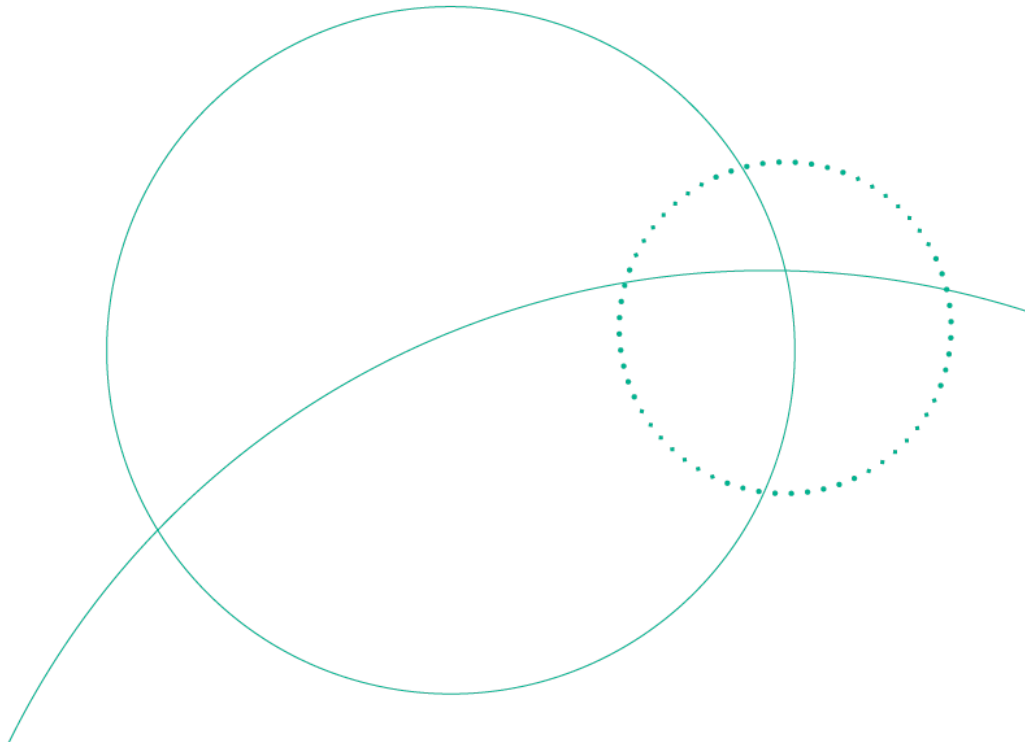
World Health Organization

WHO Prequalification Programme / Vector Control Product Assessment

WHO Public Assessment Report: WHOPAR Part 3

UNET G3 LN
(Sino Africa Medical Devices Company Ltd)
P-13228

Quality Assessment



Contents

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, Yorkool G3 LN (Product Ref # 021-003) pre-treated fabric, were provided. These data reflected those presented in the currently published WHOPAR for Yorkool G3 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. Yorkool G3 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: 20180074, 20180515, 20180516, 20200326, 20200415, 20200513, 20200518.

Complete results from Studies TSNT01152359, 2440, 20199, and 21046, as per currently published WHOPAR for Yorkool G3 LN are replicated in Appendix 1 for easy of reference.

Table 1. Chemical and physical properties for the starting material UNET G3 LN pre-treated fabric (Batches 20180074, 20180515, 20180516, 20200326, 20200415, 20200513, 20200518)

Data requirement	*Test method ID*	*Result*
Identification of deltamethrin and piperonyl butoxide	Deltamethrin CIPAC (N) 333/LN/(M2)/3 Piperonyl butoxide CIPAC (N) 33/LN/(M)/3	The active ingredients each comply with an identity test
Deltamethrin mean content Accelerated storage deltamethrin retention	CIPAC (N) 333/LN/(M2)/3	(3.07 -3.48 g/kg)* (2.965 - 3.52 g/kg)** (97.1 -97.7%)**
R-alpha deltamethrin mean content	CIPAC (O) 333/TC	0.022 g/kg (~0.7% wrt Deltamethrin)
Piperonyl butoxide content Accelerated storage piperonyl butoxide retention	CIPAC (N) 33/LN/(M)/3	(11.55 -12.32 g/kg)* (11.04 - 12.562 g/kg)** (97.2 -99.1%)**
Wash resistance index (Deltamethrin) Accelerated storage deltamethrin WRI	CIPAC (O) MT 195	(97.08 -98.43%)** (96.59 -98.95%)**
Wash resistance index (piperonyl butoxide) Accelerated storage piperonyl butoxide WRI	CIPAC (O) MT 195	(90.61 - 98.26%)** (92.75 - 97.36%)**
Mesh size	See Appendix 2	20 (16-21) holes/cm^2 **
Fabric weight	ISO 3801/EN 12127 EN 20139-1992	(37.7- 40.82 g/m^2)**
Dimensional stability of netting to washing Accelerated storage dimensional stability	ISO3759-2011 / ISO5077-2007 / ISO6330-2012	Length: (-2.8% to -1.8%)** Width: (+0.3% to +2.4%)** Length: (-2.1% to +0.3%)** Width: (-2% to +2.4%)**
Bursting strength (fabric) Accelerated storage bursting strength (fabric)	ISO 13938-2-1999 (30mm Diaphragm Diameter)	(440 - 497.9 kPa)** (411 - 482.4 kPa)**
Flammability (Batch 1 178 20)	EN 1102:2016	No ignition or propagation. Maximum hole length 100 mm, width 23 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 G3 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: G3240501TT, G3240601TT, G3240602TT, G3240701TT, G3240702TT.

Complete results from the Study TE2024-111 are available in Appendix 1.

Table 2. Physical properties for the finished constructed UNET G3 LN (Batches G3240501TT, G3240601TT, G3240602TT, G3240701TT, G3240702TT)

Data requirement	*Test method ID*	*Result*
Fabric Bursting strength	ISO 13938-2-1999 (30mm Diaphragm Diameter)	(425.8 - 466.5 kPa)*
Seam bursting strength	ISO 13938-2-1999 (30mm Diaphragm Diameter)	(466.0 - 493.0 kPa)*

* range of means

1.3 Manufacturing, composition and formulant information

Data on the manufacturing process and product composition for UNET G3 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 G3 LN

Description of starting material	Yorkool G3 LN pre-treated fabric (white, blue, green). Quality acceptability intake criteria as per Yorkool G3 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 G3 LN pre-treated fabric, addition of label tag, folding prior to packaging, packing, and baling.
Packaging	Nets may be packed individually in 46 cm × 38 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	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	UNET G3 LN Deltamethrin: 3.0 g/kg, acceptable limits 2.25-3.75 g/kg Piperonyl butoxide: 11.0 g/kg, acceptable limits 8.25-13.75 g/kg

1.4 Enforcement analytical method

Table 4. Details of the analytical method used to determine deltamethrin and piperonyl butoxide in UNET G3 LN

Quantification of deltamethrin and piperonyl butoxide	Deltamethrin: CIPAC (N) 333/LN/(M2)/3 Piperonyl butoxide: CIPAC (N) 33/LN/(M)/3

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 G3 (021-003) were submitted to characterize the availability of active ingredients and insecticidal effect of the UNET G3 fabric. This was deemed acceptable to support the prequalification of the product based on the defined starting material and identicality 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 G3 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**
BIT 030	Phase I equivalency evaluation of Yorkool G3 long-lasting insecticidal nets compared to Tsara Boost and Olyset Plus long-lasting insecticidal nets using laboratory reared strains of pyrethroid susceptible *Anopheles gambiae* s.s. and pyrethroid resistant *Anopheles arabiensis* in Tanzania.
BIT030	Chemical content analysis of Yorkool G3 LN at the Ifakara Health Institute (IHI) in Tanzania
TSNT01152359, 2440, 20199, and 21046	Yorkool G3 LN - Quality evaluation of deltamethrin and piperonyl butoxide long lasting (incorporated into filaments) insecticidal net
TE2024-111	Bursting Strength Test of 5 batches of UNET G3 LN
Studies that were not used to inform decision making	
	None

4 Manufacturing release specifications

4.1 Summary of manufacturing release specifications

Table 6. Summary of manufacturing release specifications

Description
The material shall be in the form of netting, consisting of 130 denier* knitted mono-filament polyethylene yarn, incorporating technical deltamethrin complying with the requirements of WHO specification 333/TC (current version) and with technical piperonyl butoxide complying with the requirements of WHO specification 33/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*.

ID	*Property*	*Method*	*Declared value*
1*	Sampling Plan	See Appendix 2	
2*	Deltamethrin content	CIPAC (N) 333/LN/(M2)/3, p. 34 2012	3.0 g/kg ± 25%
3	Piperonyl butoxide content	CIPAC (N) 33/LN/(M)/3, p. 111 2012	11.0 g/kg ± 25%
4*	Deltamethrin wash resistance index	MT195, CIPAC Handbook O, p. 205, 2017	Within the range 93% to 100%
5*	Piperonyl butoxide wash resistance index	MT195, CIPAC Handbook O, p. 205, 2017	Within the range 90% to 100%
6	Fabric weight	ISO 3801 / EN 12127	40 g/m^2 ± 10%
7*	Bursting strength – fabric	ISO 13938:2	Not less than 400 kPa
8*	Bursting strength – seam	ISO 13938:2	Not less than the average bursting strength for fabric
9*	Netting mesh size	See Appendix 2	Average ≥ 17 holes/cm^2 Min. 16 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.

4.2 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 G3 LN

Batch Number	Date of Production	Formulation	Uses
20180074	05/2018	Blue	Storage stability
20180515	05/2018	-	In-use stability (laboratory), semi-field studies
20180516	05/2018	Light blue	Storage stability, semi-field studies
20200326	03/2020	-	Semi-field studies
20200415	04/2020	Blue	Storage stability, semi-field studies
20200513	05/2020	Blue	Storage stability
20200518	05/2020	-	Semi-field studies

Batches used to generate the physical/chemical data for the final constructed UNET G3 product

Batch Number	Date of Production	Formulation	Uses
G3240501TT	05/2024	White	Bursting strength test
G3240601TT	06/2024	White	Bursting strength test
G3240602TT	06/2024	White	Bursting strength test
G3240701TT	07/2024	White	Bursting strength test
G3240702TT	075/2024	White	Bursting strength test

Characteristics for the pre-treated fabric (starting material) as per currently published WHOPAR for Yorkool G3 LN

Studies TSNT01152359, 2440, 20199, and 21046

Property	Batch ID	Test Method	Results
Deltamethrin mean content	20180516	CIPAC(N) 333/LN/(M2)/-	3.07 g/kg (RSD 2.426%)
	20200415		3.48 g/kg (RSD 0.96%)
	20200513		3.45 g/kg (RSD 0.73%)
Deltamethrin distribution (Numbers in parenthesis indicate percentage of target dose)	20180515		3.02-3.33 g/kg (100.7-111.0%)
	20180516		2.965-3.188 g/kg (98.8-106.3%)
	20200326		3.01-3.16 g/kg (100.3-105.3%)
	20200415		3.43-3.52 g/kg (114.3-117.3%)
	20200513		3.42-3.48 g/kg (114.0-116.0%)
	20200518		3.01-3.16 g/kg (100.3-105.3%)
Piperonyl butoxide (PBO) mean content	20180516	CIPAC (N) 33/LN/(M)/-	12.32 g/kg (RSD 1.197%)
	20200415		11.56 g/kg (RSD 0.78%)
	20200513		11.55 g/kg (RSD 0.35%)
PBO distribution (Numbers in parenthesis indicate percentage of target dose)	20180515		11.95-12.23 g/kg (108.6-111.2%)
	20180516		12.059-12.562 g/kg (109.6-114.2%)
	20200326		11.04-12.05 g/kg (100.4-109.5%)
	20200415		11.44-11.64 g/kg (104.0-105.8%)
	20200513		11.51-11.61 g/kg (104.6-105.5%)
	20200518		11.05-12.05 g/kg (100.5-109.5%)
R-alpha deltamethrin content	20180516	CIPAC (O) 333/TC	0.022 g/kg (~0.7% wrt Deltamethrin)
	20200415		Nil
	20200513		Nil
Wash resistance index (Deltamethrin)	20180516	CIPAC (O) MT 195	98.43%
	20200415		97.16%
	20200513		97.08%
Wash resistance index (PBO)	20180516		98.26%
	20200415		92.67%
	20200513		92.61%

Property	Batch ID	Test Method	Results
Physical state of netting	20180515 20180516 20200326 20200415 20200513 20200518	OPPTS 830.6303	Clean with no visible defects
Colour	20180515 20180516 20200326 20200415 20200513 20200518	OPPTS 830.6302	Blue Light blue Blue Blue Blue Blue
Odour	20180516 20200415 20200513	OPPTS 830.6304	Mild plastic-like No specific odour No specific odour
Dimensional stability	20180074 20180515 20200326 20200415 20200513 20200518	ISO3759-2011 / ISO5077-2007 / ISO6330-2012	-2.8%, +0.3% -2.5%, +2.2% -1.8%, +2.1% -1.9%, +2.4% -1.9%, +2.1% -1.8%, +2.1%
Bursting strength (fabric)	20180074 20180515 20200326 20200415 20200513 20200518	ISO 13938-2-1999 (30mm Diaphragm Diameter)	440 kPa 485 kPa 461 kPa 493.5 kPa 497.9 kPa 461 kPa
Mesh size	20180074 20180515 20200326 20200415 20200513 20200518	ISO 139 (1973)	16-18 holes/cm^2 (mean 17) 19 holes/cm^2 19 holes/cm^2 19-21 /cm^2 (mean 20) 19-21 /cm^2 (mean 20) 19 holes/cm^2
Fabric weight	20180074 20180515 20200326 20200415 20200513 20200518	ISO 3801/EN 12127 EN 20139-1992	37.7 g/m^2 38 g/m^2 39 g/m^2 40.82 g/m^2 40.75 g/m^2 39 g/m^2
Fabric weight (conditioned)	20180516		39.154 g/m^2
Fabric weight (oven-dry)	20180516		37.977 g/m^2
Flammability	20180074 20180515 20200326 20200513 20200415 20200518	EN 1102:2016	No ignition or propagation. Maximum hole length 100 mm, width 23 mm.

Study TSNT01152359**:** The mesh size results reported are the mean and minimum of five determinations. The flammability results are a composite of six replicates. The numbers of samples and/or replicates tested for the other parameters was not clear as the report did not contain either full test methods or raw data.

Study 2440: Deltamethrin and PBO contents shown are the maximum and minimum values reported for five samples from one net, as well as means and relative standard deviations. R-alpha deltamethrin content was determined from a single sample. Deltamethrin and PBO were identified by comparing the retention times of the principal peaks in the assay chromatograms with those for the reference standards. Wash resistance index values were calculated from the means of three samples each before and after washing.

Study 20199: Deltamethrin and PBO contents shown are the maximum and minimum values reported for five samples from one net, as well as means and relative standard deviations. R-alpha deltamethrin content was determined from a single sample. Wash resistance

index values were calculated from the means of three samples each before and after washing. Fabric weight, mesh size, and bursting strength values are means of five determinations (the minimum value is also reported for mesh size). Dimensional stability values are means of duplicate determinations on two samples. The flammability results are a composite of six replicates.
Study 21046: Deltamethrin and PBO contents shown are the maximum and minimum values reported for five samples from one net, as well as means and relative standard deviations. R-alpha deltamethrin content was determined from a single sample. Wash resistance index values were calculated from the means of three samples each before and after washing. Fabric weight, mesh size, and bursting strength values are means of five determinations (the minimum value is also reported for mesh size). Dimensional stability values are means of duplicate determinations on two samples. The flammability results are a composite of six replicates.

Final constructed UNET G3 product characteristics

Study TE2024-111:

Property	Batch ID	Test method	Results
Bursting strength (fabric)	G3240501TT	ISO 13938-2	449.4 kPa
	G3240601TT		464.3 kPa
	G3240602TT		458.2 kPa
	G3240701TT		466.5 kPa
	G3240702TT		425.8 kPa
	Mean		452.8 kPa
	RSD		3.6%
Bursting strength (seam)	G3240501TT		493.0 kPa
	G3240601TT		466.0 kPa
	G3240602TT		477.7 kPa
	G3240701TT		482.7 kPa
	G3240702TT		472.9 kPa
	Mean		478.5 kPa
	RSD		2.1%

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 G3 LN

Studies TSNT01152359, 20199, and 21046:

Property	Batch ID	Before	After	Change
Deltamethrin content	20180516	3.07 g/kg	2.999 g/kg	-0.071 g/kg (-2.3%)
	20200415	3.48 g/kg	3.39 g/kg	-0.09 g/kg (-2.6%)
	20200513	3.45 g/kg	3.35 g/kg	-0.10 g/kg (-2.9%)
PBO content	20180516	12.32 g/kg	12.206 g/kg	-0.114 g/kg (-0.9%)
	20200415	11.56 g/kg	11.25 g/kg	-0.31 g/kg (-2.7%)
	20200513	11.55 g/kg	11.23 g/kg	-0.32 g/kg (-2.8%)
Wash resistance index (Deltamethrin)	20180516	98.43%	98.95%	+0.52%
	20200415	97.16%	96.72%	-0.44%
	20200513	97.08%	96.59%	-0.49%
Wash resistance index (PBO)	20180516	98.26%	97.36%	-0.90%
	20200415	92.67%	92.77%	+0.10%
	20200513	92.61%	92.75%	+0.14%
Dimensional stability	20180074	-2.8%, +0.3%	+0.3%, -2.0%	-
	20200415	-1.9%, +2.4%	-2.1%, +2.4%	-
	20200513	-1.9%, +2.1%	-2.1%, +2.2%	-
Bursting strength (fabric)	20180074	440 kPa	411 kPa	-29 kPa
	20200415	493.5 kPa	481.7 kPa	-11.8 kPa
	20200513	497.9 kPa	482.4 kPa	-15.5 kPa

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.
- Two different master batches of polyethylene are used together for the yarn, one with deltamethrin and the other one with piperonyl butoxide. The yarn contained the active ingredient and synergist are used for the net by knitting.
- 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 lifespan and through a number of washes (public health products) or in worst-case expected climatic conditions (agricultural products).

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:

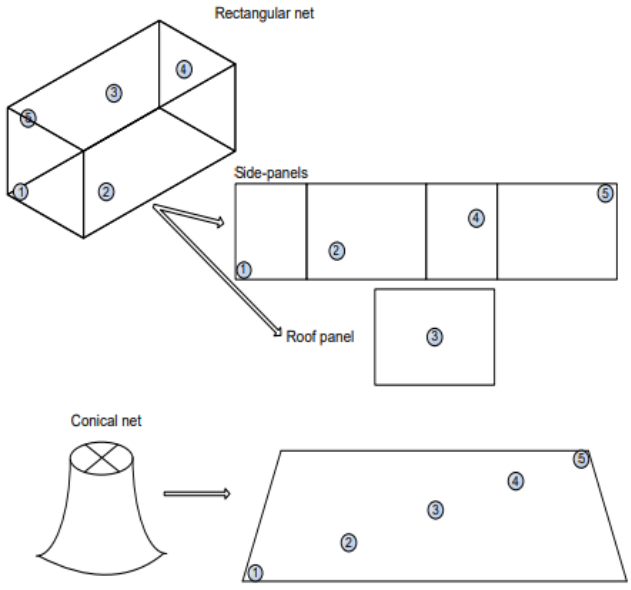


Figure 2:

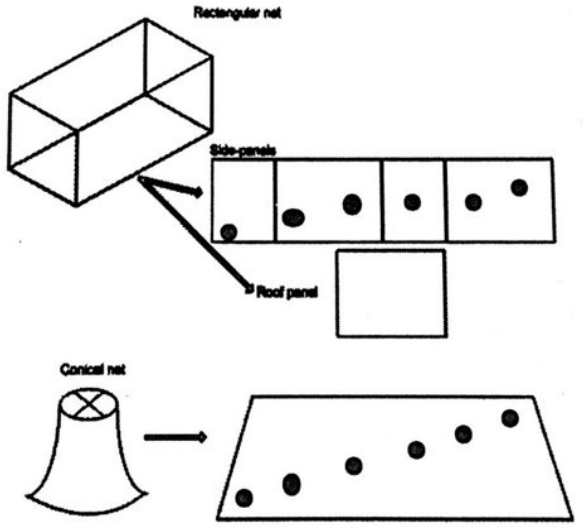
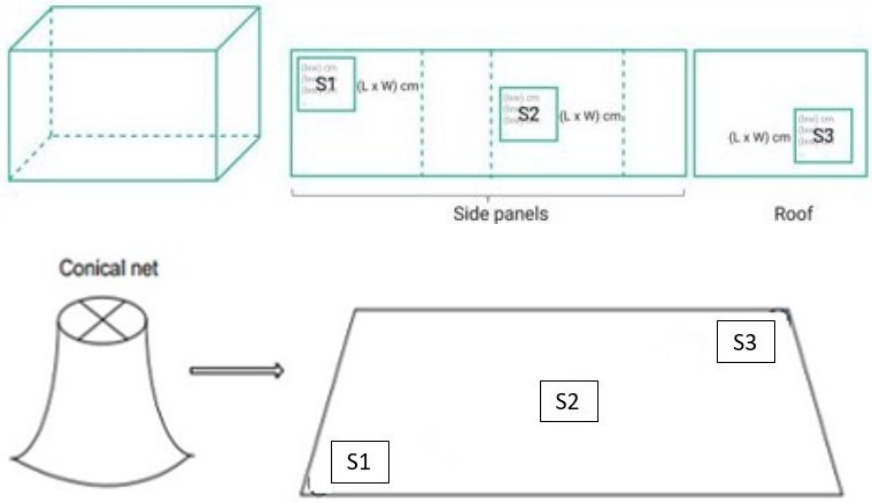


Figure 3:



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 selvedges.

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.

Attribute 2: Deltamethrin content

For complete identification and good quantification, deltamethrin which is a single pyrethroid stereoisomer consisting of [αS,1R,3R]-isomer (also known as the S-isomer) must be separated from the [αR,1R,3R]-isomer (otherwise known as the R-isomer), which is not part of the active ingredient and not a relevant impurity. These diastereomers may be separated by non-chiral techniques as provided in the CIPAC method for deltamethrin.

Attributes 4 and 5: Deltamethrin and piperonyl butoxide wash resistance index

The content of deltamethrin in the net pieces before and after washing should be determined by the method 333/LN/(M2)/3, CIPAC Handbook N, p.34, 2012. The content of piperonyl butoxide in the net pieces before and after washing should be determined by the method 33/LN/(M)/3, CIPAC Handbook N, p.111, 2012.

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 cm^2 areas of fabric. Proposed specifications based on tests of 50 cm^2 area must be supported by data showing the suitability of the proposed value and its relationship to minimum of 400 kPa (which is based on 7.3 cm^2 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, 20ºC, 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 ≥ ½ are counted as complete holes, whereas those < ½ 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.