

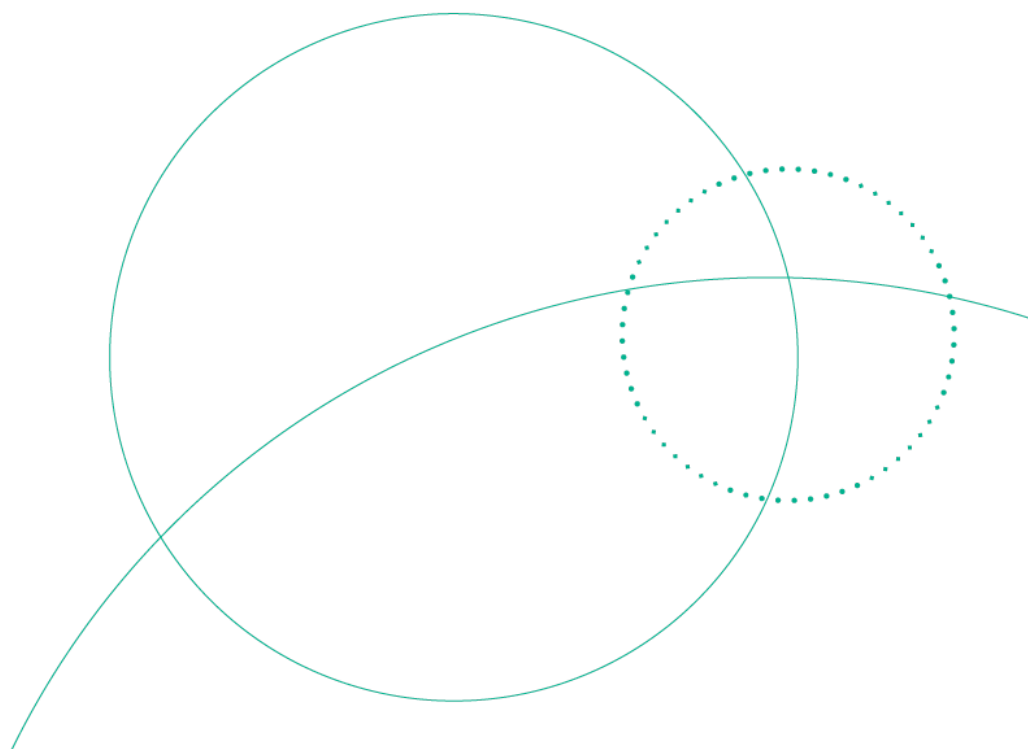
WHO Prequalification Programme / Vector Control Product Assessment

WHO Public Assessment Report: WHOPAR Part 3

UNET G5 LN
(Sino Africa Medical Devices Company Ltd.)

P-13229

Quality Assessment



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1 Chemical and physical data

1.1 Chemical and physical properties for the pre-treated fabric (starting material)

Data on the chemical and physical properties for the starting material, Yorkkool G5 LN (Product Ref # P-12507) pre-treated fabric, were provided. These data reflected those presented in the currently published WHOPAR for Yorkkool G5 LN. These data are replicated in this section for ease of reference. These data were obtained from studies conducted according to established standards and/or Good Laboratory Practices (GLP) and are considered complete. Yorkkool G5 LN pre-treated fabric 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: 20190830, 20191101, 20201201, 20210107, 20210309.

Complete results from Studies 19240, 20185, 21045 and TE2022-003, as per currently published WHOPAR for Yorkkool G5 LN are replicated in Appendix 1 for easy of reference.

Table 1. Chemical and physical properties for the starting material UNET G5 LN pre-treated fabric (Batches 20190830, 20191101, 20201201, 20210107, 20210309)		
Data requirement	Test method ID	Result
Identification of alpha-cypermethrin and chlorfenapyr	CIPAC/5220/m for alpha-cypermethrin and chlorfenapyr and 454/LN/M/2, CIPAC Handbook M, p. 40, 2009 for alphacypermethrin	The active ingredients each comply with an identity test
Alpha-cypermethrin mean content	CIPAC/5220/m and 454/LN/M/3.1, CIPAC Handbook M, p. 40, 2009	(2.26 -2.70 g/kg)* (2.22-2.83 g/kg)** (95.80 -98.30%)*
Accelerated storage alpha-cypermethrin retention		
Wash resistance index (Alpha-cypermethrin)	MT 195, CIPAC Handbook O, p. 205, 2017	(96.13 -98.16%)* (96.40 -97.84%)*
Accelerated storage alpha-cypermethrin WRI		
Chlorfenapyr mean content	CIPAC/5220/m	(3.93 -5.64 g/kg)* (3.85-5.78 g/kg)** (96.10 -98.30%)*
Accelerated storage chlorfenapyr retention		
Wash resistance index (Chlorfenapyr)	MT 195, CIPAC Handbook O, p. 205, 2017	(91.90 -96.14%)* (92.30 -94.84%)*
Accelerated storage chlorfenapyr WRI		
Mesh size	See Appendix 2	(24-29) holes/cm ² *
Fabric weight	ISO 3801/EN 12127 EN 20139-1992	(40.9- 42.1 g/m ²)*
Dimensional stability of netting to washing	ISO3759-2011 / ISO5077-2007 / ISO6330-2012	Length: (-4.1% to -0.5%)* Width: (-0.4% to +2.2%)*
Accelerated storage dimensional stability		Length: (-3.2% to -0.4%)* Width: (-0.6% to +2.1%)*
Bursting strength (fabric)	ISO 13938-2-1999 (30mm Diaphragm Diameter)	(417.5 - 455.4 kPa)* (412.2 - 448.0 kPa)*
Accelerated storage bursting strength (fabric)		
Flammability	EN 1102:2016	No ignition or propagation. Maximum hole dimension 107 mm.

* range of means

** range of individual measurements in samples

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

1.2 Chemical and physical properties for the finished constructed ITN product

Data on the bursting strength of the finished constructed product UNET G5 LN were provided and are summarized in Table 2. These data were obtained from studies conducted according to established standards and/or Good Laboratory Practices (GLP) and are considered complete. Numerical results are presented as: mean (range). These summary results are based on the analysis of batches: G5240701TT1, G5240702TT1, G5240801TT1, G5240901TT1, G5240902TT1.

Complete results from the Study TSNT01741501 are available in Appendix 1.

Table 2. Physical properties for the finished constructed UNET G5 LN (Batches G5240701TT1, G5240702TT1, G5240801TT1, G5240901TT1, G5240902TT1)		
Data requirement	Test method ID	Result
Fabric Bursting strength	ISO 13938-2-1999 (30mm Diaphragm Diameter)	(422.7 - 438.1 kPa)*
Seam bursting strength	ISO 13938-2-1999 (30mm Diaphragm Diameter)	(483.8 - 543.0 kPa)*

* range of means

1.3 Manufacturing, composition and formulant information

Data on the manufacturing process and product composition for UNET G5 LN have been provided and are adequate. A summary is presented in Table 3. Detailed information on the manufacturing process and product formulation is considered Confidential Business Information (CBI).

Table 3. Manufacturing process and product composition data submitted for UNET G5 LN	
Description of starting material	Yorkool G5 LN pre-treated fabric (white, blue, green). Quality acceptability intake criteria as per Yorkool G5 LN manufacturing release specifications. 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 process	The finished product is manufactured by cutting and sewing of the Yorkool G5 LN pre-treated fabric, addition of label tag, folding prior to packaging, packing, and baling.
Packaging	Nets may be packed individually in 42 cm × 32 cm plastic bags with printed labels or tied into bundles of five loose nets. Then, ten bundles (50 nets) are placed into woven polypropylene bags, pressed, and strapped. The sizes of the bags and bales may vary depending on the customer requirements.
Discussion of impurities	There are no relevant impurities of toxicological concern.
Certification of limits	UNET G5 LN Alpha-cypermethrin: 2.4 g/kg, acceptable limits 2.04-3.00 g/kg Chlorfenapyr: 4.8 g/kg, acceptable limits 3.60-6.00 g/kg

1.4 Enforcement analytical method

Table 4. Details of the analytical method used to determine alpha-cypermethrin and chlorfenapyr in UNET G5 LN	
Quantification of alpha-cypermethrin and chlorfenapyr	Alpha-cypermethrin: CIPAC/5220/m and 454/LN/M/3.1, CIPAC Handbook M, p. 40, 2009. Chlorfenapyr: CIPAC/5220/m.

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

2 Chemical and entomological pre-treated fabric characterisation (starting material)

Laboratory studies that were previously submitted and assessed supporting the prequalified product Yorkool G5 (P-12507) were submitted to characterize the availability of active ingredients and insecticidal effect of the UNET G5 fabric. This was deemed acceptable to support the prequalification of the product based on the defined starting material and identity of manufacturing release specifications for the two products. It is not expected that there would be any deviations in performance between the two products. Therefore, for full information on the supporting studies, please refer to the Yorkool G5 WHOPAR Part 3.

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, 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 5. List of studies submitted to WHO as part of the prequalification dossier	
Studies that were relied upon for decision making	
Study number	Study title
BIT060	The laboratory equivalence study of Yorkool G5 Insecticide treated nets in Tanzania
TE2022-016	Determination of Alpha-cypermethrin and chlorfenapyr in Yorkool G5 LN and Interceptor G2 LN (long-lasting (coated on polyester) insecticidal mosquito net) collected from Yorkool G5 LN Phase I study
19240	Physical and Chemical Analysis of Alpha-cypermethrin 2.4 g/kg and Chlorfenapyr 4.8 g/kg Long- Lasting (Coated onto Filaments) Insecticidal Net (Yorkool G5 LN)
20185	Physical and Chemical Analysis of Yorkool G5 LN Long- Lasting (Coated onto Filaments) Insecticidal Net having Alpha-cypermethrin 2.4 g/kg and Chlorfenapyr 4.8 g/kg
21045	Physical and Chemical Analysis of Yorkool G5 LN Long-Lasting (Coated onto Filaments) Insecticidal Net having Alpha-cypermethrin 2.4 g/kg and Chlorfenapyr 4.8 g/kg (3rd Production)
TE2022-003	Physical and Chemical Analysis of 2 batches of Yorkool G5 LN(Alpha-cypermethrin 2.4 g/kg + Chlorfenapyr 4.8 g/kg) Long- Lasting (Coated onto Filaments) Insecticidal Net
TSNT01741501	Intertek Test report for bursting strength for ten pieces 100% polyester UNET G5 LN
Studies that were not used to inform decision making	
	None

Manufacturing release specifications

3.1 Summary of manufacturing release specifications

Table 6. Summary of manufacturing release specifications

Description			
The material shall be in the form of netting*, consisting of 100 denier* multi-filament polyester yarn, treated with technical alpha-cypermethrin complying with the requirements of WHO specification 454/TC (current version) and 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 free from visible extraneous matter,* visible damage (such as splitting or tearing) and visible manufacturing defects (such as poorly made seams or a weave that is either not uniform or too loose to remain uniform in use) and shall be suitable for use as an insecticidal net with long-lasting activity*.			
<i>ID</i>	<i>Property</i>	<i>Method</i>	<i>Declared value</i>
1*	Sampling Plan	See Appendix 2	
2*	Alpha-cypermethrin content	CIPAC/5220/m and 454/LN/M/3.1, CIPAC Handbook M, p. 40, 2009.	2.4 g/kg + 25% 2.4 g/kg - 15%
3*	Chlorfenapyr content	CIPAC/5220/m	4.8 g/kg + 25% 4.8 g/kg - 25%
4*	Alpha-cypermethrin wash resistance index	MT 195, CIPAC Handbook O, p. 205, 2017	Within the range 93% to 99%
5*	Chlorfenapyr wash resistance index	MT 195, CIPAC Handbook O, p. 205, 2017	Within the range 91% to 98%
6	Fabric weight	ISO 3801 / EN 12127	40 g/m ² ± 10%
7*	Bursting strength – fabric	ISO 13938:2	Not less than 405 kPa
8*	Bursting strength – seam	ISO 13938:2	Seam bursting strength average shall be not less than the average bursting strength for fabric
9*	Netting mesh size	See Appendix 2	Average ≥ 24 holes/cm ² Min. 24 holes/cm ²

* 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.

3.2 Storage

Accelerated storage stability data were generated for the pre-treated fabric as per CIPAC MT 46.3. 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

Batches used to generate the physical/chemical data for the pre-treated fabric (starting material) as per currently published WHOPAR for Yorkool G5 LN

Batch Number	Date of Production	Formulation	Uses
20190830	08/2019	White	Storage stability
20191101	11/2019	White	Storage stability
20201201	12/2020	White	Storage stability
20210107	01/2021	White	Storage stability, in-use stability
20210309	03/2021	White	Storage stability

Batches used to generate the physical/chemical data for the final constructed UNET G5 product

Batch Number	Date of Production	Formulation	Uses
G5240701TT1	07/2024	White	Bursting strength test
G5240702TT1	07/2024	White	Bursting strength test
G5240801TT1	08/2024	White	Bursting strength test
G5240901TT1	09/2024	White	Bursting strength test
G5240902TT1	09/2024	White	Bursting strength test

Characteristics for the pre-treated fabric (starting material) as per currently published WHOPAR for Yorkool G5 LN

Studies 19240, 20185, 21045 and TE2022-003

Study 19240:

Property	Batch ID	Test Method	Results
Alpha-cypermethrin mean content (5 net pieces)	20190830	CIPAC 5220/M, CIPAC 454/LN/M/2	2.60 g/kg (RSD 2.81%)
Alpha-cypermethrin distribution (5 net pieces)	20190830		2.51-2.73 g/kg (104.6-113.8%)
Chlorfenapyr mean content (5 net pieces)	20190830		5.64 g/kg (RSD 1.92%)
Chlorfenapyr distribution (5 net pieces)	20190830		5.46-5.78 g/kg (113.8-120.4%)
Alpha-cypermethrin wash resistance index	20190830	CIPAC MT 195	96.13%
Chlorfenapyr wash resistance index	20190830		95.38%
Fabric weight	20190830	ISO 3801 / EN 12127, EN 20139-1992	42.1 g/m ²
Mesh size	20190830	WHO specification 454+570/LN	25-26 holes/cm ²
Dimensional stability	20190830 Re-analysis	ISO 3759(2011), ISO 6330(2012), ISO 5077(2007)	-1.3%, -1.2% -0.5%, -0.4%
Bursting strength (fabric)	20190830	ISO 13938-2:1999	417.5 kPa
Flammability	20190830	EN 1102	No ignition or propagation. Maximum hole dimension 38 mm.

Study 20185:

Property	Batch ID	Test Method	Results
Alpha-cypermethrin mean content (5 net pieces)	20191101	CIPAC 5220/M, CIPAC 454/LN/M/2	2.39 g/kg (RSD 2.39%)
Alpha-cypermethrin distribution (5 net pieces)	20191101		2.28-2.47 g/kg (95.0-102.9%)
Chlorfenapyr mean content (5 net pieces)	20191101		5.32 g/kg (RSD 1.27%)
Chlorfenapyr distribution (5 net pieces)	20191101		5.21-5.44 g/kg (108.5-113.3%)
Alpha-cypermethrin wash resistance index	20191101	CIPAC MT 195	98.16%
Chlorfenapyr wash resistance index	20191101		96.14%
Fabric weight	20191101	ISO 3801 / EN 12127, EN 20139-1992	42.1 g/m ²
Mesh size	20191101	WHO specification 454+570/LN	25-27 holes/cm ²
Dimensional stability	20191101	ISO 3759(2011), ISO 6330(2012), ISO 5077(2007)	-1.0%, +0.8%
Bursting strength (fabric)	20191101	ISO 13938-2:1999	455.4 kPa
Flammability	20191101	EN 1102	No ignition or propagation. Maximum hole dimension 95 mm.

Study 21045:

Property	Batch ID	Test Method	Results
Alpha-cypermethrin mean content (5 net pieces)	20201201	CIPAC 5220/M, CIPAC 454/LN/M/2	2.67 g/kg (RSD 1.86%)
Alpha-cypermethrin distribution (5 net pieces)	20201201		2.61-2.80 g/kg (108.8-116.7%)
Chlorfenapyr mean content (5 net pieces)	20201201		4.89 g/kg (RSD 1.07%)
Chlorfenapyr distribution (5 net pieces)	20201201		4.78-4.96 g/kg (99.6-103.3%)
Alpha-cypermethrin wash resistance index	20201201	CIPAC MT 195	97.24%
Chlorfenapyr wash resistance index	20201201		95.28%
Fabric weight	20201201	ISO 3801 / EN 12127, EN 20139-1992	42.1 g/m ²
Mesh size	20201201	WHO specification 454+570/LN	24-26 holes/cm ²
Dimensional stability	20201201	ISO 3759(2011), ISO 6330(2012), ISO 5077(2007)	-0.6%, -0.4%
Bursting strength (fabric)	20201201	ISO 13938-2:1999	434.0 kPa
Flammability	20201201	EN 1102	No ignition or propagation. Maximum hole dimension 40 mm.

Study TE2022-003:

Property	Batch ID	Test Method	Results
Alpha-cypermethrin mean content (5 net pieces)	20210107 20210309	CIPAC 454/LN/M2/3	2.26 g/kg (RSD 1.16%) 2.70 g/kg (RSD 2.89%)
Alpha-cypermethrin distribution (5 net pieces)	20210107 20210309		2.22-2.29 g/kg (92.5-95.4%) 2.63-2.83 g/kg (109.6-117.9%)
Chlorfenapyr mean content (5 net pieces)	20210107 20210309	CIPAC 570/LN/M/3	3.93 g/kg (RSD 1.64%) 5.41 g/kg (RSD 1.49%)
Chlorfenapyr distribution (5 net pieces)	20210107 20210309		3.85-4.01 g/kg (80.2-83.5%) 5.33-5.54 g/kg (111.0-115.4%)
Alpha-cypermethrin wash resistance index	20210107 20210309	CIPAC MT 195	96.2% 96.5%
Chlorfenapyr wash resistance index	20210107 20210309		91.9% 92.2%
Fabric weight	20210107 20210309	ISO 3801 / EN 12127, EN 20139-1992	41.3 g/m2 40.9 g/m2
Mesh size	20210107 20210309	WHO specification 454+570/LN	27-29 holes/cm2 27-28 holes/cm2
Dimensional stability	20210107 20210309	ISO 3759(2011), ISO 6330(2012), ISO 5077(2007)	-2.2%, +1.9% -4.1%, +2.2%
Bursting strength (fabric)	20210107 20210309	ISO 13938-2:1999	432.1 kPa 433.9 kPa
Flammability	20210107 20210309	EN 1102	No ignition or propagation. Maximum hole dimension 91 mm. No ignition or propagation. Maximum hole dimension 107 mm.

Final constructed UNET G5 product characteristics

Study TSNT01741501:

Property	Batch ID	Test method	Results
Bursting strength (fabric)	G5240701TT1	ISO 13938-2	438.1 kPa
	G5240702TT1		432.9 kPa
	G5240801TT1		436.0 kPa
	G5240901TT1		422.7 kPa
	G5240902TT1		425.5 kPa
	Mean		431.0 kPa
	RSD		1.55%
Bursting strength (seam)	G5240701TT1		483.8 kPa
	G5240702TT1		543.0 kPa
	G5240801TT1		511.7 kPa
	G5240901TT1		510.8 kPa
	G5240902TT1		519.4 kPa
	Mean		513.7 kPa
	RSD		4.13%

The results reported are means of two samples per net from two nets per batch.

Storage stability for the pre-treated fabric (starting material) as per currently published WHOPAR for Yorkool G5 LN

Studies 19240, 20185, 21045 and TE2022-003

Study 19240:

Property	Batch ID	Before	After	Change
Alpha-cypermethrin mean content	20190830	2.60 g/kg	2.49 g/kg	-0.11 g/kg (-4.2%)
Chlorfenapyr mean content	20190830	5.64 g/kg	5.47 g/kg	-0.18 g/kg (-3.2%)
Alpha-cypermethrin wash resistance index	20190830	96.13%	96.83%	+0.70%
Chlorfenapyr wash resistance index	20190830	95.38%	94.37%	-1.01%
Dimensional stability	20190830	-1.3%, -1.2%	-1.3%, -1.2%	
	re-analysis	-0.5%, -0.4%	-0.4%, -0.3%	
Bursting strength (fabric)	20190830	417.5 kPa	412.2 kPa	-

Study 20185:

Property	Batch ID	Before	After	Change
Alpha-cypermethrin mean content	20191101	2.39 g/kg	2.33 g/kg	-0.06 g/kg (-2.5%)
Chlorfenapyr mean content	20191101	5.32 g/kg	5.19 g/kg	-0.13 g/kg (-2.4%)
Alpha-cypermethrin wash resistance index	20191101	98.16%	97.84%	-0.32%
Chlorfenapyr wash resistance index	20191101	96.14%	94.84%	-1.30%
Dimensional stability	20191101	-1.0%, +0.8%	-0.9%, +0.6%	-
Bursting strength (fabric)	20191101	455.4 kPa	448.0 kPa	-

Study 21045:

Property	Batch ID	Before	After	Change
Alpha-cypermethrin mean content	20201211	2.67 g/kg	2.59 g/kg	-0.08 g/kg (-3.0%)
Chlorfenapyr mean content	20201211	4.89 g/kg	4.70 g/kg	-0.19 g/kg (-3.9%)
Alpha-cypermethrin wash resistance index	20201211	97.24%	96.67%	-0.57%
Chlorfenapyr wash resistance index	20201211	95.28%	94.78%	-0.50%
Dimensional stability	20201211	-0.6%, +0.4%	-0.6%, -0.6%	-
Bursting strength (fabric)	20201211	434.0 kPa	422.0 kPa	-

Study TE2022-003:

Property	Batch ID	Before	After	Change
Alpha-cypermethrin content (1 sample)	20210107	2.29 g/kg	2.25 g/kg	-0.04 g/kg (-1.7%)
	20210309	2.73 g/kg	2.67 g/kg	-0.06 g/kg (-2.2%)
Chlorfenapyr content (1 sample)	20210107	3.94 g/kg	3.86 g/kg	-0.08 g/kg (-2.0%)
	20210309	5.43 g/kg	5.34 g/kg	-0.09 g/kg (-1.7%)
Alpha-cypermethrin wash resistance index	20210107	96.2%	96.8%	+0.6%
	20210309	96.5%	96.4%	-0.1%
Chlorfenapyr wash resistance index	20210107	91.9%	94.0%	+2.1%
	20210309	92.2%	92.3%	+0.1%
Dimensional stability	20210107	-2.2%, +1.9%	-1.7%, +0.2%	-
	20210309	-4.1%, +2.2%	-3.2%, +2.1%	-
Bursting strength (fabric)	20210107	432.1 kPa	427.9 kPa	-
	20210309	433.9 kPa	432.5 kPa	-

Appendix 2. Manufacturing release specifications: methods and notes

Description

- The specification applies to netting in bulk and manufactured nets. The netting may be white or coloured, for example, green or blue.
- 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.
- Occasional short lengths of loose thread present in the netting are not considered to be extraneous matter.
- Long-lasting insecticidal netting is expected to retain its insecticidal activity during its life span and through a specified number of washes.

Sampling Plan

Figure 1 applicable to all attributes (except of Attributes 4, 5, 7 and 8) for which samples are to be taken from various parts of the constructed ITN.

Attributes 4 and 5 should be sampled according to Figure 2 according to MT195, CIPAC Handbook O, p. 205, 2017.

Attributes 7 and 8 should be sampled according to Figure 3.

Figure 1:

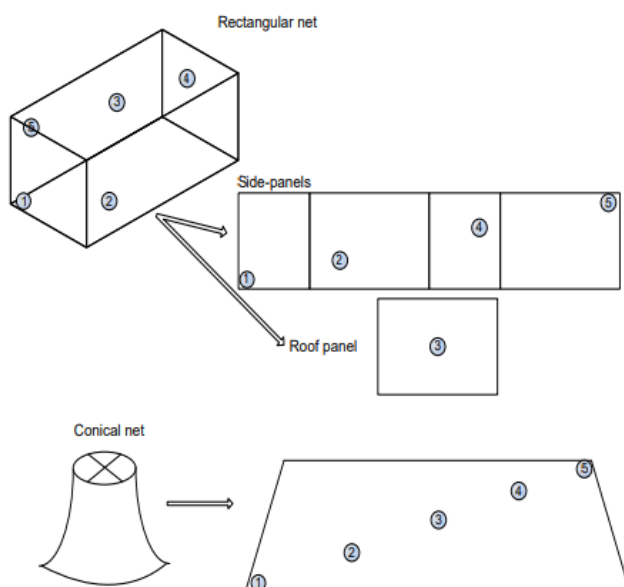


Figure 2:

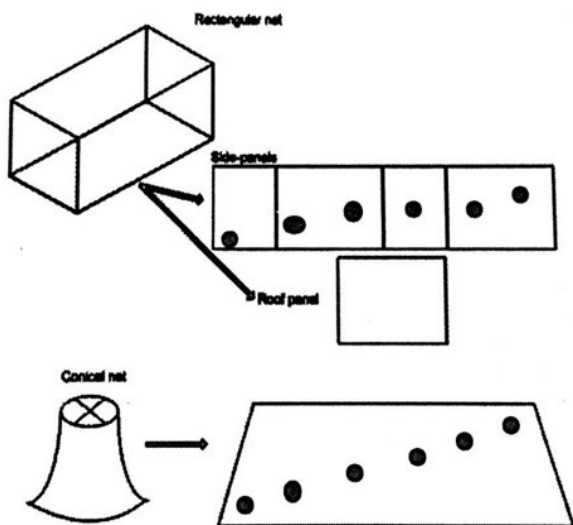
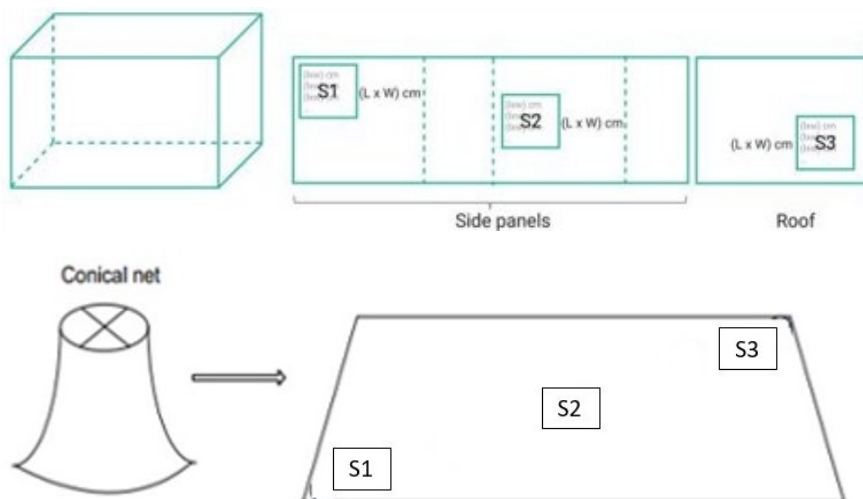


Figure 3:



Samples should be taken according to the above figures or on a convenient diagonal across the width of bulk material. Samples must be sufficiently large to conduct all tests required and representative of the net or netting. Except where seams are to be tested, do not test material within 10 cm of seams or selvages.

Use sharp scissors, or equivalent, to minimize damage to the fibres and fabric and thus avoid any consequential bias in the results of certain tests. Roll up the strips or squares and place them in labelled, new, clean aluminium foil prior to analysis. Samples should be kept cool, avoiding heat sources (including direct sunlight) or freezing, and analyzed/tested with minimum delay. Representative portions (sub-samples) for testing should be taken as described in each test method.

Attributes 2 and 3: Alpha-cypermethrin and chlorfenapyr content

The capillary GC method using internal standard (CIPAC/5220/m) for the determination of alpha-cypermethrin and chlorfenapyr in coated onto polyester LN was accepted as a provisional CIPAC method in 2019, the formal method 454/LN/M2/3 and 570/LN/M/3 is published in CIPAC Handbook P, p.62. 2021.. Prior to publication of the Handbook, copies of the method may be obtained through the CIPAC website, <https://www.cipac.org/index.php/methods-publications/pre-published-methods>

The target alpha-cypermethrin content of 2.4 g/kg for the 100 denier yarn netting or net, corresponds to 100 mg/m². The target chlorfenapyr content of 4.8 g/kg for the 100 denier yarn netting or net, corresponds to 200 mg/m². These values can be calculated from values for active ingredients content in g/kg and mass of net/m². Mass of net/m² should be determined according to ISO 3801 / EN 12127. In cases of dispute, g/kg values shall be used.

Attributes 4 and 5: Alpha-cypermethrin and chlorfenapyr wash resistance index

The content of alpha-cypermethrin and chlorfenapyr in the net pieces before and after washing should be determined by the method CIPAC/5220/m.

Attributes 7 and 8: Bursting strength – fabric and bursting strength – seam

Test method: ISO 13938 part 2 with conditioning of the fabric as specified in the ISO standard and WHO PQT/VCP Implementation Guidance Declaration of ITN construction and sampling procedure. The declared bursting strength, and testing for compliance with it, should be based on tests of 7.3 cm² areas of fabric. Proposed specifications based on tests of 50 cm² area must be supported by data showing the suitability of the proposed value and its relationship to minimum of 405 kPa (which is based on 7.3 cm² area). Bursting strength test sampling of the fabric and the seam should be conducted as shown in Figure 3.

Position and size of sample for the fabric and seam bursting strength test:

Bursting strength-fabric (S1 and S3, 25 cm × 25cm)

Bursting strength-seam (two seams: one of the side seams and one of the roof seams).

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 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.