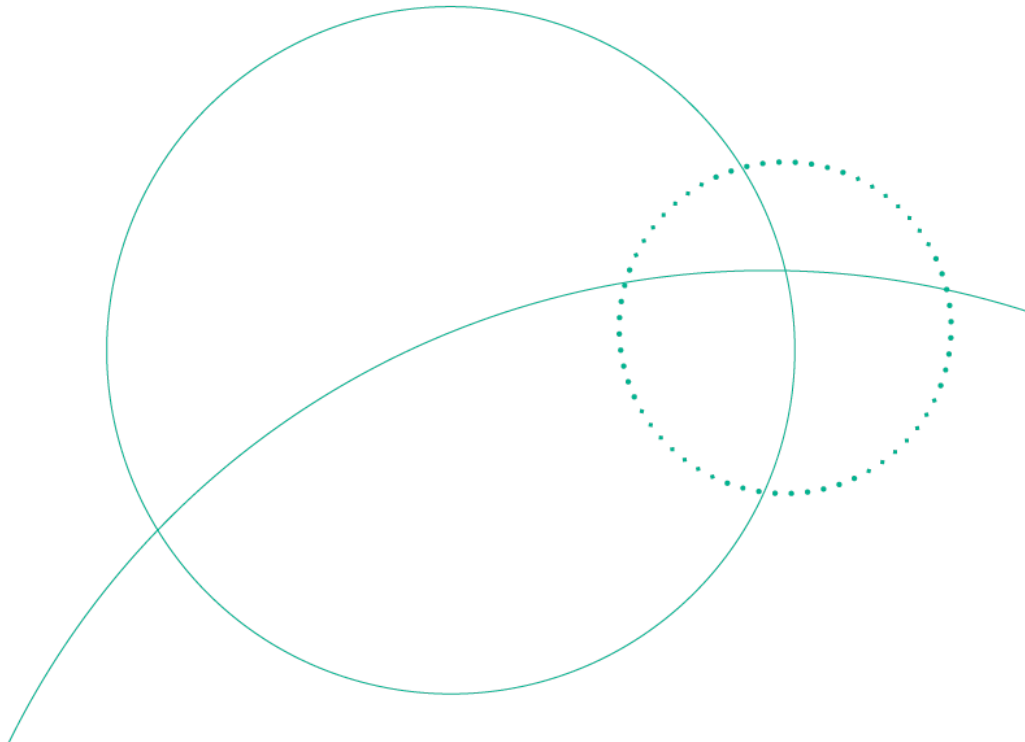
World Health Organization

WHO Prequalification Programme / Vector Control Product Assessment

WHO Public Assessment Report: WHOPAR Part 3

UNET G1 LN
(Sino Africa Medical Devices Company Ltd)
P-13227

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, Yorkool G1 LN (Product Ref # P-11664) 100D pre-treated fabric, were provided. These data reflected those presented in the currently published WHOPAR for Yorkool G1 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 G1 (100D) 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: SC200704PA1, SC200803VU1, SC200702PK1.

Complete results from Studies 23118 and TE2023-002, as per currently published WHOPAR for Yorkool G1 LN (100D) are replicated in Appendix 1 for easy of reference.

Table 1. Chemical and physical properties for the starting material Yorkool G1 LN (100D) pre-treated fabric (Batches SC200704PA1, SC200803VU1, SC200702PK1)

Data requirement	*Test method ID*	*Result*
Identification of deltamethrin	Deltamethrin CIPAC (N) 333/LN/(M)/2	The active ingredients each comply with an identity test
Deltamethrin mean content Accelerated storage deltamethrin retention	CIPAC (N) 333/LN/(M)/3	(1.27 -1.49 g/kg)* (1.21 - 1.54 g/kg)** (96.6 -114.2%)*
R-alpha deltamethrin mean content	CIPAC (O) 333/TC	-
Wash resistance index (Deltamethrin) Accelerated storage deltamethrin WRI	CIPAC (O) MT 195	(93.1 -94.3%)* (93.7 -94.9%)*
Mesh size	See Appendix 2	(26-27) holes/cm^2 *
Fabric weight	ISO 3801/EN 12127 EN 20139-1992	(37.6- 38.5 g/m^2)*
Dimensional stability of netting to washing Accelerated storage dimensional stability	ISO3759-2011 / ISO5077-2007 / ISO6330-2012	Length: (-0.7% to +0.4%)* Width: (+0.5% to +1.1%)* Length: (-0.6% to +0.4%)* Width: (+0.7% to +1.8%)*
Bursting strength (fabric) Accelerated storage bursting strength (fabric)	ISO 13938-2-1999 (30mm Diaphragm Diameter)	(436.4 - 450.8 kPa)* (406.3 - 415.6 kPa)*
Flammability	EN 1102:2016	No ignition or propagation. Maximum hole width 32 mm, length 141 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 G1 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: G1240301TT1, G1240401TT1, G1240402TT1, G1240601TT1, G1240801TT1.

Complete results from the Study TSNT01741496 are available in Appendix 1.

Table 2. Physical properties for the finished constructed UNET G1 LN (Batches G1240301TT1, G1240401TT1, G1240402TT1, G1240601TT1, G1240801TT1)

Data requirement	*Test method ID*	*Result*
Fabric Bursting strength	ISO 13938-2-1999 (30mm Diaphragm Diameter)	(390.9 - 409.7 kPa)*
Seam bursting strength	ISO 13938-2-1999 (30mm Diaphragm Diameter)	(420.5 - 493.7 kPa)*

* range of means

1.3 Manufacturing, composition and formulant information

Data on the manufacturing process and product composition for UNET G1 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 G1 LN

Description of starting material	Yorkool G1 LN (100D) pre-treated fabric (white, blue, green). Quality acceptability intake criteria as per Yorkool G1 LN (100D) 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 G1 LN (100D) 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	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 G1 LN Deltamethrin: 1.4 g/kg, acceptable limits 1.05-1.75 g/kg

1.4 Enforcement analytical method

Table 4. Details of the analytical method used to determine Deltamethrin in UNET G1 LN

Quantification of deltamethrin	Deltamethrin: CIPAC (N) 333/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)

The data that were submitted for Yorkool G1 (P-11664) were submitted for UNET G1. These were laboratory studies to characterize the availability of the active ingredient and the insecticidal effect of the pre-treated Yorkool G1 LN fabric on Anopheline mosquito species that were conducted by WHOPES under the WHOPES evaluation scheme. These data were not re-evaluated as part of the Yorkool G1 assessment.

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
23118	Chemical properties and accelerated storage stability tests for 100 denier Yorkool LN [deltamethrin long-lasting (coated onto filaments) insecticidal mosquito net (LN)]
19241	Physical and Chemical Analysis of Deltamethrin based Long Lasting (coated onto polyester filament) Insecticidal Net (Yorkool LN 1.4 g/kg, 150D)
TE2023-002	Physical and Chemical Analysis of 3 batches of each fabric of Yorkool LN (Yorkool G1 LN)(75D, 1.8 g/kg Deltamethrin; 100D, 1.4g/kg Deltamethrin; 150D, 1.4g/kg Deltamethrin) Long-Lasting (Coated onto Filaments) Insecticidal Net
TSNT01745026	Intertek Test report for bursting strength for ten pieces 100% polyester UNET G1 LN
Studies that were not used to inform decision making	
TSNT00506381	Intertek Test report for physical properties for four pieces of submitted tricot Mosquito Net in white, 100 Denier
TSNT01203507	Intertek Test report for physical properties for one 100% polyester knitted Mosquito Net in white, 100 Denier
TSNT00212245	Intertek Test report for physical properties for four pieces of submitted tricot Mosquito Net in white, 75 Denier
TSNT01203498	Intertek Test report for physical properties for one 100% polyester knitted Mosquito Net in white, 75 Denier
TE2024-097	Physical and Chemical Analysis of 5 batches of Yorkool G1 LN (100D, 1.4g/kg Deltamethrin) Long-Lasting (Coated onto Filaments) Insecticidal Net

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 100 denier* multi-filament polyester yarn, treated with technical deltamethrin complying with the requirements of WHO specification 333/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. 66 2009	1.4 g/kg ± 25%
3*	Deltamethrin wash resistance index	MT195, CIPAC Handbook O, p. 205, 2017	Within the range 80% to 98%
4	Fabric weight	ISO 3801 / EN 12127	40 g/m^2 ± 10%
5*	Bursting strength – fabric	ISO 13938:2	Not less than 350 kPa
6*	Bursting strength – seam	ISO 13938:2	Seam bursting strength average shall be not less than the average bursting strength for fabric
7*	Netting mesh size	See Appendix 2	Average ≥ 24 holes/cm^2 Min. 24 holes/cm^2
8*	Dimensional stability of netting to washing	See Appendix 2	Not more than 10% shrinkage and not more than 5% expansion in both directions.

* 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 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 for the pre-treated fabric (starting material) as per currently published WHOPAR for Yorkool G1 LN (100 D)

Batch Number	Date of Production	Formulation	Uses
1211TJ	11/2012	100 D white	Storage stability
SC200704PA1	07/2020	100 D green	Storage stability, in-use stability (semi-field)
SC200803VU1	08/2020	100 D green	Storage stability, in-use stability (semi-field)
SC200702PK1	07/2020	100 D green	Storage stability, in-use stability (semi-field)

Batches used to generate the physical/chemical data for the final constructed UNET G1 product

Batch Number	Date of Production	Formulation	Uses
G1240301TT1	03/2024	100 D white	Bursting strength test
G1240401TT1	04/2024	100 D white	Bursting strength test
G1240402TT1	04/2024	100 D white	Bursting strength test
G1240601TT1	06/2024	100 D white	Bursting strength test
G1240801TT1	08/2024	100 D white	Bursting strength test

Characteristics for the pre-treated fabric (starting material) as per currently published WHOPAR for Yorkool G1 LN (100 D)

Studies 23118, 19241 and TE2023-002

Study 23118:

Property	Batch ID	Test Method	Results
Deltamethrin mean content	1211TJ	CIPAC(N) 333/LN/(M2)/-	1.41 g/kg (RSD 0.4%)
Deltamethrin distribution (Numbers in parenthesis indicate percentage of target dose)	1211TJ		1.29-1.57 g/kg (92.1-112.1%)
R-alpha deltamethrin content	1211TJ	CIPAC (O) 333/TC	< 0.01 g/kg
Wash resistance index (WRI)	1211TJ	CIPAC (O) MT 195	93.7%
Fabric weight	1211TJ	In-house	39.87 g/m^2

Deltamethrin mean content and *R*- alpha deltamethrin content are the means of three analyses performed on a homogenized sample prepared from five net pieces. Deltamethrin distribution is the minimum/maximum of one analysis each performed on five individual net pieces. Fabric weight is the mean of one analysis each performed on three individual pieces. WRI was calculated from the means of one analysis each on three pieces before and three after washing.

Study TE2023-002:

Property	Batch ID	Test Method	Results
Deltamethrin mean content (Numbers in parenthesis indicate percentage of target dose)	SC200704PA1 SC200803VU1 SC200702PK1 Mean RSD%	CIPAC(N) 333/LN/(M2)/-	1.27 g/kg 1.44 g/kg 1.48 g/kg 1.40 g/kg 7.98%
Deltamethrin distribution (Numbers in parenthesis indicate percentage of target dose)	SC200704PA1 SC200803VU1 SC200702PK1 Mean RSD		1.21-1.40 g/kg (86.4-100.0%) 1.40-1.54 g/kg (100.0-110.0%) 1.37-1.53 g/kg (97.9-109.3%) 1.40 g/kg 8.18%
Wash resistance index (WRI) Deltamethrin	SC200704PA1 SC200803VU1 SC200702PK1 Mean RSD	CIPAC (O) MT 195	93.9% 93.1% 94.3% 93.8% 0.65%
Dimensional stability	SC200704PA1 SC200803VU1 SC200702PK1 Mean	ISO3759-2011 / ISO5077-2007 / ISO6330-2012	-0.1%, +0.5% -0.7%, +1.1% +0.4%, +0.6% -0.2%, +0.7%
Bursting strength (fabric)	SC200704PA1 SC200803VU1 SC200702PK1 Mean RSD	ISO 13938-2	436.4 kPa 440.8 kPa 450.8 kPa 442.7 kPa 3.73%
Mesh size	SC200704PA1 SC200803VU1 SC200702PK1 Mean RSD	ISO 139	Mean: 27 holes/cm^2, Min: 26 holes/cm^2 Mean: 27 holes/cm^2, Min: 26 holes/cm^2 Mean: 27 holes/cm^2, Min: 26 holes/cm^2 27 holes/cm^2 1.91%
Fabric weight	SC200704PA1 SC200803VU1 SC200702PK1 Mean RSD	ISO 3801/EN 12127 EN 20139-1992	38.3 g/m2 38.5 g/m2 37.6 g/m2 38.2 g/m^2 1.6%
Flammability	SC200704PA1 SC200803VU1 SC200702PK1	EN 1102:2016	No ignition or propagation. Maximum hole width 27 mm, length 126 mm.

Deltamethrin mean content is the mean of duplicate analyses performed on two portions taken from a homogenized sample prepared from five net pieces. Deltamethrin distribution is the minimum and maximum of duplicate analyses of five individual samples. WRI is calculated from the means of duplicate analyses performed on three samples each before and after washing. Mesh size is the minimum and maximum of five determinations. Fabric weight and bursting strength are the means of five determinations. Dimensional stability is the means of duplicate determinations performed on two samples. Flammability was a single determination.

Final constructed UNET G1 product characteristics

Study TSNT01741496:

Property	Batch ID	Test method	Results
Bursting strength (fabric)	G1240301TT1	ISO 13938-2	406.2 kPa
	G1240401TT1		409.7 kPa
	G1240402TT1		402.7 kPa
	G1240601TT1		401.4 kPa
	G1240801TT1		390.9 kPa
	Mean		402.2 kPa
	RSD		3.91%
Bursting strength (seam)	G1240301TT1		420.5 kPa
	G1240401TT1		454.6 kPa
	G1240402TT1		476.3 kPa
	G1240601TT1		493.7 kPa
	G1240801TT1		478.2 kPa
	Mean		464.7 kPa
	RSD		7.22%

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 G1 LN (100 D)

Studies 23118 and TE2023-002

Study 23118:

Property	Batch ID	Before	After	Change
Deltamethrin content	1211TJ	1.41 g/kg	1.34 g/kg	-0.07 g/kg (-5.0%)
R-alpha deltamethrin content	1211TJ	< 0.01 g/kg	< 0.01 g/kg	-
Wash resistance index (WRI)	1211TJ	93.7%	96.0%	+2.3%

Study TE2023-002:

Property	Batch ID	Before	After	Change
Deltamethrin content	SC200704PA1	1.27 g/kg	1.45 g/kg	+0.18 g/kg (+14.2%)
	SC200803VU1	1.44 g/kg	1.44 g/kg	-
	SC200702PK1	1.48 g/kg	1.43 g/kg	-0.05 g/kg (-3.4%)
Wash resistance index (WRI)	SC200704PA1	93.9%	93.7%	-0.2%
	SC200803VU1	93.1%	94.9%	+1.8%
	SC200702PK1	94.3%	94.5%	+0.2%
Dimensional stability	SC200704PA1	-0.1%, +0.5%	-0.6%, +0.8%	-
	SC200803VU1	-0.7%, +1.1%	+0.4%, +0.7%	-
	SC200702PK1	+0.4%, +0.6%	-0.2%, +1.8%	-
Bursting strength (fabric)	SC200704PA1	436.4 kPa	406.3 kPa	-30.1 kPa
	SC200803VU1	440.8 kPa	414.8 kPa	-36.0 kPa
	SC200702PK1	450.8 kPa	415.6 kPa	-45.2 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, yellow, pink, khaki or light brown, blue or dark blue, green or dark green.
- 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.

Sampling Plan

Figure 1 applicable to all attributes (except of Attribute 3, Attributes 5 and 6) for which samples are to be taken from various parts of the constructed ITN.

Attribute 3 should be sampled according to Figure 2 according to MT195, CIPAC Handbook O, p. 205, 2017.

Attributes 5 and 6 should be sampled according to Figure 3.

Figure 1:

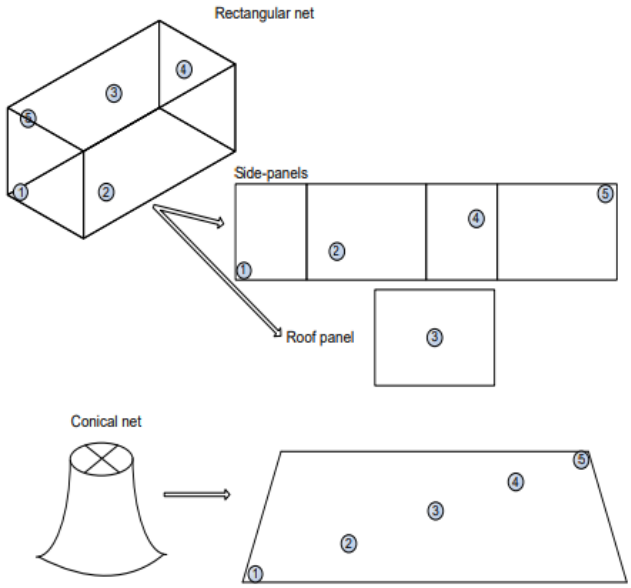


Figure 2:

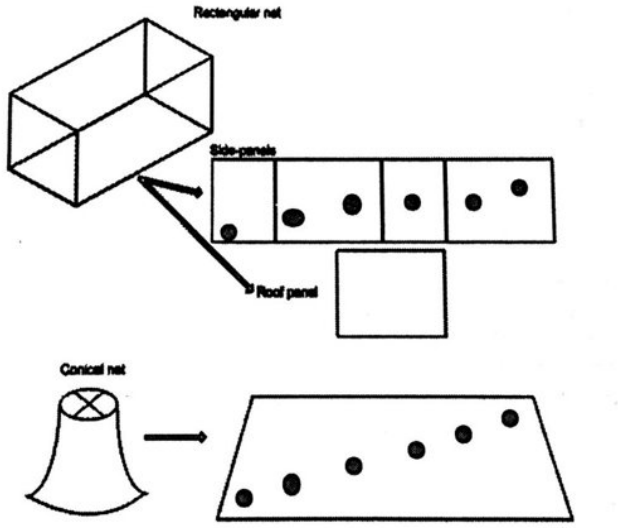
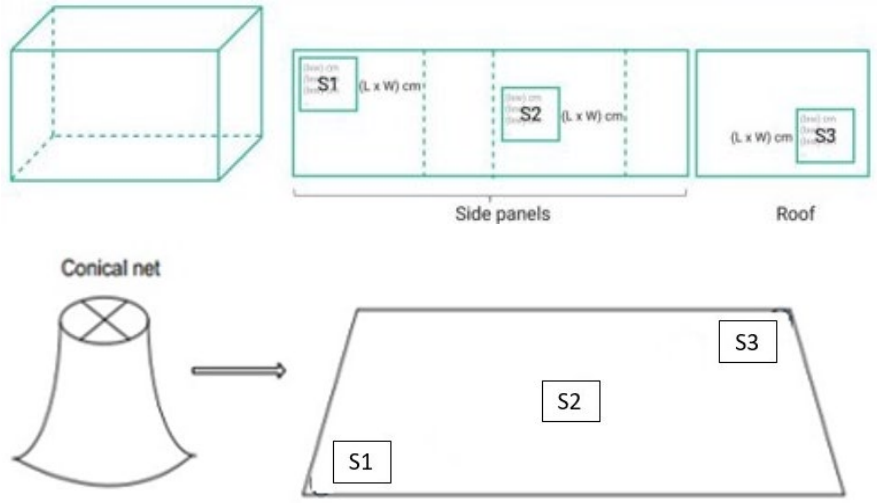


Figure 3:



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.

The deltamethrin content may be declared as both g/kg and mg/m2 but, in case of dispute, g/kg values shall be used. If the active ingredient content is also specified as mg/m2 of netting material, the actual content on this basis is calculated from the measured values for active ingredient content in g/kg and mass of net/m2. Mass of net/m2 should be determined according to ISO 3801 / EN 12127.

Attribute 3: Deltamethrin wash resistance index

The content of deltamethrin in the net pieces before and after washing should be determined by the method 333/LN/(M)/3, CIPAC Handbook M, p.66, 2009.

Attributes 5 and 6: 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 350 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 7: 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.

Attribute 8: Dimensional stability of netting to washing

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: 30ºC 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.