studies SLA-552.6&11 and SLA-552.20 are available in Appendix 1.

Table 1. Chemical and physical properties for PermaNet Dual		
Data requirement	Test method ID	Result
Identification of Deltamethrin and Chlorfenapyr	Deltamethrin 333/LN/(M)/2, CIPAC Handbook M, p. 66, 2009 Combination – CIPAC/5297	The active ingredients each comply with an identity test
Deltamethrin mean content	CIPAC 333/LN/(M)/3	2.21 g/kg (1.84-2.49 g/kg)
Accelerated storage Deltamethrin retention		98.9% (96.2-100.8%)
R-alpha Deltamethrin mean content	CIPAC 333/LN/(M)/3	0.5% (0.5-0.5%)
Chlorfenapyr content	CIPAC 5291m (VCL-098-20)	5.16 g/kg (4.27-6.16 g/kg)
Accelerated storage Chlorfenapyr retention		97.9% (95.6-99.5%)
Wash resistance index (Deltamethrin)		95.6% (93.8-97.3%)
Accelerated storage wash resistance index (Deltamethrin)	CIPAC MT195	96.2% (93.9-98.0%)
Wash resistance index (Chlorfenapyr)		92.0% (90.2- 94.0%)
Accelerated storage wash resistance index (Chlorfenapyr)	CIPAC MT195	92.8% (89.0 – 94.8%)
Mesh size (mean)	See Appendix 2	26.5 (25.6-27.8) holes/cm <sup>2</sup>
Fabric weight	ISO 3801	41.9 g/m <sup>2</sup> (40.3-43.6 g/m <sup>2</sup> )
Dimensional stability of netting to washing		Length: -0.9% (-2.8% to -0.1%) Width: -0.1% (-0.6% to +0.5%)
Accelerated storage dimensional stability	ISO 3759; ISO 5077; ISO 6330 Type A, ballast type III, flat drying	Length: -0.9% (-2.9% to -0.1%) Width: -0.2% (-0.7% to +0.1%)
Bursting strength		454 kPa (403-484 kPa)
Accelerated storage bursting strength	ISO 13938-2	452 kPa (407-483 kPa)
Seam bursting strength	ISO 13938-2	545 kPa (478-625 kPa)
Flammability (Batch 1 178 20)	EN 1102	No ignition or propagation. Maximum hole dimension 92 mm length.

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 PermaNet Dual 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 PermaNet Dual	
Description of Starting Material	Deltamethrin TC and Chlorfenapyr TC formulated as part of the production process as aqueous dispersions. 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.
Production / Formulation Process	The fabric is manufactured by warp-knitting of the polyethylene terephthalate (PET) (common name polyester) yarn, heat setting, mixing of the AI dispersions with the binder formulation, and coating.  The finished product is manufactured by cutting and sewing of the fabric, addition of label tag, folding prior to packaging, packing, and baling.
Packaging	Nets may be packed individually in plastic bags with printed labels or in bulk bales, of typically 50 nets (with 40, 50 or 100 nets depending on customer requirements) with one adhesive label per bale. The sizes of the bags and bales vary depending on the size of the net version being packed. Columns of nets are pressed by a hydraulic press to the desired height then strapped.
Discussion of Impurities	The R-alpha-diastereomer of deltamethrin was analysed and reported as a percentage of the total deltamethrin concentration.  There are no relevant impurities of toxicological concern.
Certification of Limits	Deltamethrin: 2.1 g/kg, acceptable limits 1.6-2.6 g/kg Chlorfenapyr: 5.0 g/kg, acceptable limits 3.8-6.3 g/kg

## 1.3 Enforcement analytical method

Table 3. Details of the analytical method used to determine Deltamethrin and Chlorfenapyr in PermaNet Dual	
Quantification of Deltamethrin and Chlorfenapyr	Deltamethrin 333/LN/(M)/3, CIPAC Handbook M, p. 66, 2009 Combination – CIPAC/5297/m

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 active ingredients and insecticidal effect of the fabric of PermaNet Dual on Anopheline mosquitoes were submitted to WHO as part of the prequalification dossier. Sampled pieces of ITNs used in the biological laboratory studies were characterized for their deltamethrin and chlorfenapyr content using HPLC.

### 2.1 Laboratory studies

#### 2.1.1 Entomological characterisation

Data on the wash regeneration and wash resistance properties of the PermaNet Dual 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 batches 100720-57, 100720-89, 062220.

One laboratory study and one supplemental study were submitted to characterise the PermaNet Dual fabric. Bioavailability was evaluated in wash regeneration and wash resistance studies. Sampled ITN pieces were washed in shaker baths using 2g/l Savon de Marseille. The endpoint used to evaluate bioavailability was 72-hour mortality. 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 and  $\geq 80\%$  mortality or  $\geq 90\%$  blood feeding inhibition in tunnel tests were used to determine wash resistance.

The bioavailability of deltamethrin on the surface of the ITN was characterized using the insecticide susceptible test system *Anopheles gambiae* Kisumu strain. The bioavailability of chlorfenapyr on the surface of the fabric was characterized using the pyrethroid resistant test system *An. gambiae s.l.* strain (Covè) carrying *kdr* gene frequencies of  $>90\%$  L1014F and metabolic resistance through over-expression of CYP6P3. In a supplemental laboratory study, the pyrethroid resistant *Anopheles arabiensis* Kingani strain, which carries metabolic resistance mechanisms through P450 monooxygenases and esterases, was used to evaluate wash resistance. WHO cone tests and tunnel tests were the experimental methods used in bioavailability studies.

The wash interval was determined to be one day. Using this wash interval, PermaNet Dual was wash resistant to 20 washes using insecticide susceptible and pyrethroid resistant mosquito test systems.

These results are summarized in Tables 4-6.

**Table 4. Wash regeneration study results for PermaNet Dual using the insecticide susceptible *An. gambiae* Kisumu test system in WHO cone tests to characterize the bioavailability of deltamethrin and the pyrethroid resistant *An. gambiae* Cove test system in tunnel tests to characterize the bioavailability of chlorfenapyr**

Days post-wash	<i>An. gambiae</i> Kisumu (WHO cone test)					<i>An. gambiae</i> s.l. Cove (tunnel test)				
	n	%KD (95% CI)	%M24 (95% CI)	%M48 (95% CI)	%M72 (95% CI)	n	%BFI	%M24 (95% CI)	%M48 (95% CI)	%M72 (95% CI)
UW	204	91 (87-95)	72 (66-78)	76 (70-82)	77 (71-83)	203	93	98 (97-100)	98 (97-100)	98 (97-100)
0	205	88 (84-93)	79 (73-85)	82 (77-87)	88 (83-92)	209	74	94 (90-97)	94 (90-97)	95 (91-98)
1	195	81 (75-86)	82 (77-87)	87 (82-91)	89 (85-94)	232	85	98 (96-100)	98 (96-100)	98 (96-100)
2	207	72 (65-78)	80 (74-85)	86 (81-91)	89 (84-93)	213	59	92 (89-96)	92 (89-96)	92 (89-96)
3	195	72 (65-78)	80 (74-85)	81 (76-87)	84 (79-90)	221	76	92 (89-96)	92 (89-96)	92 (89-96)
5	215	87 (82-91)	86 (81-90)	92 (88-96)	94 (91-97)	166	83	96 (93-99)	96 (93-99)	96 (93-99)
7	201	77 (71-83)	79 (73-84)	81 (75-86)	84 (78-89)	190	80	95 (92-98)	95 (92-98)	95 (92-98)

**Table 5. Wash resistance study results for PermaNet Dual using insecticide susceptible *An. gambiae* Kisumu strain mosquitoes using WHO cone tests**

Wash No.	<i>An. gambiae</i> Kisumu (WHO cone test)				
	n	%KD (95% CI)	%M24 (95% CI)	%M48 (95% CI)	%M72 (95% CI)
0	201	78 (72-83)	38 (32-45)	42 (35-48)	43 (37-50)
1	196	88 (83-92)	69 (62-75)	78 (73-84)	85 (80-90)
3	199	81 (75-86)	76 (70-82)	80 (74-85)	81 (75-86)
5	201	84 (79-89)	76 (70-82)	80 (75-86)	84 (79-89)
10	203	85 (80-90)	70 (63-76)	76 (70-82)	81 (76-87)
15	204	83 (78-88)	73 (67-79)	79 (73-84)	86 (81-90)
20	204	75 (69-81)	45 (38-52)	53 (46-60)	62 (56-69)

**Table 6. Wash resistance study results for PermaNet Dual for insecticide susceptible *An. gambiae* s.s Kisumu strain, pyrethroid resistant *An. gambiae* Cove mosquitoes and pyrethroid resistant *An. arabiensis* Kingani strain using tunnel tests**

Wash no.	n	%BFI	%M24 (95% CI)	%M48 (95% CI)	%M72 (95% CI)
<i>An. gambiae</i> Kisumu (tunnel test)					
0	193	93	100	100	100
10	214	86	100	100	100
20	220	98	98 (96-100)	98 (96-100)	98 (96-100)
<i>An. gambiae</i> s.l. Cove (tunnel test)					
0	207	93	98 (96-100)	98 (96-100)	98 (96-100)
10	235	82	97 (95-99)	97 (95-99)	97 (95-99)
20	212	73	84 (79-89)	88 (84-93)	91 (87-95)
<i>An. arabiensis</i> Kingani (tunnel test)					
Wash no.	n	%BFI	%M24 (95% CI)	%M48 (95% CI)	%M72 (95% CI)
0	400	94.6 (88.9-100)			78.0 (65.4-90.5)
3	400	95.4 (89.3-100)			72.1 (59.6-84.6)
20	400	91.5 (85.0-98.1)			74.9 (68.3-81.6)
Mean	1,200	93.9 (90.5-97.2)			75.0 (69.1-80.9)

### Chemical characterization of samples

Data on the deltamethrin and chlorfenapyr content of sampled pieces of the PermaNet Dual 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 100720-57, 100720-89, 062220. The results are summarized in Tables 7 and 8.

**Table 7. AI content and retention of sampled pieces of PermaNet Dual used in the entomological wash resistance study (batch numbers 100720-57, 100720-89, 062220)**

Wash No.	Mean deltamethrin content (g/kg)	RSD (%)	Deltamethrin retention	Deltamethrin retention per wash	Mean chlorfenapyr content (g/kg)	RSD (%)	Chlorfenapyr retention	Chlorfenapyr retention per wash
0	2.15 (1.98-2.41)	8.6	-	-	4.30 (3.63-5.28)	17.1	-	-
1	1.97 (1.84-2.12)	5.9	91.7%	91.7%	4.13 (3.89-4.41)	6.3	96.1%	96.1%
3	1.79 (1.69-1.89)	5.0	83.2%	94.0%	3.18 (2.70-3.41)	10.4	73.9%	90.4%
5	1.59 (1.41-1.77)	11.1	74.1%	94.2%	2.45 (1.98-2.74)	14	56.9%	89.3%
10	1.14 (1.08-1.20)	4.9	53.1%	93.9%	0.96 (0.83-1.04)	10.2	22.4%	86.1%
15	0.88 (0.71-1.10)	19.7	40.8%	94.2%	0.58 (0.23-1.00)	57.7	13.6%	87.5%
20	0.52 (0.40-0.58)	16.2	24.2%	93.2%	0.23 (<0.01-0.27)	20.9	5.4%	86.4%

The mean AI content presented in Table 7 was determined based on 4 net samples belonging to 3 batches, indicating ranges to the AI content in parenthesis.

AI retention per wash in Table 7 is calculated as:

- AI retention per wash =  $100 \times \sqrt[n]{(t_n/t_0)}$  where:
  - $t_n$  = total active ingredient content after n washing cycles
  - $t_0$  = total active ingredient content before washing
  - n = number of washes.

**Table 8. AI content of sampled pieces of PermaNet Dual used in the entomological supplementary laboratory study (batch numbers 100720-57, 100720-89)**

Wash No.	Deltamethrin content (g/kg)	Chlorfenapyr content (g/kg)
0	2.45, 2.48	5.85, 4.96
20	1.89, 1.78	2.20, 1.18

The AI content presented in Table 8 refers to the AI content for two individual sample values separated by a coma (for batches 100720-57 and 100720-89) at 0 washes and 20 washes.

## 2.2 Chemical and entomological fabric characterisation conclusions

The submitted laboratory studies characterize the fabric of PermaNet Dual against three 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 one day after washing.

Wash resistance to 20 washes using standardised washing methods was demonstrated against two *An. gambiae* complex test systems. Based on the submitted studies, PermaNet Dual is wash resistant to 20 washes using a one-day wash interval against pyrethroid susceptible *An. gambiae* Kisumu and against two pyrethroid resistant strains of the *An. gambiae* complex with different combinations of resistance mechanisms.



### 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 submitted to WHO as part of the prequalification dossier**

Studies that were relied upon for decision making	
Study number	Study title
20-07/GLP	WHO/PQ Phase I laboratory evaluation of the regeneration time, efficacy and wash-resistance of PermaNet P191 (a deltamethrin and chlorfenapyr mixture net) by Vestergaard Sàrl against susceptible and pyrethroid-resistant strains of <i>Anopheles gambiae s.l.</i>
25227	Chemical analysis of net samples from the Phase I laboratory study of PermaNet P191 compared to PermaNet 2.0 and Interceptor G2
BIT077	Tunnel test evaluation of prototype net samples in comparison to the sides of PermaNet 3.0 nets against pyrethroid resistant <i>Anopheles arabiensis</i>
VCL-012-18	Chemical content analysis of P191 and PermaNet 3.0 side from tunnel tests at the Ifakara Health Institute (IHI) in Tanzania
Study SLA-552.6&11	PermaNet® P191 - Quality evaluation of Chlorfenapyr and Deltamethrin long lasting (coated onto filaments) insecticidal net
SLA-552.20	PermaNet® Dual - Quality assessment of chlorfenapyr and deltamethrin long lasting (coated onto filaments) insecticidal net
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 100 denier\* multi-filament polyethylene terephthalate (PET) (common name polyester) yarn, treated with technical deltamethrin complying with the requirements of WHO specification 333/TC (current version) and with technical chlorfenapyr complying with the requirements of WHO specification 570/TC (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
1*	Sampling Plan	See Appendix 2	
2	Chlorfenapyr content	CIPAC/5297/m	5.0 g/kg ± 25%
3	Deltamethrin content	CIPAC/5297/m	2.1 g/kg ± 25%
4	Chlorfenapyr wash resistance index	MT195, CIPACHandbook O, p. 205, 2017	Min. 85%
5	Deltamethrin wash resistance index	MT195, CIPACHandbook O, p. 205, 2017	Min. 85%
6	Fabricweight	ISO 3801	40 g/m <sup>2</sup> ± 10%
7*	Bursting strength – fabric	ISO 13938:2	Not less than 350 kPa
8*	Bursting strength – seam	ISO 13938:2	Not less than the average bursting strength for fabric
9*	Netting mesh size	See Appendix 2	Min. 24.0 holes/cm <sup>2</sup>

\*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 46.3. Test samples were stored for 8 weeks at 40°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

### Batches used to generate the physical/chemical data

Batch number	Date	Formulation	Uses
100720-57	07/2020	White	In-use stability (laboratory), storage stability, semi-field studies
100720-89	07/2020	White	In-use stability (laboratory), storage stability, semi-field studies
1 178 20	-	White	storage stability
1 187 20	-	White	storage stability
1 188 20	-	White	storage stability
1 189 20	-	White	storage stability
1 116 21	-	White	storage stability

### Product characteristics

#### Study SLA-552.6&11

Property	Batch ID	Test method	Results
Deltamethrin content (Numbers in parenthesis indicate percentage of target dose)	100720-57	CIPAC 333/LN/(M)/3	2.47-2.55 g/kg (117.6-121.4%)
	100720-89		2.36-2.53 g/kg (112.4-120.5%)
	1 178 20		2.19-2.34 g/kg (104.3-111.4%)
	1 187 20		2.14-2.34 g/kg (101.9-111.4%)
	1 188 20		2.22-2.31 g/kg (105.7-110.0%)
	1 189 20		2.07-2.35 g/kg (98.6-111.9%)
	Mean		2.30 g/kg
	Relative standard deviation (RSD %)		5.8%
<i>R</i> -alpha Deltamethrin content	100720-57	CIPAC 333/LN/(M)/3	1.7%
	100720-89		2.3-2.6%
	1 178 20		0.5%
	1 187 20		0.5%
	1 188 20		0.5%
	1 189 20		0.5%
	Mean		0.9%
	RSD		-
Chlorfenapyr content (Numbers in parenthesis indicate percentage of target dose)	100720-57	VCL-098-20	5.38-5.55 g/kg (107.6-111.0%)
	100720-89		4.80-5.35 g/kg (96.0-107.0%)
	1 178 20		5.13-5.58 g/kg (102.6-111.6%)
	1 187 20		5.18-5.72 g/kg (103.6-114.4%)
	1 188 20		4.38-5.53 g/kg (87.6-110.6%)
	1 189 20		4.75-5.52 g/kg (95.0-110.4%)
	Mean		5.20 g/kg
	RSD		7.5%
Wash resistance index (Deltamethrin)	100720-57	CIPAC MT195	97.2-97.5%
	100720-89		96.3-97.5%
	1 178 20		95.8%
	1 187 20		96.0%

Property	Batch ID	Test method	Results
	1 188 20 1 189 20 Mean RSD		97.5% 96.8% 96.8% 0.7%
Wash resistance index (Chlorfenapyr)	100720-57 100720-89 1 178 20 1 187 20 1 188 20 1 189 20 Mean RSD		94.1-94.9% 92.3-94.5% 91.9% 92.2% 93.4% 93.2% 93.3% 1.2%
Mesh size	100720-57 100720-89 1 178 20 1 187 20 1 188 20 1 189 20 Mean RSD	WHO specification 333/LN/1	26.4-26.5 holes/cm <sup>2</sup> 25.8-26.5 holes/cm <sup>2</sup> 25.6 holes/cm <sup>2</sup> 26.5 holes/cm <sup>2</sup> 26.5 holes/cm <sup>2</sup> 26.5 holes/cm <sup>2</sup> 26.3 holes/cm <sup>2</sup> 1.4%
Fabric weight	100720-57 100720-89 1 178 20 1 187 20 1 188 20 1 189 20 Mean RSD	ISO 3801	40.4 g/m <sup>2</sup> 40.1-40.9 g/m <sup>2</sup> 40.3 g/m <sup>2</sup> 40.6 g/m <sup>2</sup> 41.7 g/m <sup>2</sup> 40.6 g/m <sup>2</sup> 40.6 g/m <sup>2</sup> 1.2%
Dimensional stability	100720-57 100720-89 1 178 20 1 187 20 1 188 20 1 189 20 Mean RSD	ISO 3759; ISO 5077; ISO 6330 Type A, ballast type III, flat drying	-1.6%, -0.4% -1.0%, -0.4% -1.6%, -0.1% -1.9%, 0.0% -2.8%, +0.1% -0.5%, +0.5% -1.4%, -0.1% -
Bursting strength	100720-57 100720-89 1 178 20 1 187 20 1 188 20 1 189 20 Mean RSD	ISO 13938-2	445 kPa 429 kPa 449 kPa 453 kPa 436 kPa 403 kPa 440 kPa 4%
Seam bursting strength	100720-57 100720-89 1 178 20 1 187 20 1 188 20 1 189 20		517 kPa 465 kPa 496 kPa 516 kPa 498 kPa 515 kPa

Property	Batch ID	Test method	Results
	Mean RSD		508 kPa 4.4%
Flammability	1 178 20	EN 1102:2016	No ignition or propagation. Maximum hole dimension 92 mm.

### Study SLA-552.20

Property	Batch ID	Test method	Results
Deltamethrin mean content	1 178 20	CIPAC 5291m	2.20 g/kg
	1 187 20		2.12 g/kg
	1 188 20		2.27 g/kg
	1 189 20		2.20 g/kg
	1 116 21		2.26 g/kg
	Mean		2.21 g/kg
	RSD		5.8%
Deltamethrin distribution (Numbers in parenthesis indicate percentage of target dose)	1 178 20	CIPAC 5291m	2.10-2.34 g/kg (100-111.4%)
	1 187 20		1.84-2.34 g/kg (87.6-111.4%)
	1 188 20		2.09-2.49 g/kg (99.5-118.6%)
	1 189 20		2.07-2.35 g/kg (98.6-111.9%)
	1 116 21		2.21-2.31 g/kg (105.2-110.0%)
	Mean		2.21 g/kg
	RSD		5.8%
<i>R</i> -alpha Deltamethrin mean content	1 178 20	CIPAC 5291m	0.5%
	1 187 20		0.5%
	1 188 20		0.5%
	1 189 20		0.5%
	1 116 21		0.5%
	Mean		0.5%
	RSD		-
Chlorfenapyr mean content	1 178 20	CIPAC 5291m	5.05 g/kg
	1 187 20		5.14 g/kg
	1 188 20		5.13 g/kg
	1 189 20		5.02 g/kg
	1 116 21		5.44 g/kg
	Mean		5.16 g/kg
	RSD		9.2%
Chlorfenapyr distribution (Numbers in parenthesis indicate percentage of target dose)	1 178 20	CIPAC 5291m	4.47-5.58 g/kg (89.4-111.6%)
	1 187 20		4.27-5.72 g/kg (85.4-114.4%)
	1 188 20		4.38-6.16 g/kg (87.6-123.2%)
	1 189 20		4.66-5.52 g/kg (93.2-110.4%)
	1 116 21		5.16-5.78 g/kg (103.2-115.6%)
	Mean		5.16 g/kg
	RSD		9.2%
Wash resistance index (Deltamethrin)	1 178 20	CIPAC MT195	96.0%
	1 187 20		95.0%
	1 188 20		96.4%
	1 189 20		96.1%
	1 116 21		94.5%

Property	Batch ID	Test method	Results
	Mean RSD		95.6% 1.1%
Wash resistance index (Chlorfenapyr)	1 178 20		92.3%
	1 187 20		91.6%
	1 188 20		92.5%
	1 189 20		92.0%
	1 116 21		91.6%
	Mean		92.0%
	RSD		1.1%
Mesh size	1 178 20	WHO specification 333/LN/1	26.4 holes/cm <sup>2</sup>
	1 187 20		26.6 holes/cm <sup>2</sup>
	1 188 20		26.6 holes/cm <sup>2</sup>
	1 189 20		26.5 holes/cm <sup>2</sup>
	1 116 21		26.3 holes/cm <sup>2</sup>
	Mean		26.5 holes/cm <sup>2</sup>
	RSD		1.9%
Fabric weight	1 178 20	ISO 3801	42.0 g/m <sup>2</sup>
	1 187 20		41.9 g/m <sup>2</sup>
	1 188 20		42.3 g/m <sup>2</sup>
	1 189 20		41.9 g/m <sup>2</sup>
	1 116 21		41.7 g/m <sup>2</sup>
	Mean		41.9 g/m <sup>2</sup>
	RSD		1.9%
Dimensional stability	1 178 20	ISO 3759; ISO 5077; ISO 6330 Type A, ballast type III, flat drying	-1.3%, -0.1%
	1 187 20		-0.8%, -0.3%
	1 188 20		-1.0%, +0.1%
	1 189 20		-0.7%, +0.2%
	1 116 21		-0.4%, -0.4%
	Mean		-0.9%, -0.1%
	RSD		-
Bursting strength	1 178 20	ISO 13938-2	459 kPa
	1 187 20		463 kPa
	1 188 20		442 kPa
	1 189 20		440 kPa
	1 116 21		476 kPa
	Mean		454 kPa
	RSD		4.4%
Seam bursting strength	1 178 20		536 kPa
	1 187 20		565 kPa
	1 188 20		513 kPa
	1 189 20		535 kPa
	1 116 21		574 kPa
	Mean		545 kPa
	RSD		6.8%
Flammability	1 178 20	EN 1102:2016	No ignition or propagation. Maximum hole dimension 92 mm.

## Storage stability

### Study SLA-552.6&11

Property	Batch ID	Results
Deltamethrin retention	100720-57	98.1-99.2%
	100720-89	97.0-98.2%
	1 178 20	99.6%
	1 187 20	97.5%
	1 188 20	99.0%
	1 189 20	99.9%
	Mean	98.6%
	RSD	1.0%
Chlorfenapyr retention	100720-57	98.2-99.0%
	100720-89	96.1-98.1%
	1 178 20	98.1%
	1 187 20	95.9%
	1 188 20	98.8%
	1 189 20	98.9%
	Mean	97.9%
	RSD	1.2%
Wash resistance index (Deltamethrin)	1 178 20	95.5%
	1 187 20	96.2%
	1 188 20	98.0%
	1 189 20	95.5%
	Mean	96.3%
	RSD	1.2%
Wash resistance index (Chlorfenapyr)	1 178 20	93.0%
	1 187 20	92.5%
	1 188 20	92.7%
	1 189 20	91.0%
	Mean	92.3%
	RSD	1.0%
Dimensional stability	1 178 20	-2.9%, -0.7%
	1 187 20	-0.9%, +0.1%
	1 188 20	-0.3%, -0.1%
	1 189 20	-0.1%, 0.0%
	Mean	-1.1%, -0.3%
	RSD	-
Bursting strength	1 178 20	442 kPa
	1 187 20	443 kPa
	1 188 20	425 kPa
	1 189 20	422 kPa
	Mean	433 kPa
	RSD	2.6%

### Study SLA-552.20

Property	Batch ID	Results
Deltamethrin retention	1 178 20	99.3%
	1 187 20	99.4%
	1 188 20	98.8%
	1 189 20	98.8%
	1 116 21	98.3%
	Mean	98.9%
	RSD	1.2%
Chlorfenapyr retention	1 178 20	98.0%
	1 187 20	97.8%
	1 188 20	98.4%
	1 189 20	97.2%
	1 116 21	97.9%
	Mean	97.9%
	RSD	1.2%
Wash resistance index (Deltamethrin)	1 178 20	96.7%
	1 187 20	96.7%
	1 188 20	96.4%
	1 189 20	96.4%
	1 116 21	94.8%
	Mean	96.2%
	RSD	1.1%
Wash resistance index (Chlorfenapyr)	1 178 20	93.2%
	1 187 20	93.1%
	1 188 20	92.5%
	1 189 20	92.1%
	1 116 21	93.2%
	Mean	92.8%
	RSD	1.5%
Dimensional stability	1 178 20	-2.9%, -0.7%
	1 187 20	-0.9%, +0.1%
	1 188 20	-0.3%, -0.1%
	1 189 20	-0.1%, 0.0%
	1 116 21	-0.5%, -0.5%
	Mean	-0.9%, -0.2%
	RSD	-
Bursting strength	1 178 20	445 kPa
	1 187 20	459 kPa
	1 188 20	440 kPa
	1 189 20	441 kPa
	1 116 21	472 kPa
	Mean	452 kPa
	RSD	4.9%



## 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.

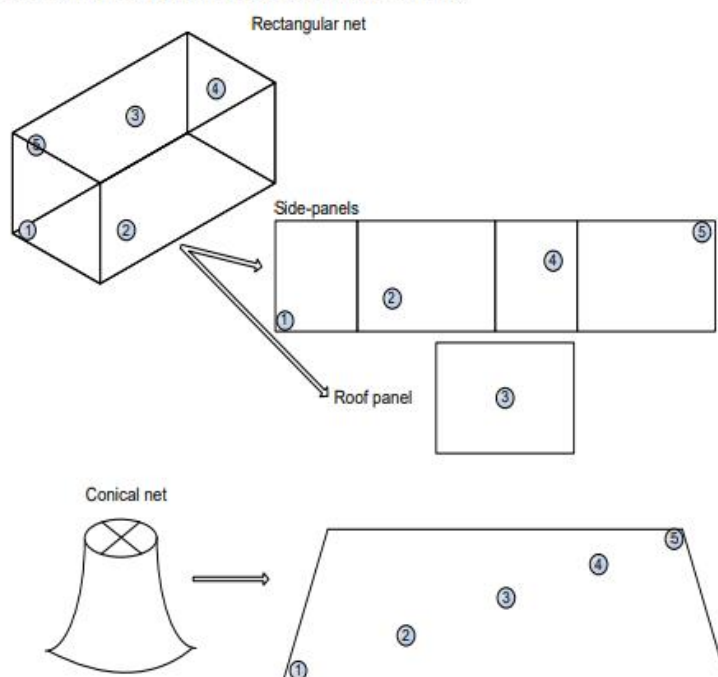
### Sampling Plan

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

- Sampling should be noted as Figure 1.

**Figure 1** General method for sampling rectangular and conical nets

Recommended positions from which 5 pieces of netting should be taken from a made up bed net and combined to form a representative sample.



### Attribute 7: 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 8: 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/cm<sup>2</sup>. 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 ( $\pm 1\%$  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.