WHO Prequalification of Vector Control Products

Module 3. Manufacturing release specifications template

Instructions when using this template:

* [text] means it is needed to introduce the related appropriate text and remove the [ ].
* (text) means the table/paragraph/text to which the () refers can be inserted or not as appropriate, depending on the product specifics.
* When submitting this data requirement for your product application, **please remove this first page of this IG document** and submit pages 2-6 which constitute the manufacturing release specifications document template

# Purpose

The purpose of this implementation guidance document template is to indicate the structure and nature of the manufacturing release specifications document to be presented in Module 3. Applicants can make use of this IG as a template to ensure that all required data for Module 3 manufacturing release specifications is submitted.

# Manufacturing release specifications

|  |  |
| --- | --- |
| Company | [Company name] |
| Product name | [Product name] |
| PQ ref # | [PQ Product Ref Number] (if not yet assigned, leave blank) |
| Version number | [Version number] Version numbers should be sequential. |
| Effective date | [Date of internal company approval] |

## Summary of manufacturing release specifications

|  |
| --- |
| Table 1. Summary of manufacturing release specifications for [ product name] |
| **Description**The material shall be in the form of netting, consisting of [value] denier\* ([knitted]) [mono or multi-filament polyethylene or polyester, or as appropriate] yarn, [incorporating technical AI or treated with technical AI , or as propriate] complying with the requirements of WHO specification [value]/TC (current version) ([and with technical AI/synergist complying with the requirements of WHO specification [value]/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  |
| [product name] sides (*insert/differentiate only if sides and roof are different fabrics*) |
| 1\* | Sampling Plan | See Appendix |  |
| 2 | [AI name] content | [test method] | [value] g/kg ± [value]% |
| 3 | [synergist, or second AI] content | [test method] | [value] g/kg ± [value]% |
| 4\* | [AI name] wash resistance index | Adapted CIPAC (O) MT 195 - IG – Determination of wash resistance index test for ITN fabric | Within the range [value]% to [value]% |
| 5\* | [synergist, or second AI] wash resistance index | Adapted CIPAC (O) MT 195 - IG – Determination of wash resistance index test for ITN fabric | Within the range [value] % to [value] % |
| 6 | Fabric weight | [ISO 3801:1977 / EN 12127:1997] | [value] g/m2 ± [value]% |
| 7\* | Bursting strength – fabric | [ISO 13938-2:1999] | Min. [value] kPa |
| 8\* | Bursting strength – seam | ISO 13938-2:1999] | Not less than the average bursting strength for fabric |
| 9\* | Netting mesh size | See Appendix | Average ≥ [value] holes/cm2Min. [value] holes/cm2 |
| 10\* | Dimensional stability of netting to washing | [ISO 3759; ISO 5077; ISO 6330]See Appendix | Not more than [value] % shrinkage and not more than [value] % expansion in both directions. |
|  | Add any other relevant property  |  |  |
| **[product name] roof (*insert/differentiate only if sides and roof are different fabrics*)** |
| 1\* | Sampling Plan | See Appendix |  |
| 2 | [AI name] content | [test method] | [value] g/kg ± [value]% |
| 3 | [synergist, or second AI] content | [test method] | [value] g/kg ± [value]% |
| 4\* | [AI name] wash resistance index | Adapted CIPAC (O) MT 195 - IG – Determination of wash resistance index test for ITN fabric | Within the range [value]% to [value]% |
| 5\* | [synergist, or second AI] wash resistance index | Adapted CIPAC (O) MT 195 - IG – Determination of wash resistance index test for ITN fabric | Within the range [value] % to [value] % |
| 6 | Fabric weight | [ISO 3801:1977 / EN 12127:1997] | [value] g/m2 ± [value]% |
| 7\* | Bursting strength – fabric | [ISO 13938-2:1999] | Min. [value] kPa |
| 8\* | Bursting strength – seam | ISO 13938-2:1999] | Not less than the average bursting strength for fabric |
| 9\* | Netting mesh size | See Appendix | Average ≥ [value] holes/cm2Min. [value] holes/cm2 |
| 10\* | Dimensional stability of netting to washing | [ISO 3759; ISO 5077; ISO 6330]See Appendix | Not more than [value] % shrinkage and not more than [value] % expansion in both directions. |
|  | Add any other relevant property  |  |  |

\* Indicates that additional information is available in Appendix.

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.

## Storage

Accelerated storage stability data were generated as per [CIPAC MT 46.3]. Test samples were stored for [value] days at [value] °C. ([No significant differences were recorded among the properties of the product kept at ambient temperature and after accelerated storage stability test conditions.])

([Real time storage stability data were generated for [value] months using the following test conditions: (*Add real time storage stability data study conditions)*])

([Products should be stored and transported in appropriate conditions in accordance with the recommendations of the manufacturer. (*Add manufacturer recommended conditions supported by the real time storage stability study/other analyses performed, as appropriate)*])

Appendix. 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 (public health products) or in worst-case expected climatic conditions (agricultural products). ])

**Sampling Plan**

* Figure [value] applicable to Attributes [values] for which samples are to be taken from various parts of the constructed ITN.
* Figure [value] applicable to Attributes [values] for which samples are to be taken from various parts of the constructed ITN.

Figure [value]:*(Insert Figure)*

Figure [value]:*(Insert Figure)*

*(Add as many as needed)*

*(Modify the methods and notes in the sampling plan example text below, as per your product specifics)* ([Samples should be taken according to Figure [value]. 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. Where a final product is made from more than one type of netting, each type of netting should be sampled and tested separately.

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 [value] and [value]: [AI name] and [synergist, or second AI] wash resistance index**

*(Modify the methods and notes in the wash resistance index example text below, as per your product specifics)*

([The content of [AI name] and [synergist, or second AI] in the net pieces before and after washing should be determined as per Adapted CIPAC (O) MT 195 - IG – Determination of wash resistance index test for ITN fabric. ])

**Attributes [value] and [value]: Bursting strength – fabric and bursting strength – seam**

*(Modify the methods and notes in the bursting strengh fabric and seam example text below, as per your product specifics)*

([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 [value]: Mesh size**

*(Modify the methods and notes in the mesh size example text below, as per your product specifics)*

([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 [value]: Dimensional stability of netting to washing**

*(Modify the methods and notes in the dimensional stability of netting to washing example text below, as per your product specifics)*

([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. ])

**Attribute [value]:** (**[any other relevant property]**)

([add product specific methods and notes])

Version tracking

| Version number | Effective dates | Reason for replacement |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

*(Add rows to the table if required.)*