

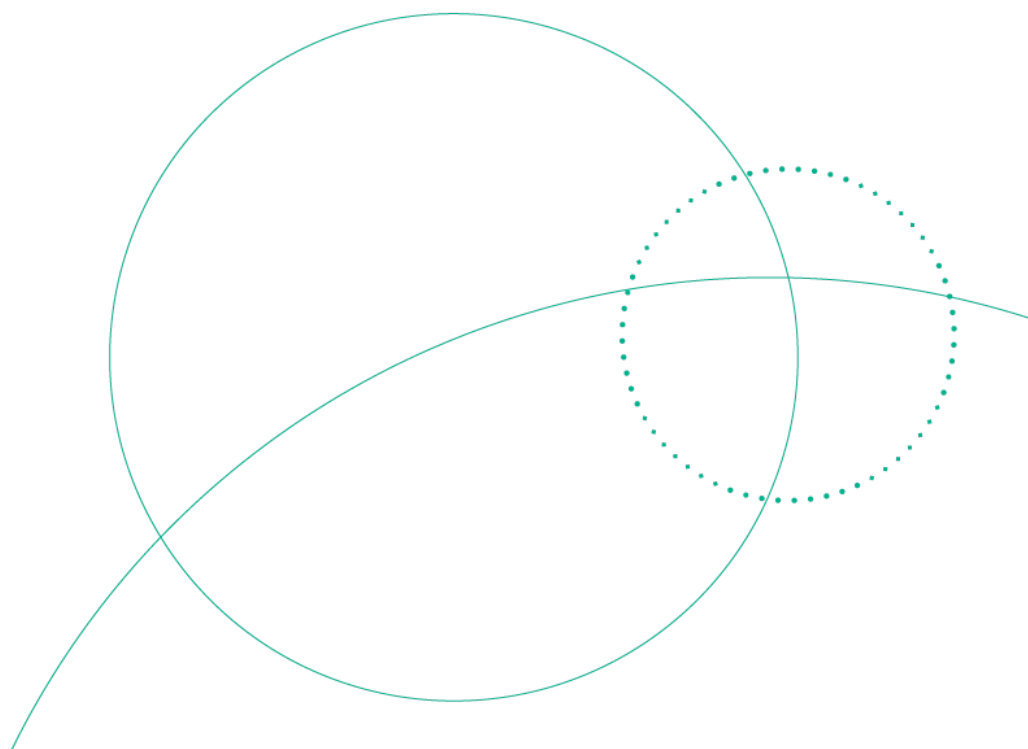
WHO Prequalification Programme / Vector Control Product Assessment

WHO Public Assessment Report: WHOPAR Part 3

Yorkool G1 LN
(Tianjin Yorkool)

P-11664

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 Yorkool G1 LN 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: 1211TJ, SC200704PA1, SC200803VU1, SC200702PK1.

Complete results from the Studies 23118 and TE2023-002 are available in Appendix 1.

Table 1. Chemical and physical properties for Yorkool G1 LN (100D) (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	CIPAC (N) 333/LN/(M)/3	(1.27 -1.49 g/kg)*
Accelerated storage deltamethrin retention		(1.21 - 1.54 g/kg)** (96.6 -114.2%)*
R-alpha deltamethrin mean content	CIPAC (O) 333/TC	-
Wash resistance index (Deltamethrin)	CIPAC (O) MT 195	(93.1 -94.3%)*
Accelerated storage deltamethrin WRI		(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	ISO3759-2011 / ISO5077-2007 / ISO6330-2012	Length: (-0.7% to +0.4%)* Width: (+0.5% to +1.1%)*
Accelerated storage dimensional stability		Length: (-0.6% to +0.4%)* Width: (+0.7% to +1.8%)*
Bursting strength	ISO 13938-2-1999 (30mm Diaphragm Diameter)	(436.4 - 450.8 kPa)*
Accelerated storage bursting strength		(406.3 - 415.6 kPa)*
Seam bursting strength	ISO 13938-2-1999 (30mm Diaphragm Diameter)	(515.5 - 568.2 kPa)*
Accelerated storage seam bursting strength		(487.2 - 530.4 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 Manufacturing, composition and formulant information

Data on the manufacturing process and product composition for Yorkool G1 LN have been provided and are adequate. A summary is presented in Table 4. Detailed information on the manufacturing process and product formulation is considered Confidential Business Information (CBI).

Table 4. Manufacturing process and product composition data submitted for Yorkool G1 LN	
Description of starting material	Deltamethrin TC formulated as part of the production process. 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 mixing the AI with the binder formulation, coating the pre-knitted polyethylene terephthalate (PET) (common name polyester) and heat setting. 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 42 cm × 32 cm plastic bags with printed labels or tied into bundles of five loose nets prior to baling with one adhesive label per bale. The sizes of the bags and bales may vary depending on the customer requirements.
Discussion of impurities	The <i>R</i> -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	Yorkool G1 LN (100D) Deltamethrin: 1.4 g/kg, acceptable limits 1.05-1.75 g/kg

1.3 Enforcement analytical method

Table 5. Details of the analytical method used to determine Deltamethrin and Piperonyl butoxide in Yorkool G3 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 fabric characterisation

Laboratory studies to characterize the availability of the active ingredient and the insecticidal effect of the fabric of Yorkool G1 LN on Anopheline mosquito species were conducted by WHOPES under the WHOPES evaluation scheme. These data were not re-evaluated as part of this submission.

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 6. 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)]
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
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

4 Manufacturing release specifications

4.1 Summary of manufacturing release specifications

Table 7. 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 $\pm$ 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 $\pm$ 10%
5*	Bursting strength – fabric	ISO 13938:2	Not less than 350kPa
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 $\geq$ 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.

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
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)

Product characteristics

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	SC200704PA1 SC200803VU1 SC200702PK1	CIPAC(N) 333/LN/(M2)/-	1.27 g/kg 1.44 g/kg 1.48 g/kg
Deltamethrin distribution (Numbers in parenthesis indicate percentage of target dose)	SC200704PA1 SC200803VU1 SC200702PK1		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%)
Wash resistance index (WRI)	SC200704PA1 SC200803VU1 SC200702PK1	CIPAC (O) MT 195	93.9% 93.1% 94.3%
Dimensional stability	SC200704PA1 SC200803VU1 SC200702PK1	ISO3759-2011 / ISO5077-2007 / ISO6330-2012	-0.1%, +0.5% -0.7%, +1.1% +0.4%, +0.6%
Bursting strength (fabric)	SC200704PA1 SC200803VU1 SC200702PK1	ISO 13938-2	436.4 kPa 440.8 kPa 450.8 kPa
Bursting strength (seam)	SC200704PA1 SC200803VU1 SC200702PK1		567.9 kPa 538.8 kPa 585.1 kPa
Mesh size	SC200704PA1 SC200803VU1 SC200702PK1	ISO 139	26-27 holes/cm2 26-27 holes/cm2 26-27 holes/cm2
Fabric weight	SC200704PA1	ISO 3801/EN 12127 EN	38.3 g/m2

Property	Batch ID	Test Method	Results
	SC200803VU1 SC200702PK1	20139-1992	38.5 g/m2 37.6 g/m2
Flammability	SC200704PA1 SC200803VU1 SC200702PK1	EN 1102:2016	No ignition or propagation. Maximum hole width 32 mm, length 141 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.

Storage stability

Studies 23118, 19241 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
Bursting strength (seam)	SC200704PA1	563.5 kPa	530.4 kPa	-33.1 kPa
	SC200803VU1	568.2 kPa	487.2 kPa	-81.0 kPa
	SC200702PK1	515.5 kPa	530.4 kPa	+14.9 kPa

Appendix 2. Manufacturing release specifications: methods and notes

Description

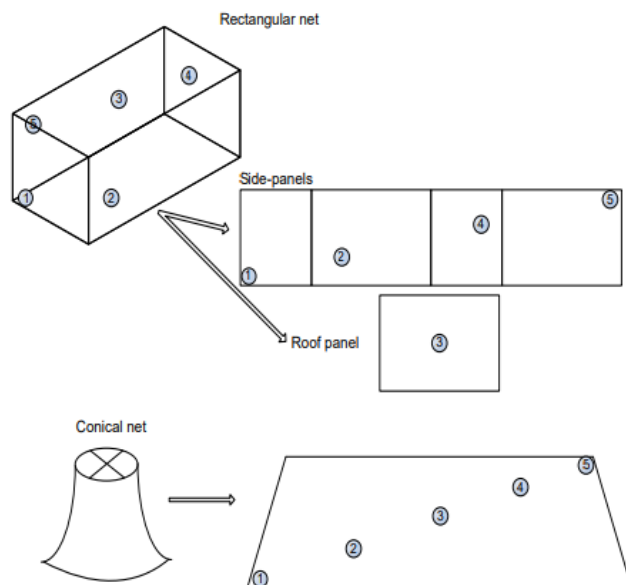
- The specification applies to netting in bulk and manufactured nets. The netting may be white or coloured, for example, yellow, pink, khaki or light brown, blue or dark blue, green or dark green.
- The linear density (denier) of the yarn cannot be measured in the netting or the manufactured bed net but it should be identified on the packaging.
- 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.

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.



Samples should be taken according to Figure 1 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.

Attribute 2: Deltamethrin content

For complete identification and good quantification, deltamethrin which is a single pyrethroid stereoisomer consisting of [α S,1R,3R]-isomer (also known as the S-isomer) must be separated from the [α R,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.

Attributes 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. 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 250 kPa (which is based on 7.3 cm² area). Five replicate tests should be conducted on samples taken at approximately equal distances on a diagonal across the netting, taking no sample within 10 cm of a border or seam. In made up rectangular nets, the “diagonal” may correspond to figure 1. The average of the 5 measurements is calculated.

The method to test seam bursting strength is identical to that used to test the fabric, except that 5 replicate tests should be made, with the seam centred on the test head. Up to 5 seams may be tested but, if there are < 5 seams, replicate measurements should be made on 1 or more seams, to provide a total of 5 measurements.

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, 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 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.