World Health Organization

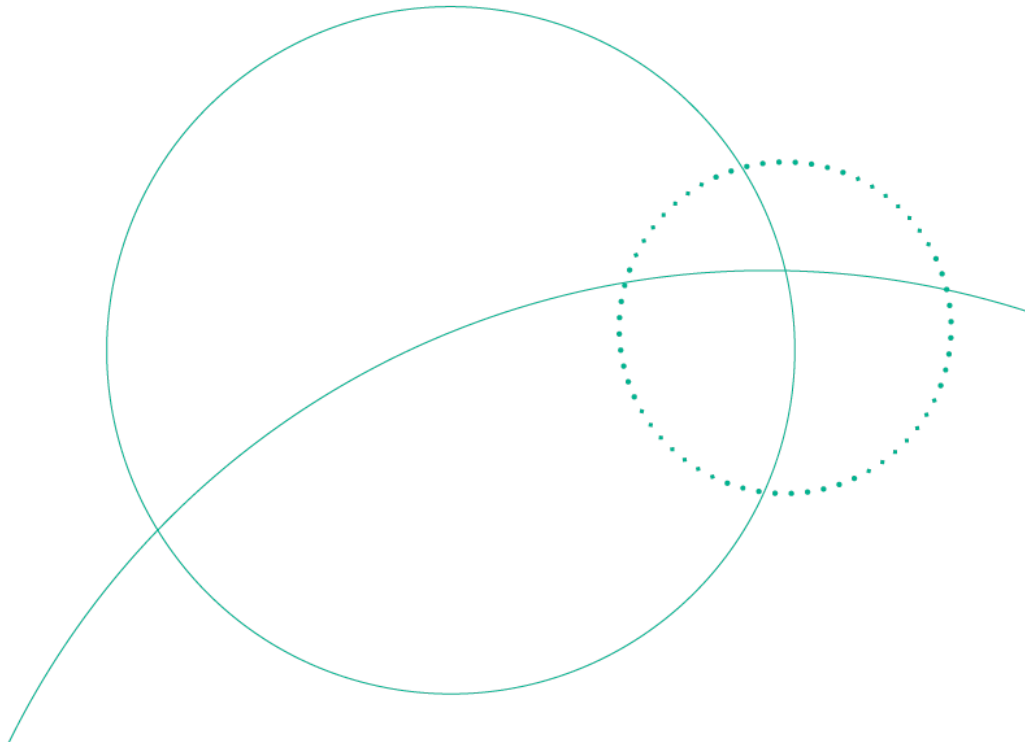
WHO Prequalification Programme / Vector Control Product Assessment

# WHO Public Assessment Report: WHOPAR Part 3

## Synera DuoForte
## (GDM Health Product Ltd.)

## P-13215

## 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 Synera DuoForte 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: 1101WT2101001, 1101WT2101002, 1101WT2101003, 1101WT2209001, 1101WT2209002.

Complete results from study 23205 are available in Appendix 1.

**Table 1. Chemical and physical properties for Synera DuoForte**

| Data requirement | Test method ID | Result |
|---|---|---|
| Identification of alpha-cypermethrin and chlorfenapyr | CIPAC 5220/m | The active ingredients each comply with an identity test |
| Alpha-cypermethrin mean content<br>Alpha-cypermethrin retention after accelerated storage | CIPAC 5220/m | 3.86 g/kg (3.76-4.01 g/kg)*<br>98.0% (97.6-98.4%)* |
| Chlorfenapyr mean content<br>Chlorfenapyr retention after accelerated storage | CIPAC 5220/m | 5.77 g/kg (5.52-6.03 g/kg)*<br>97.8% (96.8-98.7%)* |
| Wash resistance index (Alpha-cypermethrin)<br>Wash resistance index (Alpha-cypermethrin) after accelerated storage | Adapted CIPAC (O) MT 195 - IG – Determination of wash resistance index test for ITN fabric | 97.06% (96.70-97.29%)*<br>96.76% (96.35-97.17%)* |
| Wash resistance index (Chlorfenapyr)<br>Wash resistance index (Chlorfenapyr) after accelerated storage | Adapted CIPAC (O) MT 195 - IG – Determination of wash resistance index test for ITN fabric | 91.63% (91.28-92.18%)*<br>91.12% (90.46-91.75%)* |
| Mesh size (mean) | See Appendix 2 | 20.6 holes/cm$^2$ (19-21 holes/cm$^2$)* |
| Fabric weight | ISO 3801:1977 / EN 12127:1997 | 40.73 g/m$^2$ (40.45-40.94 g/m$^2$)* |
| Dimensional stability of netting to washing<br><br>Dimensional stability after accelerated storage | ISO 139:2005<br>ISO 3759:2011,<br>ISO 6330:2012,<br>ISO 5077:2007 | Length: -0.6% (-1.1% to -0.3%)*<br>Width: -0.9% (-1.1% to -0.5%)*<br><br>Length: -1.0% (-1.3% to -0.5%)*<br>Width: -1.0% (-1.2% to -0.6%)* |
| Fabric bursting strength<br>Fabric bursting strength after accelerated storage | ISO 13938-2:1999 | 373.6 kPa (371.4-379.9 kPa)*<br>372.6 kPa (368.9-376.2 kPa)* |
| Inner / outer seam bursting strength<br><br>Inner / outer seam bursting strength after accelerated storage | ISO 13938-2:1999 | 423.4 kPa / 402.5 kPa*<br>(420.0-427.3 kPa / 397.8-409.8 kPa)*<br><br>427.2 kPa / 400.9 kPa*<br>(422.8-431.4 kPa / 398.2-402.5 kPa)* |
| Flammability | EN 1102:2016 | No ignition or propagation. Maximum hole length 110 mm, width 37 mm. |

* range of means

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 Synera DuoForte 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 Synera DuoForte | |
|---|---|
| Description of starting material | Alpha-cypermethrin TC and chlorfenapyr TC formulated as part of the production process.<br><br>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.<br><br>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 polyethylene bags with printed labels or in bulk bales, of typically 50 nets (grouped into bundles of five to ten nets, and five to ten bundles). The sizes of the bags and bales may vary depending on the size of the net version being packed (the target dimensions for a bale containing 50 nets are 54 cm x 48 cm x 38 cm). The baled nets are placed into an inner polypropylene bag then into an outer polypropylene waterproof bag, which is closed by stitching. Stacks of nets are compressed by a hydraulic press to the desired height and then strapped. |
| Discussion of impurities | There are no relevant impurities of toxicological concern. |
| Certification of limits | Alpha-cypermethrin: 3.75 g/kg, acceptable limits 2.81-4.31 g/kg<br>Chlorfenapyr: 5.6 g/kg, acceptable limits 4.48-6.72 g/kg |

## 1.3 Enforcement analytical method

| Table 3. Details of the analytical method used to determine alpha-cypermethrin and chlorfenapyr in Synera DuoForte | |
|---|---|
| Quantification of alpha-cypermethrin and chlorfenapyr | Alpha-cypermethrin and chlorfenapyr: CIPAC 5220/m |

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

# 2 Chemical and entomological fabric characterisation

Laboratory studies to characterize the availability of the active ingredients and the insecticidal effect of the fabric of Synera DuoForte 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 Synera DuoForte 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 1101WT2101001, 1101WT2101002 and 1101WT2101003.

One laboratory study was submitted to characterise the Synera DuoForte fabric. Bioavailability was evaluated in wash regeneration and wash resistance studies. The indicative test system used to evaluate results was the pyrethroid resistant mosquito strain.

The endpoint used to evaluate bioavailability was 72-hour 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.

The bioavailability of alpha-cypermethrin and chlorfenapyr on the surface of the ITN was characterized using the insecticide susceptible test system *Anopheles gambiae* Kisumu strain and the pyrethroid resistant test system *An. gambiae* Covè strain, with pyrethroid resistance mediated by *kdr* L1014F (frequency greater than 90%) and the over-expression of cytochrome P450 enzymes.

The wash interval was determined to be one day. Using this wash interval, Synera DuoForte was wash resistant to 20 washes using insecticide susceptible and pyrethroid resistant mosquito test systems. These results are summarized in Tables 4-5.

**Table 4. Wash regeneration study bioassay results for Synera DuoForte batch numbers 1101WT2101001, 1101WT2101002 and 1101WT2101003 using cone and tunnel tests against insecticide susceptible *An. gambiae* Kisumu and pyrethroid resistant *An. gambiae* Covè test systems**

| Days post-wash | Cone tests | | | Tunnel tests | | |
|---|---|---|---|---|---|---|
| | *An. gambiae* Kisumu | | | *An. gambiae* Covè | | |
| | N [mos] | Mean KD60 (%) (95% CI) | Mean M72 (%) (95% CI) | N [mos] | Mean M72 (%) (95% CI) | BFI (%) (95% CI) |
| UW | 200 | 100 (98 – 100) | 82.0 (76 – 87) | 424 | 97.17 (95 - 99) | 93.68 (91 – 96) |
| 0 | 200 | 89.50 (84 – 93) | 75.0 (68 – 81) | 326 | 88.96 (85 – 92) | 79.75 (75 – 84) |
| 1 | 200 | 95.50 (92 – 98) | 91.5 (87 – 95) | 368 | 92.39 (89 – 95) | 91.59 (89 – 94) |
| 2 | 200 | 100 (98 – 100) | 96.0 (92 – 98) | 400 | 93.50 (91 – 96) | 93.81 (91 – 96) |
| 3 | 200 | 100 (98 – 100) | 96.5 (93 – 99) | 420 | 92.86 (90 – 95) | 94.60 (92 – 97) |
| 5 | 200 | 100 (98 – 100) | 97.5 (94 – 99) | 430 | 92.09 (89 – 95) | 95.68 (93 – 98) |
| 7 | 200 | 100 (98 – 100) | 100 (98 – 100) | 420 | 92.86 (90 – 95) | 94.60 (92 – 97) |

**Table 5. Wash resistance study bioassay results for Synera DuoForte batch numbers 1101WT2101001, 1101WT2101002 and 1101WT2101003 using cone and tunnel tests against insecticide susceptible *An. gambiae* Kisumu and pyrethroid resistant *An. gambiae* Covè test systems**

| N [washes] | Cone tests | | | Tunnel tests | | |
|---|---|---|---|---|---|---|
| | *An. gambiae* Kisumu | | | *An. gambiae* Covè | | |
| | N [mos] | Mean KD60 (%) (95% CI) | Mean M72 (%) (95% CI) | N [mos] | Mean M72 (%) (95% CI) | BFI (%) (95% CI) |
| 0 | 200 | 100 (98 - 100) | 100 (98 - 100) | 204 | 98.04 (95 – 99) | 95.38 (92 – 98) |
| 1 | 200 | 98 (98 - 100) | 100 (98 - 100) | | | |
| 3 | 200 | 99 (98 - 100) | 100 (98 - 100) | | | |
| 5 | 200 | 96.5 (84 - 92) | 88 (84 - 92) | | | |
| 10 | 200 | 100 (97 - 100) | 98.5 (97 - 100) | 208 | 93.75 (90 – 97) | 94.46 (91 – 97) |
| 15 | 200 | 97.5 (97 - 100) | 98.5 (97 - 100) | | | |
| 20 | 200 | 98 (97 – 100) | 98.5 (97 – 100) | 202 | 87.13 (81 – 91) | 94.30 (90 – 97) |

#### 2.1.1.1 Chemical characterisation

Data on the alpha-cypermethrin and chlorfenapyr content of sampled pieces of the Synera DuoForte 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 1101WT2101001, 1101WT2101002, and 1101WT2101003. The results are summarized in Table 6.

**Table 6. AI content and retention of sampled pieces of Synera DuoForte used in the entomological wash resistance study (batch numbers 1101WT2101001, 1101WT2101002, and 1101WT2101003)**

| 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 | 2.90 (2.82-2.98) | 2.7 | - | - | 5.89 (5.72-5.97) | 2.0 | - | - |
| 1 | 2.33 (2.24-2.55) | 6.4 | 80.3% | 80.3% | 4.74 (4.55-5.23) | 6.9 | 80.4% | 80.4% |
| 3 | 2.21 (2.02-2.51) | 9.5 | 76.3% | 91.4% | 3.85 (3.38-4.36) | 10.9 | 65.3% | 86.7% |
| 5 | 1.97 (1.86-2.07) | 4.4 | 67.9% | 92.6% | 3.01 (2.87-3.25) | 5.7 | 51.1% | 87.4% |
| 10 | 1.70 (1.57-1.81) | 6.0 | 58.6% | 94.8% | 1.84 (1.67-1.94) | 6.5 | 31.3% | 89.0% |
| 15 | 1.53 (1.23-1.72) | 14.2 | 52.6% | 95.8% | 1.19 (0.88-1.50) | 22.1 | 20.2% | 89.9% |
| 20 | 1.31 (1.12-1.52) | 15.8 | 45.3% | 96.1% | 0.73 (0.60-0.89) | 20.2 | 12.4% | 90.1% |

The mean AI content presented in Table 6 was determined based on 4 net samples belonging to 3 batches (1101WT2101001, 1101WT2101002, and 1101WT2101003), indicating ranges to the AI content in parenthesis.
AI retention per wash in Table 6 (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.

## 2.2 Chemical and entomological fabric characterisation conclusions

The submitted laboratory studies characterize the fabric of Synera DuoForte 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 insecticide susceptible and pyrethroid resistant test systems was present one day after washing.

Wash resistance to 20 washes using standardised washing methods was demonstrated against two *An. gambiae* complex test systems, one of which was insecticide susceptible and one pyrethroid resistant system carrying *kdr* and metabolic resistance mechanisms. Based on the submitted studies, Synera DuoForte is wash resistant to 20 washes using a one-day wash interval against pyrethroid susceptible *An. gambiae* Kisumu and pyrethroid resistant *An. gambiae* Covè test systems.

# 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 7. List of studies submitted to WHO as part of the prequalification dossier**

| Studies that were relied upon for decision making | |
|---|---|
| Study number | Study title |
| 23-01-/GLP | Phase I Laboratory evaluation of the regeneration time, efficacy and wash- Resistance of Candidate nets (MD1 + MD2 and MD3) against susceptible and pyrethroid-resistant strains, *Anopheles gambiae* s.l. |
| 24097 | Chemical analysis of different nets (Phase I trial) of Interceptor LN (Alpha-cypermethrin); Interceptor G2 LN (Alpha-cypermethrin + Chlorfenapyr); Mont Inari Dual 1 (MDl) LN (Alpha-cypermethrin - Side panel) and Mont Inari Dual 3 (MD3) LN (Alpha-cypermethrin + Chlorfenapyr) before and after subjecting to different washes |
| 23205 | Physical and Chemical Analysis of Mont Inari Dual 3 LN - A Long-Lasting Insecticidal Net (coated onto filaments) having Alpha-cypermethrin 3.75 g/kg ± 25% + ·Chlorfenapyr 5.6 g/kg ± 25% - 5 Batch study |
| Studies that were not used to inform decision making | |
| | None |

# 4 Manufacturing release specifications

## 4.1 Summary of manufacturing release specifications

**Table 8. 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, extension of 454/LN/M/3.2, CIPAC Handbook M, p. 41, 2009 | 3.75 g/kg + 15%<br>3.75 g/kg - 25% |
| 3 | Chlorfenapyr content | CIPAC/ 5220, extension of 454/LN/M/3.2, CIPAC Handbook M, p. 41, 2009 | 5.6 g/kg + 20%<br>5.6 g/kg - 20% |
| 4* | Alpha-cypermethrin wash resistance index | Adapted CIPAC (O) MT 195 - IG – Determination of wash resistance index test for ITN fabric | Within the range 90% to 100% |
| 5* | Chlorfenapyr wash resistance index | Adapted CIPAC (O) MT 195 - IG – Determination of wash resistance index test for ITN fabric | Within the range 85% to 100% |
| 6 | Fabric weight | ISO 3801:1977 / EN 12127:1997 | 40 g/m$^2$ ± 10% |
| 7* | Bursting strength – fabric | ISO 13938-2:1999 | Min. 350 kPa |
| 8* | Bursting strength – seam | ISO 13938-2:1999 | Not less than the average bursting strength for fabric |
| 9* | Netting mesh size | See Appendix 2 | Average ≥ 20 holes/cm$^2$<br>Min. 18 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 |
|---|---|---|---|
| 1101WT2101001 | 10/2021 | White | 5 batch analysis/storage stability study/ regeneration time study/laboratory wash study/semi-field studies |
| 1101WT2101002 | 10/2021 | White | 5 batch analysis/storage stability study/ regeneration time study/laboratory wash study/semi-field studies |
| 1101WT2101003 | 10/2021 | White | 5 batch analysis/storage stability study/ regeneration time study/laboratory wash study/semi-field studies |
| 1101WT2209001 | 10/2021 | White | 5 batch analysis/storage stability study |
| 1101WT2209002 | 10/2021 | White | 5 batch analysis/storage stability study |

## Product characteristics

**Study 23205**

| Property | Batch ID | Test method | Results |
|---|---|---|---|
| Alpha-cypermethrin mean content (RSD) | 1101WT2101001<br>1101WT2101002<br>1101WT2101003<br>1101WT2209001<br>1101WT2209002<br>Combined mean | CIPAC 5220/m | 3.76 g/kg (1.9%)<br>3.77 g/kg (1.0%)<br>3.99 g/kg (0.5%)<br>3.78 g/kg (0.9%)<br>4.01 g/kg (1.4%)<br>3.86 g/kg (3.3%) |
| Alpha-cypermethrin distribution (percentage of target dose) | 1101WT2101001<br>1101WT2101002<br>1101WT2101003<br>1101WT2209001<br>1101WT2209002 | | 3.68-3.85 g/kg (98.1-102.7%)<br>3.71-3.80 g/kg (98.9-101.3%)<br>3.96-4.01 g/kg (105.6-106.9%)<br>3.74-3.83 g/kg (99.7-102.5%)<br>3.95-4.10 g/kg (105.3-109.3%) |
| Chlorfenapyr mean content (RSD) | 1101WT2101001<br>1101WT2101002<br>1101WT2101003<br>1101WT2209001<br>1101WT2209002<br>Combined mean | | 6.02 g/kg (0.8%)<br>5.52 g/kg (1.3%)<br>5.69 g/kg (0.6%)<br>5.58 g/kg (0.5%)<br>6.03 g/kg (0.9%)<br>5.77 g/kg (4.2%) |
| Chlorfenapyr distribution (percentage of target dose) | 1101WT2101001<br>1101WT2101002<br>1101WT2101003<br>1101WT2209001<br>1101WT2209002 | | 5.96-6.08 g/kg (106.4-108.6%)<br>5.44-5.63 g/kg (97.1-100.5%)<br>5.66-5.75 g/kg (101.1-102.7%)<br>5.52-5.61 g/kg (98.6-100.2%)<br>5.94-6.07 g/kg (106.1-108.4%) |
| Alpha-cypermethrin wash resistance index | 1101WT2101001<br>1101WT2101002<br>1101WT2101003<br>1101WT2209001<br>1101WT2209002<br>Mean (RSD) | MT195, CIPAC Handbook O, p. 205, 2017 | 97.19%<br>96.91%<br>97.29%<br>96.70%<br>97.24%<br>97.06% (0.3%) |
| Chlorfenapyr wash resistance index | 1101WT2101001<br>1101WT2101002<br>1101WT2101003<br>1101WT2209001<br>1101WT2209002<br>Mean (RSD) | | 91.28%<br>91.78%<br>91.32%<br>92.18%<br>91.57%<br>91.63% (0.4%) |

| Property | Batch ID | Test method | Results |
|---|---|---|---|
| Fabric weight | 1101WT2101001<br>1101WT2101002<br>1101WT2101003<br>1101WT2209001<br>1101WT2209002<br>Mean (RSD) | ISO 3801:1977 / EN 12127:1997 | 40.74 g/m$^2$<br>40.87 g/m$^2$<br>40.94 g/m$^2$<br>40.63 g/m$^2$<br>40.45 g/m$^2$<br>40.73 g/m$^2$ (0.5%) |
| Mesh size | 1101WT2101001<br>1101WT2101002<br>1101WT2101003<br>1101WT2209001<br>1101WT2209002<br>Combined mean (RSD) | ISO 139:2005 | Mean 20 holes/cm$^2$, min. 19 holes/cm$^2$<br>Mean 21 holes/cm$^2$, min. 19 holes/cm$^2$<br>Mean 21 holes/cm$^2$, min. 18 holes/cm$^2$<br>Mean 22 holes/cm$^2$, min. 21 holes/cm$^2$<br>Mean 19 holes/cm$^2$, min. 18 holes/cm$^2$<br>20.6 holes/cm$^2$ (5.5%) |
| Dimensional stability | 1101WT2101001<br>1101WT2101002<br>1101WT2101003<br>1101WT2209001<br>1101WT2209002<br>Mean | ISO 3759:2011, ISO 6330:2012, ISO 5077:2007 | -0.7%, -0.5%<br>-0.3%, -1.0%<br>-1.1%, -1.1%<br>-0.4%, -1.0%<br>-0.7%, -1.1%<br>-0.6%, -0.9% |
| Fabric bursting strength | 1101WT2101001<br>1101WT2101002<br>1101WT2101003<br>1101WT2209001<br>1101WT2209002<br>Mean (RSD) | ISO 13938-2:1999 | 379.9 kPa<br>372.3 kPa<br>371.4 kPa<br>373.1 kPa<br>371.5 kPa<br>373.6 kPa (1.0%) |
| Inner / outer seam bursting strength | 1101WT2101001<br>1101WT2101002<br>1101WT2101003<br>1101WT2209001<br>1101WT2209002<br>Mean (RSD) | | 424.6 kPa / 409.8 kPa<br>422.0 kPa / 401.4 kPa<br>420.0 kPa / 401.1 kPa<br>423.2 kPa / 402.2 kPa<br>427.3 kPa / 397.8 kPa<br>423.4 kPa / 402.5 kPa (0.7% / 1.1%) |
| Flammability | 1101WT2101001<br>1101WT2101002<br>1101WT2101003<br>1101WT2209001<br>1101WT2209002 | EN 1102:2016 | No ignition or propagation.<br>Maximum hole length 110 mm, width 37 mm. |

Alpha-cypermethrin and chlorfenapyr mean contents and distributions shown are the means of values for five samples and the maximum and minimum values reported respectively. 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.

## Storage stability

### Study 23205

| Property | Batch ID | Before | After | Change |
|---|---|---|---|---|
| Alpha-cypermethrin mean content | 1101WT2101001 | 3.76 g/kg | 3.70 g/kg | -0.06 g/kg (-1.6%) |
| | 1101WT2101002 | 3.77 g/kg | 3.71 g/kg | -0.06 g/kg (-1.6%) |
| | 1101WT2101003 | 3.99 g/kg | 3.91 g/kg | -0.08 g/kg (-2.0%) |
| | 1101WT2209001 | 3.78 g/kg | 3.69 g/kg | -0.09 g/kg (-2.4%) |
| | 1101WT2209002 | 4.01 g/kg | 3.92 g/kg | -0.09 g/kg (-2.2%) |
| Chlorfenapyr mean content | 1101WT2101001 | 6.02 g/kg | 5.89 g/kg | -0.13 g/kg (-2.2%) |
| | 1101WT2101002 | 5.52 g/kg | 5.45 g/kg | -0.07 g/kg (-1.3%) |
| | 1101WT2101003 | 5.69 g/kg | 5.51 g/kg | -0.18 g/kg (-3.2%) |
| | 1101WT2209001 | 5.58 g/kg | 5.44 g/kg | -0.14 g/kg (-2.5%) |
| | 1101WT2209002 | 6.03 g/kg | 5.91 g/kg | -0.12 g/kg (-2.0%) |
| Alpha-cypermethrin wash resistance index | 1101WT2101001 | 97.19% | 96.68% | -0.51% |
| | 1101WT2101002 | 96.91% | 96.48% | -0.43% |
| | 1101WT2101003 | 97.29% | 97.14% | -0.15% |
| | 1101WT2209001 | 96.70% | 96.35% | -0.35% |
| | 1101WT2209002 | 97.24% | 97.17% | -0.07% |
| Chlorfenapyr wash resistance index | 1101WT2101001 | 91.28% | 90.46% | -0.82% |
| | 1101WT2101002 | 91.78% | 91.03% | -0.75% |
| | 1101WT2101003 | 91.32% | 91.14% | -0.18% |
| | 1101WT2209001 | 92.18% | 91.75% | -0.43% |
| | 1101WT2209002 | 91.57% | 91.23% | -0.34% |
| Dimensional stability | 1101WT2101001 | -0.7%, -0.5% | -1.3%, -0.6% | - |
| | 1101WT2101002 | -0.3%, -1.0% | -1.1%, -1.1% | - |
| | 1101WT2101003 | -1.1%, -1.1% | -1.1%, -1.2% | - |
| | 1101WT2209001 | -0.4%, -1.0% | -0.5%, -1.1% | - |
| | 1101WT2209002 | -0.7%, -1.1% | -0.8%, -1.2% | - |
| Fabric bursting strength | 1101WT2101001 | 379.9 kPa | 368.9 kPa | -11.0 kPa |
| | 1101WT2101002 | 372.3 kPa | 371.3 kPa | -1.0 kPa |
| | 1101WT2101003 | 371.4 kPa | 374.5 kPa | +3.1 kPa |
| | 1101WT2209001 | 373.1 kPa | 376.2 kPa | +3.1 kPa |
| | 1101WT2209002 | 371.5 kPa | 371.9 kPa | +0.4 kPa |
| Inner / outer seam bursting strength | 1101WT2101001 | 424.6 kPa / 409.8 kPa | 426.8 kPa / 400.5 kPa | +2.2 kPa / -9.3 kPa |
| | 1101WT2101002 | 422.0 kPa / 401.4 kPa | 424.8 kPa / 401.7 kPa | +2.8 kPa / +0.3 kPa |
| | 1101WT2101003 | 420.0 kPa / 401.1 kPa | 422.8 kPa / 398.2 kPa | +2.8 kPa / -2.9 kPa |
| | 1101WT2209001 | 423.2 kPa / 402.2 kPa | 431.4 kPa / 401.6 kPa | +8.2 kPa / -0.6 kPa |
| | 1101WT2209002 | 427.3 kPa / 397.8 kPa | 430.1 kPa / 402.5 kPa | +2.8 kPa / +4.7 kPa |

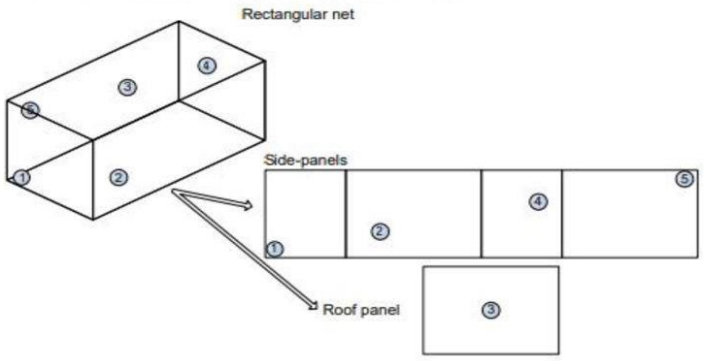
# Appendix 2. Manufacturing release specifications: methods and notes

**Description**

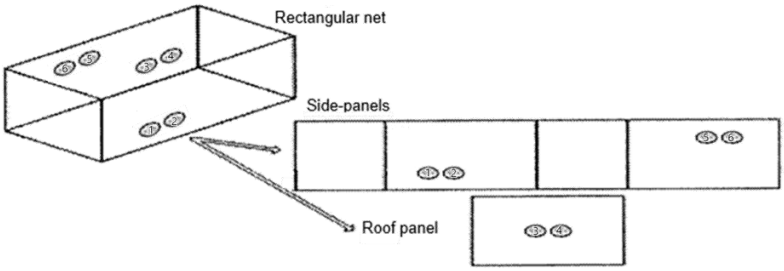
- The linear density (denier) of the yarn cannot be measured in the netting or the manufactured bed net but it should be identified on the packaging.
- Occasional short lengths of loose thread present in the netting are not considered to be extraneous matter.
- Long-lasting insecticidal netting is expected to retain its insecticidal activity during its lifespan and through a number of washes.

**Sampling Plan**

- Figure 1: Applicable to active ingredient content and physical tests attributes for which samples are to be taken from various parts of the constructed ITN.




- Figure 2: Applicable to wash resistance index attribute for which samples are to be taken from various parts of the constructed ITN.




Samples should be taken according to Figure 1 and 2. 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 the methods or Notes referenced.

**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 Adapted CIPAC (O) MT 195 - IG – Determination of wash resistance index test for ITN fabric.

**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 350 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/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.