World Health Organization

WHO Prequalification Programme / Vector Control Product Assessment

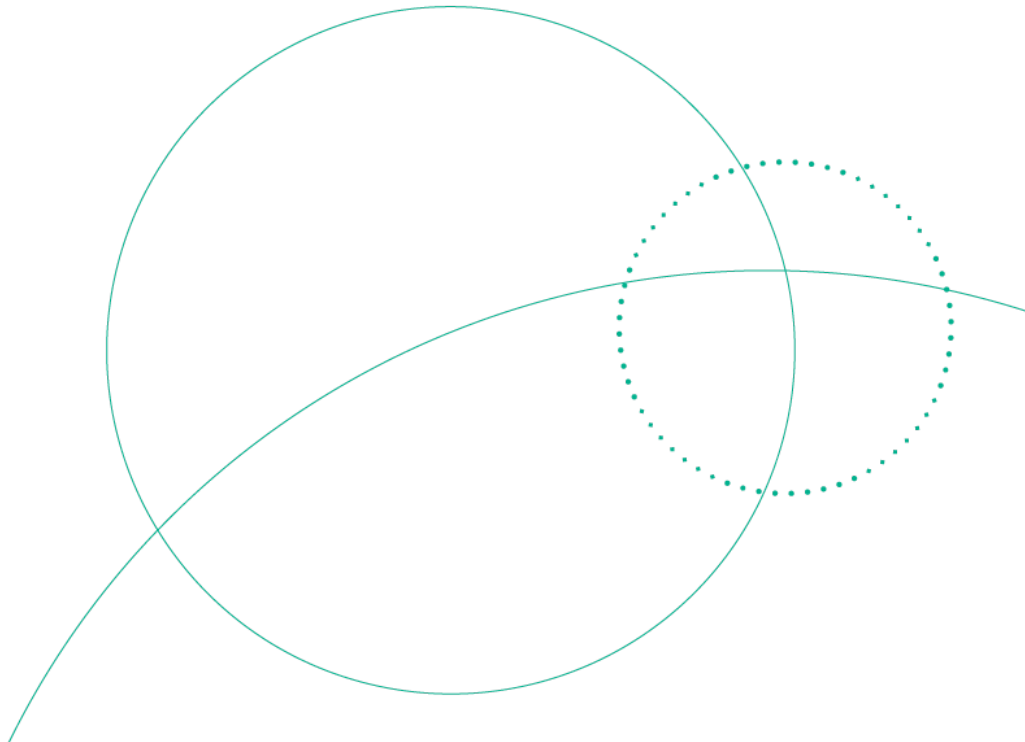
WHO Public Assessment Report: WHOPAR Part 3

Yorkool G5 LN

(Tianjin Yorkool International Trading Co., Ltd)

P-12507

Quality Assessment



Contents

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 G5 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: 20190830, 20191101, 20201201, 20210107, 20210309.

Complete results from the Studies 19240, 20185, 21045 and TE2022-003 are available in Appendix 1.

Table 1. Chemical and physical properties for Yorkool G5 LN (100D) (Batches 20190830, 20191101, 20201211, 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 Accelerated storage alpha-cypermethrin retention	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%)*
Wash resistance index (Alpha-cypermethrin) Accelerated storage alpha-cypermethrin WRI	MT 195, CIPAC Handbook O, p. 205, 2017	(96.13 -98.16%)* (96.40 -97.84%)*
Chlorfenapyr mean content Accelerated storage chlorfenapyr retention	CIPAC/5220/m	(3.93 -5.64 g/kg)* (3.85-5.78 g/kg)** (96.10 -98.30%)*
Wash resistance index (Chlorfenapyr) Accelerated storage chlorfenapyr WRI	MT 195, CIPAC Handbook O, p. 205, 2017	(91.90 -96.14%)* (92.30 -94.84%)*
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 Accelerated storage dimensional stability	ISO3759-2011 / ISO5077-2007 / ISO6330-2012	Length: (-4.1% to -0.5%)* Width: (-0.4% to +2.2%)* Length: (-3.2% to -0.4%)* Width: (-0.6% to +2.1%)*
Bursting strength Accelerated storage bursting strength	ISO 13938-2-1999 (30mm Diaphragm Diameter)	(417.5 - 455.4 kPa)* (412.2 - 448.0 kPa)*
Seam bursting strength Accelerated storage seam bursting strength	ISO 13938-2-1999 (30mm Diaphragm Diameter)	(437.1 - 543.8 kPa)* (429.5 - 542.7 kPa)*
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 Manufacturing, composition and formulant information

Data on the manufacturing process and product composition for Yorkool G5 LN have been provided and are adequate. A summary is presented in Table 2. Detailed information on the manufacturing process and product formulation is considered Confidential Business Information (CBI).

Table 2. Manufacturing process and product composition data submitted for Yorkool G5 LN

Description of starting material	Alpha-cypermethrin TC and chlorfenapyr 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. 50 nets are packed into an outside package. 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	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

1.3 Enforcement analytical method

Table 3. Details of the analytical method used to determine Alpha-cypermethrin and Chlorfenapyr in Yorkool 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 fabric characterisation

Laboratory studies to characterize the availability of the active ingredient and synergist and the insecticidal effect of the fabric of Yorkool G5 LN on Anopheline mosquito species were submitted to WHO as part of the prequalification dossier. Sampled pieces of ITNs used in the biological laboratory studies were characterized for their alpha-cypermethrin and chlorfenapyr content using GC.

2.1 Laboratory studies

2.1.1 Entomological characterisation

Data on the wash regeneration and wash resistance properties of the Yorkool G5 product were provided. These data were obtained from studies conducted according to established standards and/or Good Laboratory Practices (GLP). These summary results are based on ITNs drawn from batches 20210107, 20201210 and 20210315.

One laboratory study was submitted to characterise the Yorkool G5 fabric. Bioavailability was evaluated in wash regeneration and wash resistance studies, and baseline checks were conducted to assure the quality of the product received at the testing facility. The indicative test system used to evaluate results was the pyrethroid resistant mosquito strain.

The endpoint used to evaluate bioavailability was 72-hour control corrected mortality. Demonstration of bioavailability post-wash was used to determine the wash interval that was selected for use in the wash resistance study. WHO cone tests and tunnel tests were the experimental methods used in bioavailability studies. Thresholds of ≥95% knockdown and/or ≥80% mortality in WHO cone tests (insecticide susceptible test systems) and ≥80% mortality or ≥90% blood feeding inhibition in tunnel tests (pyrethroid resistant test systems) were used to evaluate bioassay results.

The bioavailability of alpha-cypermethrin and chlorfenapyr on the surface of the ITN was characterized using the insecticide susceptible test system *Anopheles gambiae* s.s. Ifakara strain and the pyrethroid resistant test system *Anopheles arabiensis* Kingani strain, with pyrethroid resistance mediated by the over-expression of cytochrome P450 enzymes and an observed mortality to the diagnostic dose of alpha-cypermethrin of 16%. Susceptibility to chlorfenapyr was not determined.

In baseline quality checks, the control-corrected 72-hour mortality was 31.8% (95% CI 26.4 – 37.1) for the insecticide susceptible test system in WHO cone tests and 91.5% (95% CI 89.3 – 93.7) for the pyrethroid resistant test system in tunnel tests.

The wash interval was determined to be five days, based on results from the pyrethroid resistant test system (Table 4). Using this wash interval, the decrease in entomological response over the wash series indicates that Yorkool G5 did not demonstrate consistency in wash resistance to 20 washes using the pyrethroid resistant test system in tunnel tests following either the laboratory wash method (Table 5) or a ‘field-wash’ method (Table 6). These results could be indicative of a reduction in the concentration of AI exposed on the surface of the ITN fabric and/or presentation of the AI on the surface in a less bioavailable form as the product moves through a wash series.

Table 4. Wash regeneration study results for Yorkool G5 using the insecticide susceptible *An. gambiae* Ifakara test system and the pyrethroid resistant *An. arabiensis* Kingani strain in WHO cone tests (Ifakara strain) and tunnel tests (Kingani strain) to characterize the bioavailability of alpha-cypermethrin and chlorfenapyr

Days post-wash	*An. gambiae* Ifakara			*An. arabiensis* Kingani		
	n	%KD (95% CI)	%M72 (95% CI)	n	%M72 (95% CI)	%BFI (95% CI)
1	200	77.0 (69.9 – 84.1)	8.0 (4.3 – 11.7)	200	39.7 (29.6 – 49.8)	94.7 (87.5 – 100)
2	200	76.0 (71.1 – 80.9)	29.0 (23.0 – 35.0)	199	40.7 (38.0 – 43.4)	93.6 (91.8 – 95.4)
3	200	91.5 (87.8, 95.2)	26.0 (19.8-32.2)	200	53.7 (50.4 – 57.0)	91.2 (82.1 – 100)
5	200	92.0 (88.6 – 95.4)	33.5 (27.5 – 39.5)	200	83.7 (81.5 – 85.9)	95.5 (92.3 – 98.6)
7	200	98.0 (96.1 – 99.9)	23.0 (16.8 – 29.2)	200	73.9 (62.7 – 85.1)	97.6 (95.0 – 100)

Table 5. Wash resistance study results for Yorkool G5 using the insecticide susceptible *An. gambiae* Ifakara test system and the pyrethroid resistant *An. arabiensis* Kingani strain in WHO cone tests (Ifakara strain) and tunnel tests (Ifakara and Kingani strains) to characterize the bioavailability of alpha-cypermethrin and chlorfenapyr

Wash No.	*An. gambiae* Ifakara			*An. arabiensis* Kingani		
	n	%KD (95% CI)	%M72 (95% CI)	n	%M72 (95% CI)	%BFI (95% CI)
0	200	100	100	-	-	-
1	200	100	93.0 (89.1 – 96.9)	400	68.8 (58.7 – 78.8)	100
3	200	100	74.5 (67.5 – 81.5)	400	73.0 (70.6 – 75.4)	98.8 (96.5 - 100)
5	200	100	87.5 (82.9 – 92.1)	400	73.3 (60.1 – 86.4)	100
10	200	100	36.5 (29.8 – 43.2)	399	56.1 (50.7 – 61.6)	100
15	200	100	49.5 (40.3-58.7)	400	64.8 (53.6-75.9)	99.1 (98.0 – 100)
20	200	69.0 (61.8 – 76.2)	23.5 (19.3 – 27.7)	400	35.8 (27.3-44.2)	100
25	200	53.5 (47.0 – 60.0)	27.5 (20.7 – 34.3)	400	21.5 (20.2 – 22.8)	100

Wash No.	*An. gambiae* Ifakara		
	n	%M72	%BFI
20	100	98.0	100
25	100	97.0	100

Table 6. Wash resistance study results for Yorkool G5 using the insecticide susceptible *An. gambiae* Ifakara test system and the pyrethroid resistant *An. arabiensis* Kingani strain in WHO cone tests (Ifakara strain) and tunnel tests (Ifakara and Kingani strains) to characterize the bioavailability of alpha-cypermethrin and chlorfenapyr in nets washed using a 'field' wash methodology

Wash No.	*An. gambiae* Ifakara			*An. arabiensis* Kingani		
	n	%KD (95% CI)	%M72 (95% CI)	n	%M72 (95% CI)	%BFI (95% CI)
0	800	99.4 (99.8-99.9)	44.4 (40.3 – 48.4)	400	70.3 (51.9- 88.6)	98.7 (96.0 – 100)
20	400	84.8 (80.7 – 88.8)	52.5 (47.1 – 57.9)	400	48.8 (31.4– 66.1)	100

Wash No.	*An. gambiae* Ifakara		
	n	%M72	%BFI
20	100	94.4	98.5

2.1.1.1 Chemical characterisation

Data on the alpha-cypermethrin and chlorfenapyr content of sampled pieces of the Yorkool G5 LN product used in the entomological laboratory wash resistance study were provided. These data were obtained from studies conducted according to established standards and/or Good Laboratory Practices (GLP). These summary results are based on ITNs drawn from batches 20210107, 20201210, 20210315. The results are summarized in Tables 7 and 8.

Table 7. AI content and retention of sampled pieces of Yorkool G5 used in the entomological wash resistance study (batch numbers 20210107, 20201210, 20210315)

Wash No.	Mean alpha-cypermethrin content (g/kg)	RSD (%)	Alpha-cypermethrin retention	Alpha-cypermethrin retention per wash	Mean Chlorfenapyr content (g/kg)	RSD (%)	Chlorfenapyr retention	Chlorfenapyr retention per wash
0	2.57 (2.55-2.59)	0.78	-	-	4.16 (4.12-4.20)	0.96	-	-
1	2.41 (2.37-2.45)	1.66	93.80%	93.80%	3.76 (3.65-3.87)	2.93	90.40%	90.40%
3	2.42 (2.28-2.56)	5.79	94.20%	98.10%	3.74 (3.53-3.95)	5.61	89.90%	96.50%
5	2.21 (2.15-2.27)	2.71	86.00%	97.00%	3.26 (3.12-3.4)	4.29	78.40%	95.20%
10	2.00 (1.91-2.09)	4.50	77.80%	97.50%	2.37 (2.21-2.53)	6.75	57.00%	94.50%
15	1.95 (1.89-2.01)	3.08	75.90%	98.20%	2.05 (1.94-2.16)	5.37	49.30%	95.40%
20	1.72 (1.56-1.88)	9.3	66.90%	98.00%	1.54 (1.33-1.75)	13.64	37.00%	95.10%
25	1.54 (1.47-1.61)	4.55	59.90%	98.00%	1.04 (1.00-1.08)	3.85	25.00%	94.60%

The mean AI content presented in Table 7 was determined based on 20 net samples belonging to three batches (batch numbers 20210107, 20201210, 20210315), indicating ranges to the AI content in parenthesis.

AI retention per wash in Table 7 (ranges in parenthesis) is calculated as:

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

Table 8. AI content of sampled pieces of Yorkool G5 used in the Tanzania entomological laboratory equivalence study (batch numbers 20210107, 20201210, 20210315)						
Wash No.	Mean alpha-cypermethrin content (g/kg)	Alpha-cypermethrin retention	Alpha-cypermethrin retention per wash	Mean chlorfenapyr content (g/kg)	Chlorfenapyr retention	Chlorfenapyr retention per wash
0	2.57 (2.55-2.59)	-	-	4.16 (4.12-4.20)	-	-
20	1.06 (1.04-1.11)	41.25%	95.70%	1.95 (1.93-2.01)	46.88%	96.30%

The mean AI content presented in Table 8 was determined based on 20 net samples belonging three batches (batch numbers 20210107, 20201210, 20210315), indicating ranges to the AI content in parenthesis, at 0 washes and 20 washes.

2.2 Chemical and entomological fabric characterisation conclusions

The submitted laboratory studies characterize the fabric of Yorkool G5 against two strains of *An. gambiae* complex mosquitoes. Following three washes intended to deplete the surface of the fabric of bioavailable insecticide, the laboratory results demonstrate that sufficient bioavailable insecticide to induce mortality in pyrethroid resistant test systems was present five days after washing.

Consistency in entomological response was not demonstrated against pyrethroid resistant test systems during the wash resistance study to 20 washes using standardised washing and 'field wash' methods. Based on the submitted studies, Yorkool G5 may undergo a reduction in the concentration of AI exposed on the surface of the ITN fabric and/or presentation of the AI on the surface in a less bioavailable form as the product moves through a wash series.

3 Overall quality conclusions

Based on the studies and information provided, all data requirements for the prequalification assessment of product quality have been satisfied. These data have been relied upon to assess the formulation, manufacturing process, physical/chemical characteristics, biological regeneration time, and bioavailability using products prepared with a defined wash interval of the proposed product for the purpose of establishing the identity of the product and assuring that the product can be produced consistently.

The methods for assessing the physical/chemical properties of the product were CIPAC methods and/or validated methods.

The quality component of the dossier is considered complete, and the assessment of the submitted information on quality supports prequalification of the product.

Table 9. List of studies submitted to WHO as part of the prequalification dossier	
Studies that were relied upon for decision making	
Study number	*Study title*
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
Studies that were not used to inform decision making	
	None

4 Manufacturing release specifications

4.1 Summary of manufacturing release specifications

Table 10. Summary of manufacturing release specifications

Description
The material shall be in the form of netting*, consisting of 100 denier* multi-filament 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*.

ID	*Property*	*Method*	*Declared value*
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.

4.2 Storage

Accelerated storage stability data were generated 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

Batch Number	Date	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

Product characteristics

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/m2
Mesh size	20190830	WHO specification 454+570/LN	25-26 holes/cm2
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
Bursting strength (seam)	20190830		Inner 523.6 kPa / outer 543.8 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/m2
Mesh size	20191101	WHO specification 454+570/LN	25-27 holes/cm2

Property	Batch ID	Test Method	Results
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
Bursting strength (seam)	20191101		Inner 541.4 kPa / outer 515.6 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/m2
Mesh size	20201201	WHO specification 454+570/LN	24-26 holes/cm2
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
Bursting strength (seam)	20201201		Inner 438.8 kPa / outer 437.1 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%

Property	Batch ID	Test Method	Results
Bursting strength (fabric)	20210107 20210309	ISO 13938-2:1999	432.1 kPa 433.9 kPa
Bursting strength (seam)	20210107 20210309		466.4 kPa 474.1 kPa
Flammability	20210107 20210309	EN 1102	No ignition or propagation. Maximum hole dimension 91 mm. No ignition or propagation. Maximum hole dimension 107 mm.

Storage stability

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 re-analysis	-1.3%, -1.2% -0.5%, -0.4%	-1.3%, -1.2% -0.4%, -0.3%	
Bursting strength (fabric)	20190830	417.5 kPa	412.2 kPa	-
Bursting strength (seam)	20190830	523.6 / 543.8 kPa	519.4 / 542.7 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	-
Bursting strength (seam)	20191101	541.4 / 515.6 kPa	534.2 / 504.1 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	-
Bursting strength (seam)	20201211	438.8 / 437.1 kPa	429.5 / 442.7 kPa	-

Study TE2022-003:

Property	Batch ID	Before	After	Change
Alpha-cypermethrin content (1 sample)	20210107 20210309	2.29 g/kg 2.73 g/kg	2.25 g/kg 2.67 g/kg	-0.04 g/kg (-1.7%) -0.06 g/kg (-2.2%)
Chlorfenapyr content (1 sample)	20210107 20210309	3.94 g/kg 5.43 g/kg	3.86 g/kg 5.34 g/kg	-0.08 g/kg (-2.0%) -0.09 g/kg (-1.7%)
Alpha-cypermethrin wash resistance index	20210107 20210309	96.2% 96.5%	96.8% 96.4%	+0.6% -0.1%

Chlorfenapyr wash resistance index	20210107 20210309	91.9% 92.2%	94.0% 92.3%	+2.1% +0.1%
Dimensional stability	20210107 20210309	-2.2%, +1.9% -4.1%, +2.2%	-1.7%, +0.2% -3.2%, +2.1%	-
Bursting strength (fabric)	20210107 20210309	432.1 kPa 433.9 kPa	427.9 kPa 432.5 kPa	-
Bursting strength (seam)	20210107 20210309	466.4 kPa 474.1 kPa	443.0 kPa 448.0 kPa	-

Appendix 2. Manufacturing release specifications: methods and notes

Description

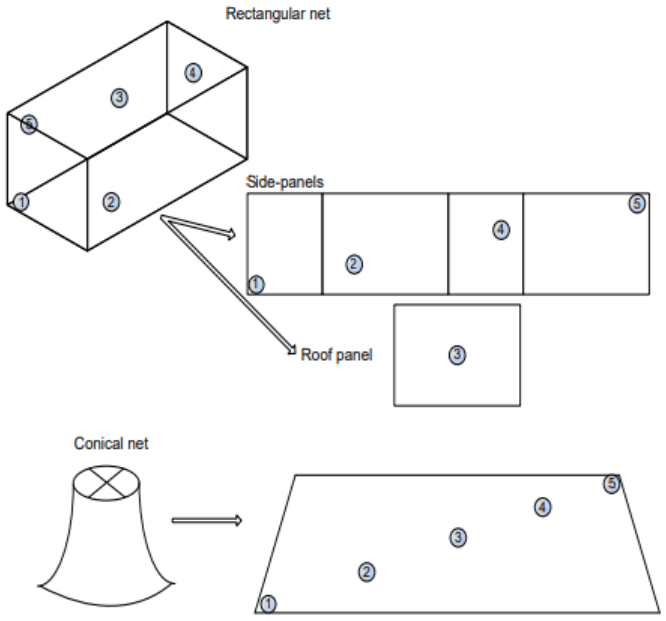
- The specification applies to netting in bulk and manufactured nets. The netting may be white or coloured, for example, green or blue.
- The linear density (denier) of the yarn cannot be measured in the netting or the manufactured bed net but it should be identified on the packaging.
- Occasional short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

For the purposes of chemical analysis, the analytical method and the number and size of test portions analyzed should be designed to provide results with a relative standard deviation (RSD) ≤ 5% or as applicable in certain justifiable cases. Test portion and replication requirements for physical test methods are defined in these methods and notes.

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. 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 250 kPa (which is based on 7.3 cm^2 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 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/cm^2. 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.