

**WHO SPECIFICATIONS AND EVALUATIONS
FOR PUBLIC HEALTH PESTICIDES**

DELTAMETHRIN

**LONG-LASTING (COATED ONTO FILAMENTS)
INSECTICIDAL NET**

(*S*)- α -cyano-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate



**World Health
Organization**

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Disclaimer¹

WHO specifications are developed with the basic objective of promoting, as far as practicable, the manufacture, distribution and use of pesticides that meet basic quality requirements.

Compliance with the specifications does not constitute an endorsement or warranty of the fitness of a particular pesticide for a particular purpose, including its suitability for the control of any given pest, or its suitability for use in a particular area. Owing to the complexity of the problems involved, the suitability of pesticides for a particular purpose and the content of the labelling instructions must be decided at the national or provincial level.

Furthermore, pesticides which are manufactured to comply with these specifications are not exempted from any safety regulation or other legal or administrative provision applicable to their manufacture, sale, transportation, storage, handling, preparation and/or use.

WHO disclaims any and all liability for any injury, death, loss, damage or other prejudice of any kind that may be arise as a result of, or in connection with, the manufacture, sale, transportation, storage, handling, preparation and/or use of pesticides which are found, or are claimed, to have been manufactured to comply with these specifications.

Additionally, WHO wishes to alert users to the fact that improper storage, handling, preparation and/or use of pesticides can result in either a lowering or complete loss of safety and/or efficacy.

WHO is not responsible, and does not accept any liability, for the testing of pesticides for compliance with the specifications, nor for any methods recommended and/or used for testing compliance. As a result, WHO does not in any way warrant or represent that any pesticide claimed to comply with a WHO specification actually does so.

¹ This disclaimer applies to all specifications published by WHO.

INTRODUCTION

WHO establishes and publishes specifications* for technical material and related formulations of public health pesticides with the objective that these specifications may be used to provide an international point of reference against which products can be judged either for regulatory purposes or in commercial dealings.

From 2002, the development of WHO specifications follows the **New Procedure**, described in the Manual for Development and Use of FAO and WHO Specifications for Pesticides. This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by WHO and the experts of the “FAO/WHO Joint Meeting on Pesticide Specifications” (JMPS).

WHO specifications now only apply to products for which the technical materials have been evaluated. Consequently, from the year 2002 onwards the publication of WHO specifications under the **New Procedure** has changed. Every specification consists now of two parts, namely the specifications and the evaluation report(s):

Part One: The Specification of the technical material and the related formulations of the pesticide in accordance with chapters 4 to 9 of the above-mentioned manual.

Part Two: The Evaluation Report(s) of the pesticide, reflecting the evaluation of the data package carried out by WHO and the JMPS. The data are provided by the manufacturer(s) according to the requirements of chapter 3 of the above-mentioned manual and supported by other information sources. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical material has been evaluated. Evaluation reports on specifications developed subsequently to the original set of specifications are added in a chronological order to this report.

WHO specifications under the **New Procedure** do not necessarily apply to nominally similar products of other manufacturer(s), nor to those where the active ingredient is produced by other routes of manufacture. WHO has the possibility to extend the scope of the specifications to similar products but only when the JMPS has been satisfied that the additional products are equivalent to that which formed the basis of the reference specification.

Specifications bear the date (month and year) of publication of the current version. Evaluations bear the date (year) of the meeting at which the recommendations were made by the JMPS.

* Footnote: The publications are available on the Internet under the WHO Prequalification Team - Vector control products (PQT-VC) website.

PART ONE
SPECIFICATIONS

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WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

INFORMATION

ISO common names

Deltamethrin (BSI, E-ISO), deltaméthrine ((f) F-ISO)

Synonyms

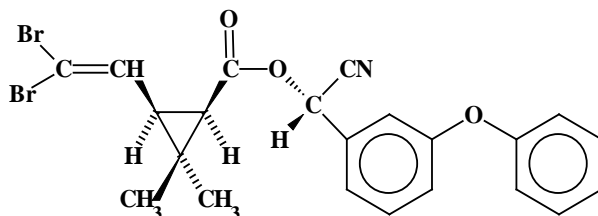
Decamethrin (rejected common name)

Chemical names

IUPAC (S)- α -cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate

CA [1R-[1 α (S*),3 α]]-cyano(3-phenoxyphenyl)methyl 3-(2,2-dibromoethenyl)-2,2-dimethylcyclopropanecarboxylate

Structural formula



Empirical formula

C₂₂H₁₉Br₂NO₃

Relative molecular mass

505.2

CAS Registry number

52918-63-5

CIPAC number

333

EEC number

258-256-6

Identity tests

Retention time in reversed phase and enantioselective HPLC, TLC, IR, NMR and mass spectra

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN LONG-LASTING (COATED ONTO FILAMENTS) INSECTICIDAL NET

WHO specification 333/LN/1 (September 2020*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (333/2006.1, 333/2009.1, 333/2010, 333/2012.3, 333/2013.1, 333/2014.1, 333+33/2015, 333+33/2018.1, 333/2018.2, 333+33/2019, 333/2019, 333/2020). It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers, irrespective of the source of TC. The evaluation reports (333/2006.1, 333/2009.1, 333/2010, 333/2012.3, 333/2013.1, 333/2014.1, 333+33/2015, 333+33/2018.1, 333/2018.2, 333+33/2019, 333/2019, 333/2020), given in PART TWO, form an integral part of this publication.

1 Description

The material shall be in the form of netting (Note 1), consisting of 75, 100 or 150 denier (Note 2) multi-filament polyester fibers, treated with technical deltamethrin complying with the requirements of WHO specification 333/TC (November 2017) together with any necessary other formulants. The product shall appear clean and shall be free from visible extraneous matter (Note 3), 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 (Note 4).

2 Active ingredient

2.1 Identity tests (333/LN/(M)/2, CIPAC Handbook M, p.66, 2009) (Notes 5)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

* This specification is applicable to long-lasting insecticidal nettings and nets commercialized under the trade names of PermaNet® 2.0 and PermaNet® 3.0 (side panels) produced by Vestergaard, Yorkool LN produced by Tianjin Yorkool International Trading Co. Ltd. and DurActive LN produced by Shobikaa Impex Private Ltd. The subject of the extension of specifications for LN has been discussed by the JMPS in 2009. The 2009 Meeting agreed that - in contrast to other formulations - an extension of a specification to nominally similar LN of other manufacturers may not be possible with the data currently available and that the manufacturer and the product should be named in a footnote or in the specification.

Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at the WHO Prequalification Team - Vector Control Products (PQT-VC) website.

2.2 Deltamethrin content (333/LN/(M)/3, CIPAC Handbook M, p.66, 2009)
(Notes 5, 6 & 7)

The deltamethrin content shall be declared as follows and, when determined, the average measured content shall not differ from that declared by more than $\pm 25\%$.

PermaNet® 2.0 : 1.8 g/kg for 75 denier yarn
1.4 g/kg for 100 and 150 denier yarn

PermaNet® 3.0 – side panels : 2.8 g/kg for 75 denier yarn
2.1 g/kg for 100 and 150 denier yarn

Yorkool LN : 1.8 g/kg for 75 denier yarn
1.4 g/kg for 100 and 150 denier yarn

DurActive LN : 1.4 g/kg for 100 denier yarn

2.3 Deltamethrin wash resistance index (MT 195, CIPAC Handbook O, p. 205, 2017) (Note 8)

The wash resistance index of deltamethrin from the netting, when determined, shall be within the range 80% to 98%.

3 Physical properties (Notes 6 & 16)

3.1 Fabric weight (mass per m²) (ISO 3801 / EN 12127)

The mass per unit area shall be declared (30 g/m² for 75 denier yarn, 40 g/m² for 100 and 150 denier yarn), and when determined, shall not differ from that declared by more than $\pm 10\%$.

3.2 Netting mesh size

When counted by the method given in Note 9, the average number of complete holes/cm² for 75 and 100 denier yarn shall be not less than 24 holes/cm² and the lowest value shall be not less than 24 holes/cm². For 150 denier yarn, the average number of complete holes/cm² shall be not less than 12.4 holes/cm² and the lowest value shall be not less than 10.6 holes/cm².

3.3 Dimensional stability of netting to washing (Note 10)

Not more than 10% shrinkage and not more than 5% expansion in both directions.

3.4 Bursting strength (ISO 13938:2) (Note 11)

The bursting strength of the fabric shall be declared (not less than 250 kPa, 350 kPa or 380kPa, respectively, for fabric made of 75, 100 or 150 denier yarn) and, when determined, the average shall be not less than that declared.

If seams are present, their average bursting strength shall be not less than the measured average for the fabric.

3.5 Flammability (EN 1102) (Note 12)

Tested according to EN 1102 the following requirements should be achieved*:

After removing the ignition source the following fire phenomena should not occur:

- ignition
- propagation of the flame or glow.
- flaming debris
- ignition of the filter paper

*Fulfilling the requirements above means that the flame speed rate is 0 mm/s, i.e., no flame or glow achieves first and third marker threads.

Formation of holes is allowed provided that the burnt or melted width and length of the holes does not exceed 50 mm and 150 mm, respectively.

4 Storage stability

4.1 Stability at elevated temperature (MT 46.4) (Note 13)

After storage at $40 \pm 2^\circ\text{C}$ for 8 weeks (Note 14), the determined average active ingredient content must not be lower than 95% of the average content found before storage (Note 15) and the netting shall continue to comply with the clauses for:

- wash resistance index (2.3);
- dimensional stability to washing (3.3);
- bursting strength (3.4).

Note 1 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.

Note 2 The linear density (denier) of the fibres cannot be measured in the netting or the manufactured bed net but it should be identified on the packaging.

Note 3 Occasional short lengths of loose thread present in the netting are not considered to be extraneous matter.

Note 4 Long-lasting insecticidal netting is expected to retain its insecticidal activity during its lifespan and / or through a number of standardized laboratory washes. The clause for deltamethrin wash resistance index (2.3) is based on a model washing regime and compliance with the limit does not guarantee that activity will be retained through any particular number of washes performed according to local practice.

Note 5 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.

Note 6 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.

Note 7 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.

Note 8 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.

Note 9 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 Note 6, 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.

Note 10 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: 30°C 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.

Note 11 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.

Note 12 Flammability test according to EN 1102, using the surface ignition method (position the burner perpendicular to the surface of the specimen).

The following observations shall be reported: the afterflame time, the afterglow time, the maximum burnt or damage width and length, whether or not flame reaches vertical edge of the specimen, whether or not a hole is burnt or melted in the sample, whether or not any flaming debris falls below the bottom edge of the sample and ignition of the filter paper.

Definitions according to ISO 4880:1997 (not included in EN 1102:2016 and EN ISO 6941: 1995):

- Ignition: initiation of combustion.
- Combustion: exothermic reaction of a combustible substance with an oxidizer, accompanied by flames and/or glowing and/or emission of smoke.

Procedure for measuring burnt or damage width and length dimensions of each sample:

Remove the sample from the sample holder and place it on a flat horizontal surface. Place a rule on top of the test sample along the line of maximum damage and parallel with the length side of the test specimen. Measure the maximum length in millimetres from the lowest point of burnt or damage to the end of the hole. To measure the burnt or damage width, proceed in the same way but with the ruler parallel to the width side of the test sample. Proceed in the same way for the other 5 samples.

Note 13 MT 46.4 is the harmonized and revised version of MT 46.3 and was accepted as full CIPAC method in 2020. Prior to its publication in a next Handbook, copies of the method can be obtained through the CIPAC website,

<http://www.cipac.org/index.php/methods-publications/pre-published-methods>

Note 14 The LN has long-term stability at temperatures up to and about 40°C. Conversion of deltamethrin to the *R*-isomer may occur at higher temperatures, particularly above 50°C, and the LN should be kept away from direct sunlight and heat sources.

Note 15 Samples of the netting taken before and after the storage stability test may be analyzed concurrently after the test in order to reduce the analytical error.

Note 16 Normative references for physical tests:

Currently the following standards are the latest versions of the documents to be used for physical tests. The updated version of the standard should always be used when available.

ISO 139:2005/Amd.1:2011 Textiles - Standard atmospheres for conditioning and testing.-
Textiles - Standard atmospheres for conditioning and testing.

ISO 3801:1977 - Textiles - Woven fabrics - Determination of mass per unit length and mass per unit area.

EN 12127:1997 - Textiles - Fabrics - Determination of mass per unit area using small samples.

ISO 3759:2011 - Textiles - Preparation, marking and measuring of fabric specimens and garments in tests for determination of dimensional change.

ISO 6330:2012 - Textiles - Domestic washing and drying procedures for textile testing.

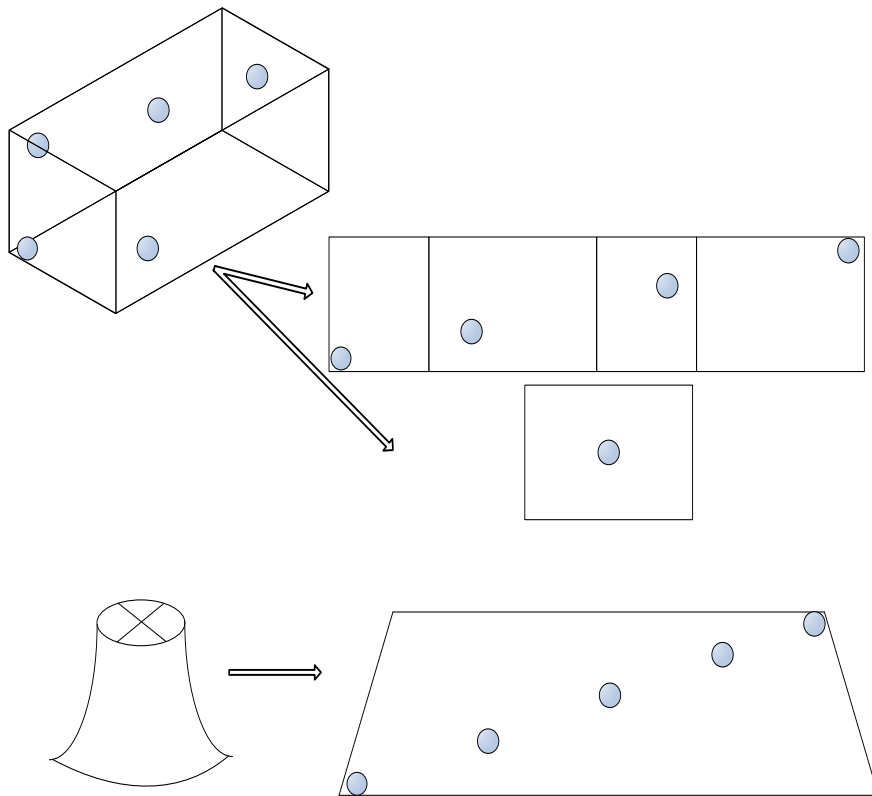
ISO 5077:2007 - Textiles - Determination of dimensional change in washing and drying.

ISO 13938-2:1999 - Textiles - Bursting properties of fabrics - Part 2: Pneumatic method for determination of bursting strength and bursting distension

EN 1102:2016 - Textiles and textile products. Burning behaviour. Curtains and drapes. Detailed procedure to determine the flame spread of vertically oriented specimens.

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.



WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN LONG-LASTING (COATED ONTO FILAMENTS) INSECTICIDAL NET

WHO specification 333/LN/2 (January 2019*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation reports (333/2009.2, 333/2014.1, 333/2017.1). It should be applicable to relevant products of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers, irrespective of the source of TC. The evaluation reports (333/2009.2, 333/2014.1, 333/2017.1), given in PART TWO, form an integral part of this publication.

1 Description

The product shall be in the form of netting (Note 1), consisting of 75, 100 or 150 denier (Note 2) multi-filament polyester fibres, treated with formulated deltamethrin complying with the requirements of WHO specification 333/SC (November 2017) together with a binder and any necessary other formulants. The product shall appear clean and shall be free from visible extraneous matter (Note 3), 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 (Notes 4).

2 Active ingredient

2.1 Identity tests (333/LN/(M)/2, CIPAC Handbook M, p.66, 2009) (Note 5)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 Deltamethrin content (333/LN/(M)/3, CIPAC Handbook M, p.66, 2009) (Notes 5, 6 & 7)

The deltamethrin content shall be declared as follows and, when determined, the average measured content shall not differ from that declared by more than $\pm 25\%$.

* This specification is applicable to long-lasting insecticidal nettings and nets produced by Tana Netting Co., Ltd. (NRS International Group) and commercialized under the trade names of DawaPlus 2.0 and DawaPlus 3.0 (side panels). The subject of the extension of specifications for LN has been discussed by the JMPS in 2009. The Meeting agreed that - in contrast to other formulations - an extension of a specification to nominally similar LN of other manufacturers may not be possible with the data currently available and that the manufacturer and the product should be named in a footnote or in the specification.

Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at the WHO Prequalification Team - Vector Control Products (PQT-VC) website.

For DawaPlus 2.0 : 2.7 g/kg for 75 denier yarn
2.0 g/kg for 100 denier yarn
2.0 g/kg for 150 denier yarn.

For DawaPlus 3.0 side panels : 2.5 g/kg for 100 denier yarn.

2.3 Deltamethrin wash resistance index (MT 195, CIPAC Handbook O, p.205, 2017) (Note 8)

The wash resistance index of deltamethrin from the netting, when determined, shall be in the range 90% to 100%.

3 Physical properties (Notes 6 & 14)

3.1 Fabric weight (mass per m²) (ISO 3801 / EN 12127)

The mass per unit area shall be declared (30 g/m² for 75 denier yarn, 40 g/m² for 100 denier yarn and 42 g/m² for 150 denier yarn), and when determined, shall not differ from that declared by more than ± 10 %.

3.2 Netting mesh size

When counted by the method given in Note 9, the average number of complete holes/cm² for 75 and 100 denier yarn shall be not less than 24 holes/cm² and the lowest value shall be not less than 23 holes/cm². For 150 denier yarn the average number of complete holes/cm² shall be not less than 14 holes/cm² and the lowest value shall be not less than 13 holes/cm².

3.3 Dimensional stability of netting to washing (Note 10)

Not more than 10% shrinkage and not more than 5% expansion in both directions.

3.4 Bursting strength (ISO 13938:2) (Note 11)

The bursting strength of the fabric shall be declared as follows and, when determined, the average shall be not less than that declared.

For DawaPlus 2.0 : not less than 250, 350 or 420 kPa, respectively, for fabric made from 75, 100 or 150 denier yarn

For DawaPlus 3.0 side panels : not less than 400 kPa for fabric made from 100 denier yarn.

If seams are present, their average bursting strength shall be not less than the measured average for the fabric.

3.5 Flammability (EN 1102) (Note 12)

Tested according to EN 1102 the following requirements should be achieved*:

After removing the ignition source the following fire phenomena should not occur:

- ignition
- propagation of the flame or glow.
- flaming debris
- ignition of the filter paper

*Fulfilling the requirements above means that the flame speed rate is 0 mm/s, i.e., no flame or glow achieves first and third marker threads.

Formation of holes is allowed provided that the burnt or melted width and length of the holes does not exceed 50 mm and 150 mm, respectively.

4 Storage stability

4.1 Stability at elevated temperature (MT 46.3.4, CIPAC Handbook O, p.176, 2017)

After storage at $54 \pm 2^\circ\text{C}$ for 14 days, the determined average active ingredient content must not be lower than 95% of the average content found before storage (Note 13) and the netting shall continue to comply with the clauses for:

- wash resistance index (2.3);
- dimensional stability to washing (3.3);
- bursting strength (3.4).

Note 1 The specification applies to netting, in bulk, and to finished bed nets, which may be rectangular or conical in design.

Note 2 The linear density (denier) of the fibres cannot be measured in the manufactured net but it should be identified on the packaging.

Note 3 Occasional short lengths of loose thread present in the netting are not considered to be extraneous matter.

Note 4 Long-lasting insecticidal netting is expected to retain its insecticidal activity during its life span and through a number of washes.

Note 5 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.

Note 6 Samples should be taken according to Figure 1 or 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.

Note 7 The declared values for deltamethrin content in g/kg are equivalent to 80 mg/m² for DawaPlus 2.0 and to 100 mg/m² for DawaPlus 3.0 side panels. 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.

Note 8 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.

Note 9 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 Note 6, 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.

Note 10 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: 30°C 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.

Note 11 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. 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.

Note 12 Flammability test according to EN 1102, using the surface ignition method (position the burner perpendicular to the surface of the specimen).

The following shall be reported: the after flame time, the afterglow time, the maximum burnt or damage width and length, whether or not flame reaches vertical edge of the specimen, whether or not a hole is burnt or melted in the specimen, whether or not any flaming debris falls below the bottom edge of the specimen and ignition of the filter paper.

Definitions according to ISO 4880:1997 (not included in EN 1102:1995 and EN ISO 6941:1995):

- Ignition: initiation of combustion.

- Combustion: exothermic reaction of a combustible substance with an oxidizer, accompanied by flames and/or glowing and/or emission of smoke.

Procedure for measuring burnt or damage width and length dimensions of each specimen:

Remove the specimen from the specimen holder and place it on a flat horizontal surface. Place a rule on top of the test specimen along the line of maximum damage and parallel with the length side of the test specimen. Measure the maximum length in mm from the lowest point of burnt or damage to the end of the hole. To measure the burnt or damage width, proceed in the same way but with the ruler parallel to the width side of the test specimen. Proceed in the same way for the other 5 specimens.

Note 13 Samples of the product taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

Note 14 Normative references for physical tests:

Currently the following standards are the latest versions of the documents to be used for physical tests. The updated version of the standard should always be used when available.

ISO 139:2005/Amd.1:2011 Textiles - Standard atmospheres for conditioning and testing.-
Textiles - Standard atmospheres for conditioning and testing.

ISO 3801:1977 - Textiles - Woven fabrics - Determination of mass per unit length and mass per unit area.

EN 12127:1997 - Textiles - Fabrics - Determination of mass per unit area using small samples.

ISO 3759:2011 - Textiles - Preparation, marking and measuring of fabric specimens and garments in tests for determination of dimensional change.

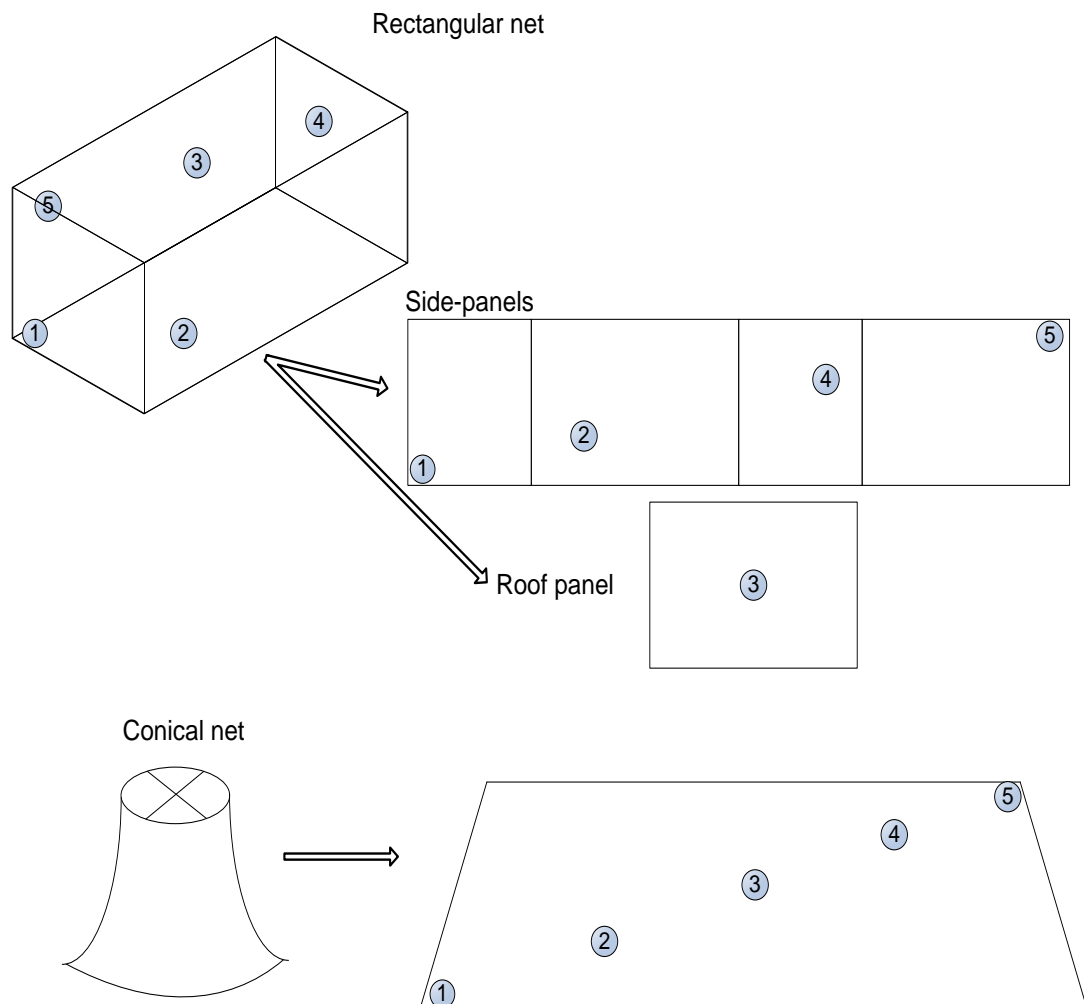
ISO 6330:2012 - Textiles - Domestic washing and drying procedures for textile testing.

ISO 5077:2007 - Textiles - Determination of dimensional change in washing and drying.

ISO 13938-2:1999 - Textiles - Bursting properties of fabrics - Part 2: Pneumatic method for determination of bursting strength and bursting distension

EN 1102:2016 - Textiles and textile products. Burning behaviour. Curtains and drapes. Detailed procedure to determine the flame spread of vertically oriented specimens.

Figure 1 Recommended positions from which 5 pieces of netting should be taken from a made up bed net and combined to form a representative sample.



WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN LONG-LASTING (COATED ONTO FILAMENTS) INSECTICIDAL NET

WHO specification 333/LN/5 (January 2019*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation reports (333/2015.3, 333/2016.1). It should be applicable to relevant products of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers, irrespective of the source of TC. The evaluation reports (333/2015.3, 333/2016.1), given in PART TWO, forms an integral part of this publication.

1 Description

The material shall be in the form of netting (Note 1), consisting of 50 denier, 75 denier or 100 denier (Note 2) multi-filament polyester fibers, treated with technical deltamethrin complying with the requirements of WHO specification 333/TC (November 2017), formulated in a 10% suspension concentrate together with a polymer coating and any necessary other formulants. The product shall appear clean and shall be free from visible extraneous matter (Note 3), 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 (Notes 4 & 5).

2 Active ingredient

2.1 Identity tests (333/LN/(M)/2, CIPAC Handbook M, p.66, 2009) (Note 6)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 Deltamethrin content (333/LN/(M)/3, CIPAC Handbook M, p.66, 2009) (Notes 6, 7 & 8)

The deltamethrin content shall be declared (2.3 g/kg for 50 denier yarn, 1.85 g/kg for 75 denier yarn and 1.4 g/kg for 100 denier yarn) and, when determined, the average measured content shall not differ from that declared by more than $\pm 25\%$.

* This specification is applicable to long-lasting insecticidal nettings and nets commercialized under the trade name of Yahe LN produced by Fujian Yamei Industry & Trade Co., Ltd. The subject of the extension of specifications for LN has been discussed by the JMPS in 2009. The Meeting agreed that - in contrast to other formulations - an extension of a specification to nominally similar LN of other manufacturers may not be possible with the data currently available and that the manufacturer and the product should be named in a footnote or in the specification.

Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at the WHO Prequalification Team - Vector Control Products (PQT-VC) website.

2.3 Deltamethrin wash resistance index (MT 195), CIPAC Handbook O, p.205, 2017 (Note 9)

The wash resistance index of deltamethrin from the netting, when determined, shall be within the range 85% to 99%.

3 Physical properties (Notes 7 & 15)

3.1 Netting mesh size

When counted by the method given in Note 10, the average number of complete holes/cm² shall be not less than 24 holes/cm² and the lowest value shall be not less than 24 holes/cm².

3.2 Dimensional stability of netting to washing (Note 11)

Not more than 5% shrinkage/expansion in both directions.

3.3 Bursting strength (Note 12)

The bursting strength of the fabric shall be declared (not less than 250 kPa for 50 and 75 denier yarn, not less than 350 kPa for 100 denier yarn) and, when determined, the average shall be not less than that declared.

If seams are present, their average bursting strength shall be not less than the measured average for the fabric.

4 Storage stability

4.1 Stability at elevated temperature (MT 46.3.4, CIPAC Handbook O, p.176, 2017)

After storage at 40 ± 2°C for 8 weeks (Note 13), the determined average active ingredient content must not be lower than 95% of the average content found before storage (Note 14) and the netting shall continue to comply with the clauses for:

- wash resistance index (2.3);
- dimensional stability (3.2);
- bursting strength (3.3).

Note 1 The specification applies to bulk netting and manufactured nets, which may be rectangular or conical in design.

Note 2 The linear density (denier) of the fibres cannot be measured in the netting or the manufactured bed net but it should be identified on the packaging.

Note 3 Occasional short lengths of loose thread present in the netting are not considered to be extraneous matter.

Note 4 Long-lasting insecticidal netting is expected to retain its insecticidal activity during its life span and through a number of washes.

Note 5 Flammability of the product is not part of the specification but it should be measured by the manufacturer, according to 16CFR Part 1610, and the result presented on the package. The linear density (denier) of the fibres cannot be measured in the netting or the manufactured net but it should be identified on the packaging.

Note 6 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.

Note 7 Samples should be taken according to Figure 1 or 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.

Note 8 The target deltamethrin content of 2.3, 1.85 and 1.4 g/kg for the 50, 75 and 100 denier yarn netting or net, respectively, corresponds to 55 mg/m² in all cases. These values can be calculated from 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. In cases of dispute, g/kg values shall be used.

Note 9 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.

Note 10 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 Note 7, 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.

Note 11 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: 30°C 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.

Note 12 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. 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.

Note 13 The LN has long-term stability at temperatures up to and about 40°C. Conversion of deltamethrin to the *R*-isomer may occur at higher temperatures, particularly above 50°C, and the LN should be kept away from direct sunlight and heat sources.

Note 14 Samples of the netting taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

Note 15 Normative references for physical tests:

Currently the following standards are the latest versions of the documents to be used for physical tests. The updated version of the standard should always be used when available.

ISO 139:2005/Amd.1:2011 Textiles - Standard atmospheres for conditioning and testing.-
Textiles - Standard atmospheres for conditioning and testing.

ISO 3801:1977 - Textiles - Woven fabrics - Determination of mass per unit length and mass per unit area.

EN 12127:1997 - Textiles - Fabrics - Determination of mass per unit area using small samples.

ISO 3759:2011 - Textiles - Preparation, marking and measuring of fabric specimens and garments in tests for determination of dimensional change.

ISO 6330:2012 - Textiles - Domestic washing and drying procedures for textile testing.

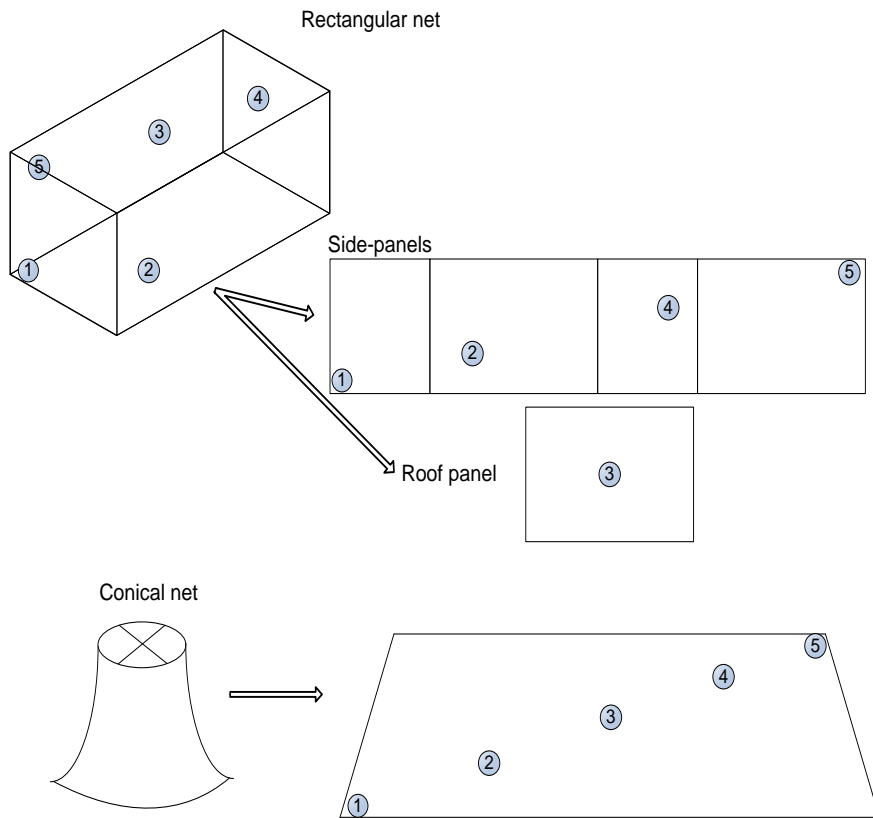
ISO 5077:2007 - Textiles - Determination of dimensional change in washing and drying.

ISO 13938-2:1999 - Textiles - Bursting properties of fabrics - Part 2: Pneumatic method for determination of bursting strength and bursting distension

EN 1102:2016 - Textiles and textile products. Burning behaviour. Curtains and drapes. Detailed procedure to determine the flame spread of vertically oriented specimens.

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.



PART TWO
EVALUATION REPORTS

DELTAMETHRIN

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| 2019 FAO/WHO evaluation report based on data submitted by Vestergaard (LN) Annex 1: References | 31 32 |
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WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

FAO/WHO EVALUATION REPORT 333/2020.1

Recommendations

The Meeting recommended the following:

- (i) The 150 denier Yorkool LN product of Tianjin Yorkool International Trading Co., Ltd. should be accepted as equivalent to the reference LN product of Vestergaard.
- (ii) The existing WHO specification 333/LN/1 for deltamethrin (coated onto filaments) LN should be extended to encompass the 150 denier Yorkool LN product of Tianjin Yorkool International Trading Co., Ltd.

Appraisal

Supporting data and information for deltamethrin long-lasting (coated onto filaments) insecticidal net (LN), provided by Tianjin Yorkool International Trading Co., Ltd. in 2019, were considered by the Meeting for the extension of the existing WHO specification 333/LN/1 (July 2019) to their 150 denier Yorkool LN and the equivalence of their product with the reference LN from Vestergaard.

The LN under consideration (Yorkool LN, 150 denier) is in the form of a finished mosquito net consisting of 150 denier multi-filament polyester fibers treated with deltamethrin at a target rate of 1.4 g/kg. The treatment is performed by coating the polyester fibers with deltamethrin technical material in a working liquid. The deltamethrin technical material is from a source compliant with the existing WHO specification for deltamethrin TC. The WHO specification 333/LN/1 already covers the 75 denier, 100 denier and 150 denier LN from this manufacturer.

Description

Data provided by the manufacturer on one net showed that the product appeared clean and free from visible extraneous matter, without visible damage (such as splitting or tearing) nor visible manufacturing defect. Seams appeared good and the weave was uniform. The LN therefore complies with the description clause of the existing WHO specification 333/LN/1.

Active ingredient content

Yorkool LN, 150 denier is produced from 150 denier yarn and the target deltamethrin content is 1.4 g/kg, corresponding to 56 mg/m² (fabric weight = 40 g/m²).

Data provided by the manufacturer for deltamethrin content on one net (one batch) showed that the product complies with the target dose of 1.4 g/kg ± 25% (1.37 g/kg). The recommended CIPAC method 333/LN/(M)/3 published in the Handbook M was used for determination of deltamethrin content.

The manufacturer provided spatial variation data on one net by measuring deltamethrin content on 5 individual net pieces taken according to Figure 1 of the

specification. Data showed an acceptable within-net homogeneity of the active ingredient (RSD = 1.78%, n = 5).

Active ingredient wash resistance index

An adequate amount of active ingredient must be present at the surface of the LN, for efficacy reasons, whereas the majority must reside within the coating of the LN, to avoid excessive losses during washing and to provide a reservoir from which the surface is replenished with active ingredient. The depth and properties of coating therefore strongly influence the retention of deltamethrin when the LN is subjected to repeated washing. The monitoring of the depletion of the active ingredient content by washing is accomplished by analysing separate washed and unwashed pieces of the same fabric using the CIPAC method MT 195 for determination of wash resistance index of LN, published in the Handbook O.

The manufacturer provided the Meeting with data on one net (one batch) tested using the CIPAC method that showed that the deltamethrin wash resistance index was 97.1%, which complies with the specification range of 80% to 98%.

Relevant impurities

There are no relevant impurities identified in the existing WHO specifications for deltamethrin TC and LN. During the manufacturing process of deltamethrin LN, heat and base-catalyzed epimerization of deltamethrin to the (insecticidally inactive) *R*-alpha isomer may occur. This conversion can also occur if the LN is exposed to excessive heat during storage or use. This conversion must be controlled by the manufacturer to avoid significant losses of active ingredient, despite the *R*-alpha isomer is a non-relevant impurity and should remain excluded from the specification.

Data provided by the manufacturer showed that deltamethrin *R*-alpha isomer content of Yorkool LN, 150 denier is lower than 0.1 g/kg.

Physical properties

The manufacturer provided physical data on one net (one batch) using the recommended methods that showed that the net fully complies with the specification tolerances for fabric weight, netting mesh size, dimensional stability of netting to washing, bursting strength and flammability.

Storage stability

The manufacturer provided data for one net (one batch) after storage at 40°C for 8 weeks showing that the loss of deltamethrin was less than 5% and the wash resistance index remained within the limits of the specification clause. The dimensional stability to washing and the bursting strength remained unchanged after storage at 40°C for 8 weeks.

The Meeting concluded that Yorkool LN 150 denier complies with the existing WHO specification 333/LN/1 for storage stability at 40°C for 8 weeks.

ANNEX 1: REFERENCES

| Study number | Author(s) | Year | Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study |
|--------------|---|------|--|
| | Tianjin Yorkool International Trading Co., Ltd. | 2019 | Submission dossier for WHO PQT evaluation for extension of the WHO specification 333/LN/1 to Yorkool LN, 150 denier. Supporting data and information submitted by Tianjin Yorkool International Trading Co., Ltd. To WHO Prequalification Team. November 2019. |
| 19241 | S. Nagachandrudu | 2019 | Physical and Chemical Analysis of Deltamethrin based Long Lasting (coated onto polyester filament) Insecticidal Net (Yorkool LN 1.4 g/kg, 150 D). Report N° 19241 of International Institute of Biotechnology and Toxicology (IIBAT), Tamil Nadu, India for Tianjin Yorkool International Trading Co., Ltd. GLP. |

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

FAO/WHO EVALUATION REPORT 333/2019

Recommendations

The Meeting recommended the following:

- (ii) The deltamethrin long-lasting (coated onto filaments) insecticidal net (LN) from Tianjin Yorkool International Trading Co., Ltd. should again be accepted as equivalent to the reference LN product of Vestergaard.
- (iii) The revised WHO specification 333/LN/1 for deltamethrin long-lasting (coated onto filaments) insecticidal net (LN) should again be extended to encompass the LN from Tianjin Yorkool International Trading Co., Ltd.

Appraisal

The WHO specification 333/LN/1 for deltamethrin long-lasting (coated onto filaments) insecticidal net (LN) was revised and published in January 2019:

- to include the deltamethrin content in the side panels of PermaNet® 3.0, but also to include additional clauses for fabric weight (mass of net per m²) and flammability for PermaNet® 2.0 and 3.0 (FAO/WHO evaluation report 333+33/2018.1). These two additional parameters are included in the LN specification template of the third revision (2016) of the first edition of the FAO/WHO Manual on pesticides specifications.
- to encompass the 100 denier DuraActive LN product of Shobikaa Impex Private Ltd which also complied with the additional clauses for fabric weight and flammability (FAO/WHO evaluation report 333+33/2018.2).

The specification 333/LN/1 was further revised and published in April 2019 to encompass the 150 denier products of Vestergaard (PermaNet® 2.0 and PermaNet® 3.0 side panels) (FAO/WHO evaluation report 333+33/2019).

The Meeting had also noted that there is an extension of the current specification 333/LN/1 to Yorkool LN from Tianjin Yorkool International Trading Co., Ltd., and recommended that the manufacturer should provide supporting data for fabric weight and flammability to prove that they still comply with the revised reference specification.

Tianjin Yorkool International Trading Co., Ltd. provided the Meeting with test reports on fabric weight and flammability on their 75 denier and 100 denier Yorkool LN. These tests were performed according to the methods recommended in the specification and confirmed that Yorkool LN still comply with the additional clauses of the revised specification 333/LN/1.

ANNEX 1: REFERENCES

| Study number | Author(s) | Year | Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study |
|--------------|--------------|------|---|
| | FAO/WHO | 2016 | Manual on development and use of FAO and WHO specifications for pesticides. Third revision of the first edition. FAO, Rome and WHO, Geneva, March 2016 (internet publications). |
| TSNT01203498 | Patrick Gong | 2019 | Fabric weight and flammability of Yorkool LN, 75 denier. Test report TSNT01203498. Intertek, May 28, 2019. |
| TSNT01203507 | Patrick Gong | 2019 | Fabric weight and flammability of Yorkool LN, 100 denier. Test report TSNT01203507. Intertek, May 28, 2019. |

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

FAO/WHO EVALUATION REPORT 333+33/2019

Recommendations

The Meeting recommended the following:

- (iv) The existing WHO specification 333/LN/1 for deltamethrin long-lasting (coated onto filaments) insecticidal net should be extended to encompass the 150 denier products of Vestergaard (PermaNet® 2.0 and PermaNet® 3.0 side panels), and revised as proposed by Vestergaard and as amended by the Meeting.
- (ii) The existing WHO specifications 333+33/LN/1 (netting and net) for deltamethrin + piperonyl butoxide long-lasting (incorporated into filaments) insecticidal netting and net should be revised as proposed by Vestergaard and as amended by the Meeting.

Appraisal

PermaNet® 2.0 and PermaNet® 3.0 side panels, 150 denier

A draft revised specification and supporting data, provided by Vestergaard, were considered by the Meeting for the extension of the existing WHO specification 333/LN/1 (January 2019) to the 150 denier yarn products (PermaNet® 2.0 and PermaNet® 3.0 side panels).

The nominal deltamethrin content of this 150 denier yarn product is 1.4 g/kg with a fabric weight of 40 g/m². Vestergaard proposed to specify 12.4 holes/cm² as the minimum average number and 10.6 holes/cm² as the minimum lowest value, and 380 kPa as minimum bursting strength. The company also proposed to revise the tolerance for dimensional stability to washing from not more than 5% shrinkage/expansion in both directions to not more than 10% shrinkage and not more than 5% expansion in both directions, to be in line with the tolerance currently recommended in the FAO/WHO Manual on pesticide specifications.

The manufacturer provided the Meeting with quality control data on several samples of PermaNet® 2.0, 150 denier. These data showed that all the samples fully comply with the proposed specification tolerances for deltamethrin content and wash resistance index, fabric weight, netting mesh size, dimensional stability of netting to washing and bursting strength. The deltamethrin content and wash resistance index after storage at 40°C for 8 weeks also complied with the specification tolerances.

ANNEX 1: REFERENCES

| Study number | Author(s) | Year | Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study |
|--------------|----------------|------|--|
| | FAO/WHO | 2016 | Manual on development and use of FAO and WHO specifications for pesticides. Third revision of the first edition. FAO, Rome and WHO, Geneva, March 2016 (internet publications). |
| | Melinda Hadi | 2018 | Draft revised specification 333/LN/1 for deltamethrin long-lasting (coated onto filaments) insecticidal net submitted to WHO PQT-VC on December 2018. |
| | Melinda Hadi | 2018 | Summary of the new proposed specification for PermaNet® 2.0, 150 denier. Document submitted to WHO PQT-VC on December 2018. |
| SLA000478 | Linh Vu | 2018 | PermaNet® 2.0 - 150 denier. Quality evaluation. Test report SLA000478. ISO 17025. Vestergaard, June 6, 2018. |
| | Melinda Hadi | 2018 | Draft revised specifications 333+33/LN (netting and net) for deltamethrin + piperonyl butoxide long-lasting (incorporated into filaments) insecticidal net submitted to WHO PQT-VC on December 2018. |
| | Melinda Hadi | 2018 | Summary of the new proposed specification for PermaNet® 3.0, 150 denier for side panels. Document submitted to WHO PQT-VC on December 2018. |
| SLA000484.1 | Linh Vu | 2018 | PermaNet® 3.0 - Roof 30 GSM. Quality evaluation. Test report SLA000484.1. ISO 17025. Vestergaard, June 6, 2018. |
| VNVL.18.001 | Rebecca Pwalia | 2018 | WHO tunnel tests on new PermaNet® 3.0 specification. Vestergaard - NMIMR Vector labs and Noguchi Memorial Institute for Medical Research, Ghana. July 30, 2018. |

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

FAO/WHO EVALUATION REPORT 333/2018.2

Recommendations

The Meeting recommended the following:

The existing WHO specification 333/LN/1 for deltamethrin (coated onto filaments) LN should be extended to encompass the 100 denier DuraActive LN product of Shobikaa Impex Private Ltd.

Appraisal

Supporting data and information for deltamethrin long-lasting (coated onto filaments) insecticidal net (LN) provided by Shobikaa Impex Private Ltd in 2017 were considered by the Meeting for extension of the existing WHO specification 333/LN/1 (October 2015). The meeting considered that data on two nets were sufficient at this time as the product is not yet in full development and will need to go through WHO testing before adoption of the specification.

The LN under consideration (DuraActive LN) is in the form of a finished mosquito net consisting of 100 denier multi-filament polyester fibers treated with deltamethrin at a target rate of 1.4 g/kg. The treatment is performed with deltamethrin technical material in solution with a binding ingredient. The deltamethrin technical material is from a source compliant with the existing WHO specification for deltamethrin TC (Tagros).

Description

The Meeting concluded that the description of DuraActive LN made of 100 denier multi-filament polyester fibres treated with deltamethrin complies with the existing WHO specification 333/LN/1.

Active ingredient content

DuraActive LN is produced from 100 denier yarn and the target deltamethrin content is 1.4 g/kg, corresponding to 56 mg/m² (fabric weight = 40 g/m²). The CIPAC method 333/LN/(M)/3 published in Handbook M, was used for the determination of the active substance content. Data provided by the manufacturer for deltamethrin content on 2 nets showed that the product complies with this target dose of 1.4 g/kg ($\pm 25\%$).

Special attention needs to be paid to control random variations in the distribution of the insecticide over the surface of the net and between nets. The manufacturer provided spatial variation data on 2 nets (deltamethrin content on 5 individual net pieces taken according to Figure 1 of the specification) showing acceptable within-net homogeneity of the active ingredient (RSD ranging from 1.2 to 1.4%, n = 5).

Active ingredient wash resistance index

An adequate amount of active ingredient must be present at the surface of the LN, for efficacy reasons, whereas the majority must reside within the coating of the LN, to avoid excessive losses during washing and to provide a reservoir from which the surface is replenished with active ingredient. The depth and properties of coating therefore strongly influence the retention of deltamethrin when the LN is subjected to repeated washing. The monitoring of the depletion of total active ingredient content by washing (wash resistance index) is accomplished by analysing separate washed and unwashed pieces of the same fabric.

The method MT 195 for determination of wash resistance index of LN was adopted as a full CIPAC method in 2013. The manufacturer provided the Meeting with data on DuraActive LN tested using the CIPAC method that showed that the deltamethrin wash resistance index was 96%, which complies with the specification range of 80% to 98%.

Data were also provided in support of the Phase I testing. DuraActive LN washed 1, 3, 5, 10, 15, 20 and 25 times using the WHO washing procedure showed a deltamethrin wash resistance index ranging from 95% to 97% (Report 17130). The meeting noted that the Phase I efficacy data had not yet been assessed.

Relevant impurities

There are no relevant impurities identified in the existing WHO specification for deltamethrin TC. During the coating process of deltamethrin LN, heat and base-catalyzed epimerization of deltamethrin to the (insecticidally inactive) *R*-alpha isomer may occur. This conversion can also occur if the LN is exposed to excessive heat during storage or use. Data provided by the manufacturer showed that deltamethrin *R*-alpha isomer content of DuraActive LN is lower than 0.1% of the deltamethrin content.

Physical properties

The manufacturer provided netting mesh size data showing that the average number of complete holes/cm² is not less than 24 holes/cm² and the lowest value is not less than 24 holes/cm² and therefore that their product complies with the specified limits. Test data provided by the manufacturer showed that the dimensional stability to washing complies with the standard of $\pm 5\%$ tolerance of the current reference specification. The bursting strength is higher than the specified limit of 350 kPa both for the fabric and the seams.

Data on flammability tested according to EN 1102 were provided demonstrating that the LN samples did not ignite (the test flame was not propagated).

Storage stability

The manufacturer provided data after storage at 40°C for 8 weeks showing that the loss of deltamethrin was less than 5% and the wash resistance index remained within the limits of the specification clause. The manufacturer also provided data showing that the dimensional stability to washing and the bursting strength remained unchanged after storage at 40°C for 8 weeks. The Meeting concluded that 100 denier DuraActive LN complies with the existing WHO specification 333/LN/1 for storage stability at 40°C for 8 weeks.

ANNEX 1: REFERENCES

| Study number | Author(s) | Year | Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study |
|--------------|-----------------|------|--|
| | S Nagachnadrudu | 2017 | Chemical Analysis of Deltamethrin based Long-Lasting (1.4 g Al/kg coated onto polyester filaments) insecticidal net (DuraActive). IIBAT, India. Study No 17129. GLP |
| | T. Jeyalakshmi | 2017 | Laboratory Study of Deltamethrin based Long-Lasting (1.4 g Al/kg coated onto polyester filaments) insecticidal net, DuraActive LN against mosquitoes for extension of specification for LNs. IIBAT, India. Study No 17130. GLP |

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN + PIPERONYL BUTOXIDE

FAO/WHO EVALUATION REPORT 333+33/2018.1

Recommendations

The Meeting recommended the following:

The existing WHO specifications 333/LN/1 for deltamethrin long-lasting (coated onto filaments) insecticidal net and 333+33/LN/1 (netting and net) for deltamethrin + piperonyl butoxide long-lasting (incorporated into filaments) insecticidal netting should be revised as proposed by Vestergaard and as amended by the Meeting.

Appraisal

The Meeting was requested by Vestergaard to revise the WHO specification 333/LN/1 for deltamethrin long-lasting (coated onto filaments) LN in order to include the deltamethrin content in the side panels of PermaNet 3.0. This clause was omitted in the current version of the specification when this specification was revised in October 2015 to withdrawn PermaNet 2.0 Extra. The Meeting agreed with the proposal of the manufacturer to specify 2.8 and 2.1 g/kg with a tolerance of $\pm 25\%$, respectively for 75 and 100 denier yarn.

The Meeting requested also Vestergaard to provide, for the WHO specifications 333/LN/1 and 333+33/LN/1 (netting), specification tolerances with supporting data for fabric weight (mass of net per m^2) and flammability, which are currently requested in the third version (March 2016) of the first edition of the FAO/WHO Manual on pesticide specifications.

The manufacturer provided the Meeting with quality control data for fabric weight on 871 samples of PermaNet 2.0, 75 denier and 5881 samples of PermaNet 2.0, 100 denier produced in 2015, 2016 and 2017. These data showed that the tolerance of $30 g/m^2 \pm 10 \%$ for 75 denier yarn and $40 g/m^2 \pm 10 \%$ for 100 denier yarn was slightly exceeded for some net samples. At the request of the Meeting, the manufacturer provided later additional quality control data for fabric weight on 127 samples of PermaNet 2.0, 75 denier and 1337 samples of PermaNet 2.0, 100 denier produced from January to September 2018 showing that all samples comply with the tolerance limit.

The manufacturer proposed a minimum limit of $30 g/m^2$ for the roof panel of PermaNet 3.0 and provided quality control data for fabric weight on 436 samples of PermaNet 3.0 (roof panel) produced in 2015, 2016 and 2017. At the request of the Meeting, the manufacturer proposed a tolerance of $36 g/m^2 \pm 10 \%$ and provided later additional quality control data for fabric weight on 253 samples of PermaNet 3.0 (roof panel) produced from January to September 2018 showing that all samples comply with the tolerance limit.

The manufacturer provided also the Meeting with a test report on the flammability of one sample of PermaNet 2.0 and one sample of PermaNet 3.0, showing that the nets did not ignite. Nevertheless, the test method used was the CFR Part 1610 which is

not recommended anymore by WHO. At the request of the Meeting, the manufacturer provided later additional flammability data according to the test method EN 1102 showing that no fire phenomena occur in PermaNet 2.0 and PermaNet 3.0 (roof panel).

The Meeting also proposed :

- in the description clause of the specifications 333/LN/1, 333/LN/5, 333+33/LN/1 (netting) and 333+33/LN/2 (netting), to refer to the updated specification 333/TC for deltamethrin TC (November 2017).
- in the description clause of the specifications 333/LN/2, to refer to the updated specification 333/SC for deltamethrin SC (November 2017).
- in the specifications 333/LN/1, 333/LN/5 and 333+33/LN/1 (netting) to updated the references to the CIPAC methods MT 195 for wash resistance index and MT 46.3.4 for stability at elevated temperature which are now published in the Handbook O.
- in the specifications 333/LN/1, 333/LN/5, 333+33/LN/1 and 333+33/LN/2 (netting and net) to updated the footnotes for the physical tests according to the third version (March 2016) of the first edition of the FO/WHO Manual on pesticide specifications.

ANNEX 1: REFERENCES

| Study number | Author(s) | Year | Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study |
|--------------------------|---------------|------|--|
| | FAO/WHO | 2006 | Manual on development and use of FAO and WHO specifications for pesticides. March 2006 third revision of the first edition. FAO, Rome and WHO, Geneva, March 2006 (internet publications). |
| R148. GSM | Linh Vu | 2017 | Determination of mass per square meter of PermaNet 2.0. Vestergaard Vector Control Laboratories, September 21, 2017. |
| R177. GSM | Linh Vu | 2017 | Determination of mass per square meter of PermaNet 3.0. Vestergaard Vector Control Laboratories, September 21, 2017. |
| R148. GSM | Linh Vu | 2018 | Determination of mass per square meter of PermaNet 2.0. Vestergaard Vector Control Laboratories, October 08, 2018. |
| R177. GSM | Linh Vu | 2018 | Determination of mass per square meter of PermaNet 3.0. Vestergaard Vector Control Laboratories, October 08, 2018. |
| 71911877669-EEC18/01-CSL | Shareen Chan | 2018 | Flammability testing of PermaNet 2.0 & PermaNet 3.0 side. Test report 7191187669-EEC18/01-CSL of TÜV SÜD PSB Singapore for Vestergaard, June 19, 2018. |
| 71911877669-EEC18/02-CSL | Shareen Chan | 2018 | Flammability testing of PermaNet 3.0 Roof. Test report 7191187669-EEC18/02-CSL of TÜV SÜD PSB Singapore for Vestergaard, June 19, 2018. |
| 275-24-01-12/ITV-1 | Tran Van Doan | 2012 | Flammability of PermaNet 2.0. Test report 275-24-04-12/TNV-1 of the Textile Research Institute, Vietnam for Vestergaard, May 07, 2012. |
| 274-24-01-12/ITV-2 | Tran Van Doan | 2012 | Flammability of PermaNet 3.0. Test report 274-24-04-12/TNV-2 of the Textile Research Institute, Vietnam for Vestergaard, May 07, 2012. |

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

FAO/WHO EVALUATION REPORT 333/2017.1

Recommendations

The Meeting recommended the following:

- (i) The existing WHO specification 333/LN/2 for deltamethrin (coated onto filaments) LN should be extended to encompass the 150 denier DawaPlus 2.0 and the 100 denier DawaPlus 3.0 side panels products of Tana Netting Co. Ltd. (NRS International Group), and include clauses for fabric weight and flammability.
- (ii) The wash resistance index tolerance of the existing WHO specification 333/LN/2 for deltamethrin (coated onto filaments) LN should be changed from 93% - 100% to 90% - 100%.
- (iii) The tolerance for dimensional stability to washing should be changed from not more than 5% shrinkage/expansion in both directions to not more than 10% shrinkage and not more than 5% expansion in both directions.

Appraisal

A draft revised specification and supporting data, provided by Tana Netting Co. Ltd. (NRS International Group), were considered by the Meeting for the extension of the existing WHO specification 333/LN/2 (December 2014) to the 150 denier yarn DawaPlus 2.0 product. The manufacturer also requested the Meeting to include clauses for fabric weight and flammability, to revise the wash resistance index tolerance from 93% - 100% to 90% - 100% and to revise the tolerance for dimensional stability to washing from not more than 5% shrinkage/expansion in both directions to not more than 10% shrinkage and not more than 5% expansion in both directions. The manufacturer also provided a draft specification for the development of a new specification for the side panels of DawaPlus 3.0. DawaPlus 3.0 is a combination net composed of deltamethrin (coated onto filaments) for the side panels and deltamethrin + piperonyl butoxide (incorporated into filaments) for the roof. The proposed specifications were in agreement with the LN specification guideline of the FAO/WHO Manual on pesticide specifications (FAO/WHO 2016). The test reports provided by the manufacturer to support this extension and revision were generated by independent laboratories.

The Meeting agreed to have two specifications for all the DawaPlus nets: one specification for the coated nets covering all the DawaPlus 2.0 (75, 100 and 150 denier) and the side panels of DawaPlus 3.0 (100 denier) and one specification for the incorporated nets covering DawaPlus 4.0 and the roof of DawaPlus 3.0 (deltamethrin + PBO incorporated LN). He agreed also to have a short specification for the DawaPlus 3.0 final net.

The new LNs under consideration are produced from 150 denier (DawaPlus 2.0) or 100 denier (DawaPlus 3.0 side panels) multi-filament polyester fibres treated with deltamethrin SC together with a binder and any necessary other formulants. As for the 75 and 100 denier DawaPlus 2.0 products, the deltamethrin SC coated onto these new LNs is from a source compliant with the existing WHO specification 333/SC (January 2015) for deltamethrin SC (Bayer).

Description, active ingredient content and netting mesh size

The nominal content of deltamethrin in the 75, 100 and 150 denier DawaPlus 2.0 is 2.7, 2.0 and 2.0 g/kg respectively, corresponding to 80 mg/m² in all cases. The 150 denier yarn product has a lower mesh size (minimum 14 holes/cm² on average) compared to the two other 75 and 100 denier yarn products (minimum 24 holes/cm² on average). The nominal content of deltamethrin in the 100 denier DawaPlus 3.0 side panels is 2.5 g/kg corresponding to 100 mg/m².

Data provided by the manufacturer on several batches of DawaPlus 2.0, 150 denier showed that the product complies with the specification tolerance of 2.0 g/kg \pm 25%. He provided also an additional study report on one batch each of the 75 and 100 denier yarn products showing that these products comply with the specification tolerances of 2.7 g/kg and 2.0 g/kg \pm 25% respectively, and that they have an acceptable homogeneity of the active ingredient content within the net (RSD ranging from 1.7% to 3.2%, n = 5).

Data provided by the manufacturer on two batches of DawaPlus 3.0 side panels showed that the product complies with the specification limit of 2.5 g/kg \pm 25%. A spatial variation study provided by the manufacturer on one sample of DawaPlus 3.0 side panels (deltamethrin content on 4 individual net pieces taken from each side of the net) showed an acceptable homogeneity of the distribution of the active ingredient within the net (within-net RSD of 2.5%).

The WHOPES Phase I testing and evaluation of DawaPlus 3.0 side panels showed that deltamethrin content in the unwashed nets comply with the target dose of 2.5 g/kg (\pm 25%), and an acceptable homogeneity of the active ingredient distribution within and between the nets. The within-net variation, expressed as the relative standard deviation (RSD) of the deltamethrin content found on 5 pieces taken from each side of the same net ranged from 1.5% to 3.9%. The between-net variation, expressed as the relative standard deviation (RSD) of the deltamethrin content found on 4 different nets, was 1.1% (CRA-W 2017, WHO 2017).

The WHOPES Phase II trials on DawaPlus 3.0 side panels conducted in India, Burkina Faso and Tanzania showed that the deltamethrin content in all unwashed nets complies with the target dose of 2.5 g/kg (\pm 25%), and an acceptable within-net homogeneity. The within-net variation, expressed as the relative standard deviation (RSD) of the deltamethrin content found on 4 different net pieces cut from side of the net ranged from 0.5% to 7.1% (CRA-W 2017, WHO 2017).

In the main studies provided by the manufacturer and in the WHOPES studies, the deltamethrin content was determined using a method comparable to the CIPAC method 333/LN/(M)/3 published in Handbook M. This method involves extraction of deltamethrin by sonication and shaking with isooctane / dioxane (80/20, v/v) in presence of dipropyl phthalate as internal standard and determination by high performance liquid chromatography with UV diode array detection (HPLC-DAD).

Active ingredient wash resistance index

Data provided by the manufacturer on 6 different batches of DawaPlus 2.0, 150 denier analysed according to the CIPAC method MT 195 showed a deltamethrin wash resistance index ranging from 90.9% to 93.4%. He provided also an additional study report on one batch each of the 75 and 100 denier yarn products showing a wash resistance index of 96.7% and 97.4% respectively. Considering the potential variation of the deltamethrin wash resistance index between products and batches, the manufacturer requested the Meeting to revise the wash resistance index clause from 93% - 100% to 90% - 100%. The Meeting agreed as it was supported by data provided by the manufacturer, and considering that the lowering of the wash resistance index lower limit from 93% to 90% has no negative significant impact on the safety of the net. The conclusion of no adverse health effects remains valid for a wash resistance index of 90%.

Data provided by the manufacturer on 2 different batches of DawaPlus 3.0, side panels analysed according to the CIPAC method MT 195 showed a deltamethrin wash resistance index ranging from 97.9% to 99.5%.

The WHOPES Phase I testing results on deltamethrin content and associated biological efficacy of DawaPlus 3.0 side panels washed up to 25 times (according to the WHO washing procedure) showed an exponential decay of the deltamethrin content in function of the number of washes (free-migration stage behaviour). The overall deltamethrin retention after 20 washes was 55.0%, corresponding to an average retention index per wash of 96.8%, as estimated by the exponential regression curve (CRA-W 2017, WHO 2017).

Physical properties

Data provided by the manufacturer on fabric weight (mass per m²) for the 75, 100 and 150 denier yarn nettings showed that they comply with the tolerance limit of 30 g/m² ± 10 % for 75 denier yarn and 40 g/m² ± 10 % for 100 denier yarn and 42 g/m² ± 10 % for 150 denier yarn.

Data provided by the manufacturer on the 150 denier DawaPlus 2.0 showed:

- an average and minimum number of complete holes/cm² in agreement with the specified minimum limit of 14 and 13 respectively.
- a dimensional stability to washing in agreement with the specified limit of not more than 10% shrinkage and not more than 5% expansion in both directions. The Meeting agreed to revise the shrinkage limit from 5% to 10% as recommended by the default limit of the FAO/WHO specification guideline for LN.
- a bursting strength (net and seams) higher than the minimum specified limit of 420 kPa.
- that no fire phenomena occurred and therefore that the product complies with the tolerance for flammability.

Data provided by the manufacturer on the 100 denier DawaPlus 3.0 side panels showed:

- an average and minimum number of complete holes/cm² in agreement with the specified minimum limit of 24 and 23 respectively.

- a dimensional stability to washing in agreement with the specified limit of not more than 10% shrinkage and not more than 5% expansion in both directions.
- a bursting strength (net and seams) higher than the minimum specified limit of 400 kPa.
- that no fire phenomena occurred and therefore that the product complies with the tolerance for flammability.

Storage stability

The manufacturer provided data on 6 different batches of DawaPlus 2.0, 150 denier and on one batch of DawaPlus 3.0 side panels stored for 14 days at 54°C showing that the loss of deltamethrin is less than 5% and that the wash resistance index, the dimensional stability to washing and the bursting strength remains within the specified limits.

The Meeting agreed also to update some footnotes of the specification to be in line with the specification guideline for LN of the 2016 third revision of the first edition of the FAO/WHO Manual.

ANNEX 1: REFERENCES

| Study number | Author(s) | Year | Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study |
|-------------------|----------------|------|---|
| 5287/2015-1 | CITEVE | 2015 | Physical properties of DawaPlus 2.0, 150 denier. Report 5287/2015-1 and complement of CITEVE, Portugal for Tana Netting, June 17 and 18, 2015. |
| 7648/2016-1 | CITEVE | 2016 | Flammability of DawaPlus 3.0 side panels and DawaPlus 4.0. Report 7648/2016-1 of CITEVE, Portugal for Tana Netting, July 28, 2016. |
| RE/14/U10/23802 | CRA-W | 2016 | Physical-chemical properties of DawaPlus 2.0, 75 and 100 denier. Report RE/14/U10/23802 of the Walloon Agricultural Research Centre, Gembloux, Belgium for Tana Netting, January 12, 2015. |
| RE/15/U10/24106 | CRA-W | 2016 | Physical-chemical properties of DawaPlus 2.0, 150 denier. Report RE/15/U10/24106 of the Walloon Agricultural Research Centre, Gembloux, Belgium for Tana Netting, January 04, 2016. |
| RE/16/U10/24301 | CRA-W | 2017 | Physical-chemical properties of DawaPlus 2.0, 150 denier. Report RE/16/U10/24301 of the Walloon Agricultural Research Centre, Gembloux, Belgium for Tana Netting, January 13, 2017. |
| RE/16/U10/24302 | CRA-W | 2017 | Physical-chemical properties of DawaPlus 3.0 side panels. Report RE/16/U10/24302 of the Walloon Agricultural Research Centre, Gembloux, Belgium for Tana Netting, January 13, 2017. |
| RE/16/U10/24353 | CRA-W | 2017 | WHOPES Phase I testing and evaluation of DawaPlus 3.0 and DawaPlus 4.0. Chemical analysis of nets. Test report RE/16/U10/24353 of the Walloon Agricultural Research Centre, Gembloux, Belgium for WHO, February 03, 2017. |
| RE/17/U10/24417/1 | CRA-W | 2017 | WHOPES Phase II testing and evaluation of DawaPlus 3.0 and DawaPlus 4.0 in India. Chemical analysis of nets. Test report RE/17/U10/24417/1 of the Walloon Agricultural Research Centre, Gembloux, Belgium for WHO, March 15, 2017. |
| RE/17/U10/24417/2 | CRA-W | 2017 | WHOPES Phase II testing and evaluation of DawaPlus 3.0 and DawaPlus 4.0 in Burkina Faso. Chemical analysis of nets. Test report RE/17/U10/24417/2 of the Walloon Agricultural Research Centre, Gembloux, Belgium for WHO, March 15, 2017. |
| RE/17/U10/24417/2 | CRA-W | 2017 | WHOPES Phase II testing and evaluation of DawaPlus 3.0 and DawaPlus 4.0 in Tanzania. Chemical analysis of nets. Test report RE/17/U10/24417/2 of the Walloon Agricultural Research Centre, Gembloux, Belgium for WHO, July 2017. |
| | Milan Ivic | 2017 | Draft specification and supporting data for DawaPlus 2.0, 150 denier. JMPS data package. Tana Netting, March 09, 2017. |
| | Milan Ivic | 2017 | Draft specification and supporting data for DawaPlus 3.0, side panels. JMPS data package. Tana Netting, February 17, 2017. |
| 16PE001 | Muhammad Tariq | 2016 | Certificate of analysis of DawaPlus 3.0 side panels, batch 16PE3105, H.Sheikh Noor-ud-Din, September 05, 2016. |
| 16SPL12 | Muhammad Tariq | 2017 | Certificate of analysis of DawaPlus 2.0, 150 denier, batch 16SPL12, H.Sheikh Noor-ud-Din, February 28, 2017. |
| 2015-95CH/VVL | VEGRO | 2015 | Active ingredient content of DawaPlus 2.0, 100 and 150 denier. Report 2015-95CH/VVL of VEGRO, Denmark for Tana Netting, July 24, 2015. |
| | WHO | 2017 | Report of the 20 th WHOPES Working Group Meeting, WHO/HQ, Geneva, 20-24 March 2017. Available at : http://www.who.int/whopes/recommendations/wgm/en/ |

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

FAO/WHO EVALUATION REPORT 333/2016.1

Recommendations

The Meeting recommended the following:

The existing WHO specification 333/LN/5 for deltamethrin (coated onto filaments) LN should be extended to encompass the 50 and 100 denier Yahe LN products of Fujian Yamei Industry & Trade Co., Ltd.

Appraisal

A draft revised specification and supporting data for the 50 and 100 denier Yahe LN [deltamethrin long-lasting (coated onto filaments) insecticidal net (LN)], provided by Fujian Yamei Industry & Trade Co., Ltd., were considered by the Meeting for extension of the existing WHO specification 333/LN/5 (November 2015) to the 50 and 100 denier yarn products. The proposed revised specification was in agreement with the LN specification guideline of the FAO/WHO Manual on pesticides specifications (FAO/WHO 2010).

The LNs under consideration are produced from 50 or 100 denier multi-filament polyester fibers treated with technical deltamethrin formulated in a 10% suspension concentrate together with a polymer coating and any necessary other formulants.

The manufacturer informed the Meeting that the technical deltamethrin coated onto their LNs was changed from Heranba to Tagros which is also a source compliant with the existing WHO specification for deltamethrin TC.

Description and active ingredient content

The nominal content of deltamethrin of 2.3, 1.85 and 1.4 g/kg for the 50, 75 and 100 denier yarn nettings, respectively, corresponds to 55 mg/m² in all cases.

Data provided by the manufacturer for deltamethrin content measured on 6 net pieces each of the 50 and 100 denier yarn products with the appropriate CIPAC method showed that they comply with the target dose \pm 25%. The content of (insecticidally inactive) *R*-alpha isomer in these same samples was lower than 3% of the deltamethrin content.

Active ingredient wash resistance index

Data provided by the manufacturer for deltamethrin wash resistance index measured on 6 net pieces each of the 50 and 100 denier yarn products with the appropriate CIPAC method MT 195 showed that they comply with the specified range of 85% to 99%.

Physical properties

Data provided by the manufacturer on the 50 and 100 denier yarn products showed:

- an average and minimum number of complete holes/cm² in agreement with the specified minimum limit of 24.
- a dimensional stability to washing in agreement with the specified limit of maximum 5% shrinkage / expansion.
- a bursting strength higher than the minimum specified limit of 250 kPa and 350 kPa respectively for the 50 and 100 denier yarn products.

The flammability of the 50 and 100 denier yarn products was tested according to 16 CFR Part 1610. The products are classified with class 1 (normal flammability).

Storage stability

The manufacturer provided data on the 50 and 100 denier yarn products after storage at 40°C for 8 weeks showing that the loss of deltamethrin is less than 5% and that the wash resistance index, the dimensional stability to washing and the bursting strength remains within the specified limits.

ANNEX 1: REFERENCES

| Study number | Author(s) | Year | Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study |
|--------------|-----------|------|--|
| | Li Rita | 2016 | Supporting report data package of addition Yahe 50 denier deltamethrin long-lasting (coated onto filaments) insecticidal net, WHO specification 333/LN/5. Data package submitted by Fujian Yamei Industry & Trade Co., Ltd., to WHO, April 29, 2016. |
| | Li Rita | 2016 | Supporting addition data package of Yahe 100 denier deltamethrin long-lasting (coated onto filaments) insecticidal net, WHO specification 333/LN/5. Data package submitted by Fujian Yamei Industry & Trade Co., Ltd., to WHO, April 29, 2016. |
| | WHO | 2015 | Determination of fabric strength of long-lasting insecticidal nets. Report of a WHO consultation, Geneva, 20-22 August 2014. WHO/HTM/NTD/WHOPES/2015.1 |

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

FAO/WHO EVALUATION REPORT 333/2015.3

Recommendations

The Meeting recommended the following:

The specification for deltamethrin long-lasting (coated onto filaments) insecticidal net, proposed by Fujian Yamei Industry & Trade Co., Ltd., and as amended, should be adopted by WHO.

Appraisal

Supporting data and information for deltamethrin long-lasting (coated onto filaments) insecticidal net (LN), provided by Fujian Yamei Industry & Trade Co., Ltd. in 2013 were considered by the Meeting for extension of the existing WHO specifications 333/LN/1 (netting and net) (November 2012). The data and test reports provided by the manufacturer to support this extension were generated by the manufacturer as well as by independent laboratories.

The LN under consideration (Yahe LN) is in the form of a finished mosquito net consisting of 75 denier multi-filament polyester fibers treated with deltamethrin at a target rate of 1.85 g/kg. The treatment is performed with a SC formulation produced in the own factory and containing 10% deltamethrin. The insecticide is bound in a polymer coating that reduces the insecticide loss during washing. The deltamethrin technical material used to formulate the SC is from a source having a WHO specification for deltamethrin TC (Heranba).

Yahe LN was previously reviewed by WHOPES for extension of WHO interim specification 333/LN/1 (netting and net) (September 2010). The outcome of the regeneration, wash resistance and efficacy studies of Yahe LN in laboratory, as part of the requirements for extension of WHO specifications, were published in the *Report of the fourteenth WHOPES Working Group Meeting, WHO/HQ, Geneva, 10-14 April 2011* (WHO 2011). The meeting noted that Yahe LN met WHOPES criteria for knockdown in the cone test. However, mortality rates in cone bioassays were always lower than those of the reference LN, and within-net deltamethrin content exhibited high heterogeneity. Therefore, the fourteenth WHOPES Working Group Meeting concluded that Yahe LN does not meet WHO requirements for extension of specifications and should be considered as an independent product requiring evidence of efficacy from phase II experimental hut studies. The Meeting also advised WHOPES to invite the manufacturer to provide supporting data on homogeneity of deltamethrin content.

Taking significant differences with the reference product (PermaNet 2.0) in the chemical and physical-chemical properties of the LN under consideration into account like description, deltamethrin content and wash resistance index, the 2013 JMPS Meeting concluded that Yahe LN could not share the existing WHO specifications 333/LN/1 for deltamethrin coated onto filaments LN.

The manufacturer was invited to develop a new specification for their LN as an independent product.

Yahe LN was re-tested and re-evaluated by WHOPEs in 2013 and 2015 in three WHOPEs-supervised Phase II (experimental hut) studies carried out in Thailand, Tanzania and Côte d'Ivoire, and a time-limited interim recommendation for its use in malaria prevention and control was issued in 2015 (WHO 2015).

Description

The Meeting concluded that the description of Yahe LN made of 75 denier multi-filament polyester fibres treated with a factory produced SC formulation containing 10% of deltamethrin does not comply with the existing WHO specification 333/LN/1 where the netting material is treated with deltamethrin TC, and agreed that it should be a new specification.

Active ingredient content

Yahe LN is produced from 75 denier yarn and the target deltamethrin content is 1.85 g/kg, corresponding to 55.5 mg/m² (fabric weight = 30 g/m²). Data provided by the manufacturer for deltamethrin content on 6 nets showed that the product complies with this target dose of 1.85 g/kg ($\pm 25\%$).

The CIPAC method 333/LN/(M)/3 published in Handbook M, involving extraction by sonication and shaking with isooctane / dioxane (80/20, v/v) followed by determination by high performance liquid chromatography with UV detection, is referred in the draft specification provided by the manufacturer. Nevertheless the manufacturer used in their studies a method involving extraction with acetone / petroleum ether (1:1) and determination by gas chromatography with electron capture detection (GC-ECD), which is completely different from the recommended CIPAC method. At the request of the Meeting, the manufacturer provided later results obtained with the CIPAC method 333/LN/(M)/3 showing that their product complies with the target dose of 1.85 g/kg ($\pm 25\%$).

Special attention needs to be paid to control random variations in the distribution of the insecticide over the surface of the net and between nets. The manufacturer provided spatial variation data on 5 nets showing both acceptable within-net homogeneity (RSD ranging from 3.6 to 8.0%, n = 5) and between-net homogeneity (RSD = 3.9%, n = 5) of the active ingredient.

In the WHOPEs Phase II evaluation of Yahe LN in Tanzania and Thailand, of 6 unwashed nets, 4 were above specifications and one net had high active ingredient within-net variability (RSD = 30.6%, n = 5) that was above the maximum recommended threshold (CRA-W 2013). The WHOPEs Working Group Meeting recommended to the manufacturer to provide the evidence and supporting information on acceptable within-net variation in deltamethrin content and on quality assurance of Yahe LN, and to WHOPEs to conduct a minimum of one additional phase II study with Yahe LN within the product specifications, as a requirement for an interim recommendation (WHO 2013).

An additional Phase II trial conducted in Côte d'Ivoire showed that Yahe LN comply with the target dose of 1.85 g/kg $\pm 25\%$ for 75 denier yarn (2.00 g/kg) and a good homogeneity of the distribution of deltamethrin within the net (RSD = 3.6%, n = 5). The method used for deltamethrin content was based on the CIPAC method 333/LN/(M)/3 (CRA-W 2015, WHO 2015).

The manufacturer provided also additional data in 2015 to show the improvement of the treatment homogeneity of their product over the years (RSD of the active ingredient content in 5 different net pieces = 2.81%).

Active ingredient wash resistance index

An adequate amount of active ingredient must be present at the surface of the LN, for efficacy reasons, whereas the majority must reside within the coating of the LN, to avoid excessive losses during washing and to provide a reservoir from which the surface is replenished with active ingredient. The depth and properties of coating therefore strongly influence the retention of deltamethrin when the LN is subjected to repeated washing. The monitoring of the depletion of total active ingredient content by washing (wash resistance index) is accomplished by analyzing separate washed and unwashed pieces of the same fabric.

The method MT 195 for determination of wash resistance index of LN was adopted as full CIPAC method in 2013. This method is a further standardization of the WHO washing method published in the "WHO Guidelines for laboratory and field testing of long-lasting insecticidal mosquito nets", document WHO/CDS/WHOPES/GCDPP/2005.11 (WHO 2005). Briefly, the wash resistance index is determined by analyzing net samples in triplicate representing wash points 0 and 4 for total active ingredient content and calculating the average wash resistance index per wash using the equation for a free migration stage behaviour. A wash resistance index per wash of 95% indicates that at least 95% of the insecticide present in samples washed 1 to 3 times is still present after an additional wash step. The wash resistance index applies to the average obtained from triplicate tests performed on net pieces removed from the same net or batch of netting (CIPAC 2013).

The manufacturer initially provided the Meeting with a wash resistance index limit according to the old WHO interim specification (not less than 0.85 after the first wash) and in the range of 0.85-0.95 from the second to the third wash step) and generated using the old WHO washing method. The data provided on Yahe LN washed 1, 3, 5, 10, 15, 20 and 25 times (complete wash curve) showed that the deltamethrin wash resistance index ranges from 91% to 97%. The WHOPES Phase I trial performed on Yahe LN washed 1, 3, 5, 10, 15, 20 and 25 times and using also the WHO washing method showed a deltamethrin wash resistance index ranging from 94% to 98% (CRA-W 2011, WHO 2011).

Additional wash resistance index data using the CIPAC method MT 195 were provided by the manufacturer at the request of the Meeting and showed a wash resistance index of 96.8%. Considering the uncertainty of measurement of the CIPAC method MT 195 and the potential inter-laboratory variation, the Manufacturer and the Meeting agreed to specify a range of 85% to 99% for the wash resistance index.

Relevant impurities

There are no relevant impurities identified in the existing WHO specification for deltamethrin TC. During the coating process of deltamethrin LN, heat and base-catalyzed epimerization of deltamethrin to the (insecticidally inactive) *R*-alpha isomer may occur. This conversion must be controlled by the manufacturer to avoid significant losses of active ingredient. This conversion can also occur if the LN is exposed to excessive heat during storage or use. Data provided by the manufacturer showed that deltamethrin *R*-alpha isomer content in Yahe LN is lower than 4% of the deltamethrin content. The WHOPES Phase I and II testing and evaluation of Yahe LN

showed that the content of deltamethrin *R*-alpha isomer is also lower than 4% of the deltamethrin content and that this amount does not increase in the LN washed up to 25 times (CRA-W 2011, CRA-W 2013, CRA-W 2015, WHO 2011, WHO 2013, WHO 2015).

Physical properties

The manufacturer provided netting mesh size data showing that the average number of complete holes/cm² is not less than 24 holes/cm² and the lowest value is not less than 24 holes/cm² and therefore that their product comply with the specified limits. Test reports provided by the manufacturer showed that the dimensional stability to washing complies with the standard of $\pm 5\%$ tolerance of the LN specification guideline (FAO/WHO 2010). The bursting strength is higher than the specified limit of 250 kPa both for the fabric and the seams.

Storage stability

The manufacturer initially provided raw data after storage at 54°C for 2 weeks and stated that the deltamethrin content is not lower than 95%. Nevertheless based on raw data a degradation of 7.32% of deltamethrin was observed. The manufacturer provided also test reports showing that the dimensional stability to washing and bursting strength remains unchanged after storage at 54°C for 2 weeks.

The manufacturer finally agreed to specify an accelerated storage of 40°C for 8 weeks, and provided data showing that, in these conditions, the loss of deltamethrin is less than 2% after storage and that the wash resistance index remains within the specified range.

ANNEX 1: REFERENCES

| Study number | Author(s) | Year | Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study |
|-----------------|--------------|------|---|
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| W12032109B | NTGQSTC | 2012 | Dimensional stability to washing of Yahe LN. Report W12032109B of the National Textile And Garment Quality Supervision Testing Centre (Fujian) for Fujian Yamei Industry & Trade Co., Ltd., September 2012. |
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| Study number | Author(s) | Year | Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study |
|--------------|-----------|------|---|
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WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN + PIPERONIL BUTOXIDE

FAO/WHO EVALUATION REPORT 333+33/2015

Recommendations

The Meeting recommended the following.

- (i) The existing WHO interim specifications 333+33/LN (NETTING) for deltamethrin + piperonyl butoxide long-lasting (incorporated into filaments) insecticidal netting and the existing WHO interim specification 333+33/LN (NET) for deltamethrin long-lasting (coated onto filaments) insecticidal net combined with deltamethrin + piperonyl butoxide long-lasting (incorporated into filaments) insecticidal net should be revised as proposed by Vestergaard and as amended by the Meeting.
- (ii) The revised specifications should get the status of full WHO specifications.
- (iii) The existing WHO specification for deltamethrin long-lasting (coated onto filaments) insecticidal net with a strengthened border (PermaNet 2.0 Extra) should be withdrawn, as proposed by Vestergaard. Consequently the existing WHO specification 333/LN/1 (NET) should be withdrawn and the existing WHO specification 333/LN/1 (NETTING) should be revised as proposed by the Meeting.

Appraisal

Wash resistance index

The method MT 195 for determination of wash resistance index of LN was adopted as full CIPAC MT method in 2013. This method is a further standardization of the WHO washing method published in the “WHO Guidelines for laboratory and field testing of long-lasting insecticidal mosquito nets”, document WHO/CDS/WHOPES/GCDPP/2005.11, WHO, Geneva, 2005 (WHO 2005). Briefly, the wash resistance index is determined by analyzing net samples in triplicate representing wash points 0 and 4 for total active ingredient content and calculating the average wash resistance index per wash using the equation for free migration stage behaviour. A wash resistance index per wash of 95% indicates that at least 95% of the insecticide present in samples washed 1 to 3 times is still present after an additional wash step. The wash resistance index applies to the average obtained from triplicate tests performed on individual net pieces collected from the same net or batch of netting (CIPAC 2012 and 2013).

The Meeting requested Vestergaard, producing deltamethrin long-lasting (coated onto filaments) insecticidal net combined with deltamethrin + piperonyl butoxide long-lasting (incorporated into filaments) insecticidal net (PermaNet 3.0), to generate wash resistance index data using the new CIPAC washing method MT 195 and to propose a revised wash resistance index range based on these data.

The manufacturer provided the Meeting with quality control data (55 PermaNet 3.0 nets manufactured from 2012 to 2014) on the wash resistance index of deltamethrin and piperonyl butoxide in the polyethylene roof using the CIPAC method MT 195.

The wash resistance index ranged from 92% to 99% with a mean of 96% for deltamethrin and from 88% to 95% with a mean of 91% for piperonyl butoxide. Based on the mean and standard deviation of the results obtained from this study and considering the potential inter-laboratory variation in the measurement of the wash resistance index, the manufacturer proposed to specify a range of 88% to 100% for deltamethrin and a range of 81% to 100% for piperonyl butoxide. The data generated by another laboratory on 3 samples of PermaNet 3.0 confirmed that the ranges proposed for deltamethrin and piperonyl butoxide wash resistance index are acceptable (98.7% to 99.4% and 84.7% to 88.2% respectively) (CRA-W 2013). The Meeting agreed therefore with this proposal.

The manufacturer provided also wash resistance index data for the side of PermaNet 3.0 (75 denier with strengthened border and 100 denier without strengthened border) and proposed to specify a wash resistance index range of 85% to 100%. Nevertheless, the specification 333/LN/1 (netting) was already revised in 2012 to specify a range of 80% to 98% according to the new CIPAC washing method, as proposed by Vestergaard (FAO/WHO evaluation report 333/2012.3). Vestergaard finally confirmed that a wash resistance index of 80% to 98% should be specified.

The manufacturer informed the Meeting that PermaNet 2.5 or PermaNet 2.0 Extra is no longer produced and should be removed from the WHO specifications. The Meeting agreed therefore to withdraw the existing WHO specification 333/LN/1 (NET) and to revise the existing WHO specification 333/LN/1 (NETTING).

The Meeting considered also data and information submitted by Vestergaard to support their request to revise the WHO interim specification 333+33/LN (NET) (November 2012) for deltamethrin long-lasting (coated onto filaments) insecticidal net combined with deltamethrin + piperonyl butoxide long-lasting (incorporated into filaments) insecticidal net (PermaNet 3.0) for the following parameters.

100 denier sides with strengthened border

The manufacturer requested the Meeting to include in the specifications the option of 100 denier sides with strengthened border in order to improve the strength of the most vulnerable part of the net. The manufacturer provided quality control data on several samples of PermaNet 3.0, 100 denier side with strengthened border, including chemical properties (deltamethrin content and wash resistance index before and after accelerated storage at 40°C for 8 weeks) and physical properties (netting mesh size, bursting strength, dimensional stability to washing). These data showed that the new optional product fully comply with the clauses of the existing specifications. The data generated by another laboratory on 5 samples of PermaNet 3.0, 100 denier side with strengthened border, confirmed that the new optional product fully comply with the specification for deltamethrin content and wash resistance index (CRA-W 2015).

Bursting strength

The manufacturer requested the Meeting to reduce the limit for bursting strength in the border of 75 denier sides of PermaNet 3.0 to “not lower than 280 kPa” instead of “not lower than 320 kPa”. The company stated that the original limit proposed in the specification was based on a too small data set that did not reveal the wider variation in production. The manufacturer provided the Meeting with quality control data on 415 samples of PermaNet 3.0, 75 denier side with strengthened border manufactured from 2011 to 2014 to support this change. He provided also data from inter-laboratory studies between different quality control laboratories that fully supported the proposed

reduction of the bursting strength limit for the PermaNet 3.0, 75 denier side with strengthened border.

Vestergaard confirmed also a bursting strength of minimum 380 kPa for PermaNet 3.0 side of 100 denier with strengthened border and 350 kPa for PermaNet 3.0 side of 100 denier without border.

Supplementary information to the Note for accelerated storage stability

The manufacturer requested the Meeting to clarify the note on the storage stability test in order to further clarify on how this test should be conducted in order to minimise the impact of sample heterogeneity on the repeatability of the test.

He proposed to add the following sentence : “Samples of the formulation shall be well homogenized by cutting the sub-sampling patches into small pieces of less than 1 x 1cm each; mixing well, taking 2 equivalent portions, one for before storage stability, the other for being stored in the chosen condition as per CIPAC MT 46.3.4”. The Meeting did not accept this deviation to the newly adopted CIPAC method MT 46.3.4 (requiring 5 net pieces of 25 cm x 25 cm in a glass bottle to be exposed to the standard combination of temperature and time) because it is unlikely that the method would not be applicable for their products.

The Meeting agreed also:

- to update into the specification 333+33/LN (NETTING) the methods for deltamethrin and piperonyl butoxide identity and content as well as some footnotes of the specification to be in line with the current CIPAC methods.
- to refer only to the standard pneumatic method (EN ISO 13938-2) for bursting strength, as recommended in the report of the WHO consultation of August 2014 on fabric strength of LNs.
- to refer to the method MT 46.3.4 adopted as full CIPAC MT method in 2015 for accelerated storage procedure.

ANNEX 1: REFERENCES

| Study number | Author(s) | Year | Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study |
|-----------------|-----------------------|------|--|
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| | CIPAC | 2012 | MT 19X. Wash resistance index of LN, small scale collaborative trial, CIPAC report 4828/R. |
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WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

FAO/WHO EVALUATION REPORT 333/2014.1

Recommendations

The Meeting recommended the following:

- (iv) The wash resistance index tolerance of the existing WHO specification 333/LN/2 for deltamethrin long-lasting (coated onto filaments) insecticidal net (LN) using the new CIPAC washing method MT 195 should be revised to the range of 93% to 100%.
- (v) The revised specification should get the status of full WHO specification.

Appraisal

The CIPAC method MT 195 for determination of wash resistance index of LN was adopted as full CIPAC method in 2013. This method is a further standardization of the WHO washing method published in the “WHO Guidelines for laboratory and field testing of long-lasting insecticidal mosquito nets”, document WHO/CDS/WHOPES/GCDPP/ 2005.11, WHO, Geneva, 2005 (WHO 2005). Briefly, the wash resistance index is determined by analyzing net samples in triplicate representing wash points 0 and 4 for total active ingredient content and calculating the average wash resistance index per wash using the equation for free migration stage behaviour. A wash resistance index per wash of 95% indicates that at least 95% of the insecticide present in samples washed 1 to 3 times is still present after an additional wash step. The wash resistance index applies to the average obtained from triplicate tests performed on net pieces removed from the same net or batch of netting (CIPAC 2012 and 2013).

The Meeting requested Tana Netting Co. Ltd. (NRS International Group) producing deltamethrin long-lasting (coated onto filaments) insecticidal net (LN) (DawaPlus 2.0) to generate wash resistance index data using the new CIPAC washing method MT 195 and to propose a revised wash resistance index clause based on these data.

The manufacturer provided the Meeting with wash resistance index data generated by two different laboratories using the CIPAC method MT 195.

In a first study report, the wash resistance index was measured on 4 DawaPlus 2.0 nets of white color (2 of 75 denier and 2 of 100 denier) from 4 different batches using the CIPAC method MT 195 for wash resistance and the CIPAC method 333/LN/(M)/3 (HPLC-DAD) for deltamethrin content on the unwashed and washed nets pieces. The wash resistance index ranged from 94.1% to 96.2%.

In a second study report, the wash resistance index was measured on 4 DawaPlus 2.0 nets of blue color (2 of 75 denier and 2 of 100 denier) from 4 different batches using the CIPAC method MT 195 for wash resistance and a validated GC-FID method for deltamethrin content on the unwashed and washed nets pieces. The wash resistance index ranged from 96.5% to 99.5%.

Based on the mean and standard deviation of the results obtained from these studies, the Meeting and the manufacturer agreed to specify a range of 93% to 100% for the deltamethrin wash resistance index.

The Meeting agreed also:

- in the specification 333/LN/2, to refer to the method MT 46.3.4 adopted as provisional CIPAC MT method in 2014 for accelerated storage procedure and to update some notes of the existing specification to be in line with the draft specification guideline for LN of the November 2010 – second revision of the first edition of the FAO/WHO Manual.
- in the specification 333/LN/1 (NETTING and NET), to refer to the method MT 195 adopted as full CIPAC MT method in 2014 for wash resistance index, to refer to the method MT 46.3.4 adopted as provisional CIPAC MT method in 2014 for accelerated storage procedure, and to update some notes of the specification to be in line with the draft specification guideline for LN of the November 2010 – second revision of the first edition of the FAO/WHO Manual.

ANNEX 1: REFERENCES

| Study number | Author(s) | Year | Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study |
|-----------------|-----------|------|--|
| | CIPAC | 2012 | MT 19X. Wash resistance index of LN, CIPAC method 4827/m. |
| | CIPAC | 2012 | MT 19X. Wash resistance index of LN, small scale collaborative trial, CIPAC report 4828/R. |
| | CIPAC | 2013 | MT 195. Wash resistance index of LN, available at http://www.cipac.org/cipacpub.htm |
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WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

FAO/WHO EVALUATION REPORT 333/2013.1

Recommendations

The Meeting recommended the following:

- (i) The existing WHO specifications 333/LN/1 (NETTING and NET) for deltamethrin (coated onto filaments) LN should be extended to encompass the 100 denier Yorkool LN product of Tianjin Yorkool International Trading Co., Ltd.
- (ii) The wash resistance index tolerance of the existing WHO specification 333/LN/1 (NETTING) for deltamethrin (coated onto filaments) LN using the new CIPAC washing method 4827/m is applicable to 75 and 100 denier Yorkool LN products of Tianjin Yorkool International Trading Co., Ltd.

Appraisal

Supporting data and information for 100 denier Yorkool LN [deltamethrin long-lasting (coated onto 100 denier filaments) insecticidal net (LN)], provided by Tianjin Yorkool International Trading Co., Ltd., were considered by the Meeting for extension of the existing WHO specifications 333/LN/1 (NETTING and NET) (November 2012). The test reports provided by the manufacturer to support this extension were generated by independent laboratories as well as by the manufacturer.

The LN under consideration is produced from 100 denier warp-knitted multi-filament polyester fibers with technical deltamethrin coated onto the polyester netting after the knitting process. As for the 75 denier Yorkool LN product, the technical deltamethrin coated onto the LN is from a source compliant with the existing WHO specification for deltamethrin TC (Heranba).

Description clause – netting and net

The Meeting concluded that the description of Yorkool LN made of 100 denier warp-knitted multi-filament polyester fibres without a strengthened 70 cm border and treated with technical deltamethrin complies with the existing WHO specifications 333/LN/1 (NETTING and NET).

Active ingredient content clause – netting and net

100 denier Yorkool LN is produced from 100 denier yarns and the target deltamethrin content is 1.4 g/kg, corresponding to 55 mg/m². Data provided by the manufacturer for density and deltamethrin content showed that the product complies with the existing WHO specifications 333/LN/1 (NETTING and NET).

Special attention needs to be paid to control random variations in the distribution of the insecticide over the surface of the net and between nets. The spatial variation data provided by the manufacturer on 1 batch (deltamethrin content on 5 individual net pieces taken according to the Figure 1 of the specification) showed an acceptable homogeneity of the active ingredient content within the net (within-net RSD = 8.2%, n = 5).

The CIPAC method 333/LN/(M)/3 published in Handbook M, involving extraction by sonication and shaking with isooctane / dioxane (80/20, v/v) followed by determination by high performance liquid chromatography with UV detection, was used in the study provided by the manufacturer and is fully applicable for 100 denier Yorkool LN.

Active ingredient wash resistance index clause - netting

An adequate amount of active ingredient must be present at the surface of the LN, for efficacy reasons, whereas the majority must reside within the coating of the LN, to avoid excessive losses during washing and to provide a reservoir from which the surface is replenished with active ingredient. The depth and quality of coating therefore strongly influence the retention of deltamethrin when the LN is subjected to repeated washing. Depletion of total active ingredient content by washing (retention index) is accomplished by analyzing separate washed and unwashed pieces of the same fabric.

The CIPAC method for determination of wash resistance index of LN (CIPAC 4827/m) was adopted as provisional CIPAC MT method in 2012 and promoted to full method in 2013. This method is a further standardization of the WHO washing method published in the “WHO Guidelines for laboratory and field testing of long-lasting insecticidal mosquito nets”, document WHO/CDS/WHOPES/GCDPP/2005.11, WHO, Geneva, 2005. Briefly, the wash resistance index is determined by analyzing net samples in triplicate representing wash points 0 and 4 for total active ingredient content and calculating the average wash resistance index per wash using the equation for a free migration stage behaviour. A wash resistance index per wash of 95% indicates that at least 95% of the insecticide present in samples washed 1 to 3 times is still present after an additional wash step. The wash resistance index applies to the average obtained from triplicate tests performed on net pieces removed from the same net or batch of netting (CIPAC 2012).

The Meeting requested the company to generate new wash resistance index data using the new CIPAC washing method and to propose a revised wash resistance index clause based on these data. Data provided by the manufacturer on 6 batches of 100 denier Yorkool LN (white and blue color) and also on 5 batches of 75 denier Yorkool LN (white, blue and green color) showed that the two products fully comply with the deltamethrin wash resistance index specification clause of 80% to 98%. Additional data provided by the manufacturer on the same batches using the previous WHO washing method showed that there is no significant difference in the deltamethrin wash resistance index between the two washing methods.

Relevant impurities clause - netting

There are no relevant impurities identified in the existing WHO specification for deltamethrin TC. During the coating process of deltamethrin LN, heat and base-catalyzed epimerization of deltamethrin to the (insecticidally inactive) *R*-alpha isomer may occur. This conversion must be controlled by the manufacturer to avoid significant losses of active ingredient. This conversion can also occur if the LN is exposed to excessive heat during production, storage or use. A study report provided by the manufacturer showed that deltamethrin *R*-alpha isomer content in 100 denier Yorkool LN is lower than 1% of the deltamethrin content.

Physical properties clauses

The manufacturer provided a study report showing that 100 denier Yorkool LN fully comply with the clauses of the existing WHO specifications 333/LN/1 (NETTING and NET) for netting mesh size, dimensional stability of netting to washing and bursting strength.

Storage stability clause

The manufacturer provided data after storage at 40°C for 8 weeks showing that the loss of deltamethrin is less than 5% and the wash resistance index remains within the limits of the specification clause. The manufacturer provided also data showing that the dimensional stability to washing and the bursting strength remains unchanged after storage at 40°C for 8 weeks. The Meeting concluded that 100 denier Yorkool LN comply with the existing WHO specifications 333/LN/1 (NETTING) for storage stability at 40°C for 8 weeks.

ANNEX 1: REFERENCES

| Study number | Author(s) | Year | Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study |
|--------------|-------------|------|---|
| | CIPAC | 2012 | MT 19X. Wash resistance index of LN, CIPAC method 4827/m. |
| | CIPAC | 2012 | MT 19X. Wash resistance index of LN, small scale collaborative trial, CIPAC report 4828/m. |
| 23118 | CRA-W | 2013 | Chemical properties and accelerated storage stability tests for 100 denier Yorkkool LN [deltamethrin long-lasting (coated onto filaments) insecticidal mosquito net (LN)]. Report Yorkkool / RE 23118 / 2013 of the Walloon Agricultural Research Centre, Gembloux, Belgium for Tianjin Yorkkool International Trading Co., Ltd., April 08, 2013. |
| | FAO/WHO | 2010 | Manual on development and use of FAO and WHO specifications for pesticides. Second revision of the 1 st edition. FAO, Rome and WHO, Geneva, November 2010 (internet publications). |
| | Li Chenbiao | 2013 | Specification for 100 denier Yorkkool LN. JMPS Dossier. Tianjin Yorkkool International Trading Co., Ltd., March 18, 2013. |
| TSNT00506381 | Wang Alex | 2013 | Determination of dimensional stability to washing, bursting strength, weight per unit area, netting mesh size and flammability of 100 denier Yorkkool LN. Report TSNT00506381 of Intertek Testing Services (Tianjin) Ltd. for Tianjin Yorkkool International Trading Co., Ltd. March 14, 2013. |
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WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

FAO/WHO EVALUATION REPORT 333/2012.3

Recommendations

The Meeting recommended the following.

- (vi) The existing WHO interim specifications 333/LN/1 (NETTING and NET) for deltamethrin long-lasting (coated onto filaments) insecticidal netting and net should be revised as proposed by Vestergaard Frandsen and as amended by the Meeting.
- (vii) The revised specifications should get the status of full WHO specifications.

Appraisal

The Meeting considered data and information submitted by Vestergaard Frandsen to support the revision of the existing WHO interim specifications 333/LN/1 (NETTING and NET) for deltamethrin long-lasting (coated onto filaments) insecticidal netting and net regarding the retention index clause.

The company required the Meeting to change the retention index clause specified in the specification 333/LN/1 (NETTING) for PermaNet 2.0 and PermaNet 2.0 Extra to not less than 80% as specified in the original WHO specification 333/LN issued in 2006. The actual test method to support the retention index clause refer to the WHO washing method and the relevant CIPAC method for deltamethrin content in coated LN. Both of these methods are robust and valid reference methods for a single purpose. However, a poor reproducibility when combining the two methods suggest a risk of having net samples failing the criteria of the existing WHO specification for deltamethrin retention index. This is mainly due to some variations in the existing WHO washing method which is not fully standardized.

The company provided the Meeting with an inter-laboratory study report involving three separate accredited laboratories following strictly the relevant standard methods from sampling to testing, including representative sampling by a third party. This study showed that some net samples can fail the criteria of the WHO specification in one laboratory while these same samples pass in another laboratory. Another inter-laboratory comparison study on the method recommended by the actual specification to determine the deltamethrin retention index of PermaNet 2.0 has also shown that some differences in results can be observed between laboratories, leading to different conclusions regarding the compliance with the WHO specification. This is particularly critical for samples which are at the limit of the specification tolerance.

The company provided also a report of a boundary study to investigate whether PermaNet 2.0 with a retention index after the first wash of $80\% \pm 3\%$ performed according to WHO Phase 1 criteria of wash resistance up to 20 washes. Results from this study showed that these nets remained above the Phase 1 cut-off criteria up to 25 washes.

In the meantime, the method for determination of wash resistance index of LN (CIPAC 4827/m) was accepted as provisional CIPAC method in 2012. This method is a further standardization of the WHO washing method published in the “WHO Guidelines for laboratory and field testing of long-lasting insecticidal mosquito nets”, document WHO/CDS/WHOPES/GCDPP/2005.11, WHO, Geneva, 2005. Briefly, the wash resistance index is determined by analyzing net samples in triplicate representing wash points 0 and 4 for total active ingredient content and calculating the average wash resistance index per wash using the equation for a free migration stage behaviour. A wash resistance index per wash of 95% indicates that at least 95% of the insecticide present in samples washed 1 to 3 times is still present after an additional wash step. The wash resistance index applies to the average obtained from triplicate tests performed on net pieces removed from the same net or batch of netting.

The Meeting noted that the calculation of the retention index using the equation for a free migration stage behaviour [wash resistance index = $100 \times \sqrt[4]{(t_4/t_0)}$] provides a more accurate wash resistance index than the calculation comparing the active ingredient content between wash 3 and 2. This is due to the fact that the difference in active ingredient content between wash 4 and wash 0 is higher than between wash 3 and wash 2. This calculation using the equation for a free migration stage behaviour was recommended by WHO in the report of the Eleventh WHOPES Working Group Meeting (WHO 2008) and is now adopted in the new CIPAC washing method for LN.

The Meeting agreed that the actual retention index clause of not less than 0.85 after the first wash, and in the range of 0.87-0.97 from the second to the third wash was too limiting due to the variation of the actual WHO washing method and agreed therefore to revise the retention index clause. The Meeting requested the company to generate new wash resistance index data on their LN using the new CIPAC method and to propose to WHO a revised wash resistance index clause based on these data.

The company provided the Meeting with a study report where the wash resistance index was measured on 21 samples from a normal standard production of PermaNet 2.0 of 75 denier and on 27 samples of a normal standard production of PermaNet 3.0 with a 70 cm lower side of 75 denier with strengthened border and an upper side of 100 denier without strengthened border (= same technology than PermaNet 2.0 Extra). On basis on the results of this report the company and the Meeting agreed to specify that the average wash resistance index of deltamethrin from the netting shall be within the range 80% to 98%. This specification clause is in line with results obtained in the small scale collaborative trial on the CIPAC washing method (CIPAC 2012). As the new tolerance is somewhat less stringent than the older one, this has no negative impact on the deltamethrin LN specifications proposed by Tianjin Yorkool International Trading Co., Ltd who had been granted equivalence.

The Meeting agreed that it was also necessary to revise the description and bursting strength clauses of the WHO interim specification 333/LN/1 (NET) (PermaNet 2.0, PermaNet 2.0 Extra and Yorkool LN) to ensure consistency with the request of Vestergaard Frandsen to revise the description clause of PermaNet 3.0 (see evaluation report 333+33/2012 of the WHO specifications 333+33/LN (netting and net).

The Meeting proposed also to adapt the footnotes of the actual specification for flammability, net sampling, netting mesh size, dimensional stability to washing and bursting strength according to the recommendations of the draft LN guideline of the FAO/WHO Manual (November 2010 – second revision of the first edition).

ANNEX 1: REFERENCES

| Study number | Author(s) | Year | Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study |
|--------------|----------------|------|---|
| | CIPAC | 2012 | MT 19X. Wash resistance index of LN, CIPAC method 4827/m. |
| | CIPAC | 2112 | MT 19X. Wash resistance index of LN, small scale collaborative trial, CIPAC report 4828/m. |
| | FAO/WHO | 2010 | Manual on development and use of FAO and WHO specifications for pesticides. Second revision of the 1 st edition. FAO, Rome and WHO, Geneva, November 2010 (internet publications). |
| | Pates Jamet H. | 2012 | Request to revise the specification 333/LN/1 (NETTING) for PermaNet 2.0. Vestergaard Frandsen, 16 April 2012. |
| | Pates Jamet H. | 2012 | Reports from the inter-lab study on retention index of PermaNet® 2.0. Vestergaard Frandsen, April 2012. |
| | Pates Jamet H. | 2012 | PermaNet® 2.0 boundary study to investigate the bioefficacy with RI 80% ± 3%, April 2012. |
| | Pates Jamet H. | 2012 | Wash resistance index of PermaNet® 2.0 and 3.0 according to the new CIPAC washing method, 26 July 2012. |
| | WHO | 2005 | Guidelines for laboratory and field testing of long-lasting insecticidal mosquito nets. Document WHO/CDS/WHOPES/GCDPP/2005.11. WHO, Geneva, 2005. |
| | WHO | 2005 | Technical consultation on specifications and quality control of netting materials for mosquito nets (untreated and treated). 29 November–02 December 2005. WHO Headquarters, Geneva, Switzerland. |
| | WHO | 2008 | Report of the Eleventh WHOPES Working Group Meeting, WHO/HQ, Geneva, 10-13 December 2007. WHO, Geneva, document WHO/HTM/NTD/WHOPES/2008.1. |

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

FAO/WHO EVALUATION REPORT 333/2010

Recommendations

The Meeting recommended the following.

The existing WHO specifications 333/LN/1 (NETTING and NET) for deltamethrin LN should be extended to encompass the corresponding product of Tianjin Yorkkool International Trading Co., Ltd.

Appraisal

Supporting data and information for deltamethrin long-lasting (coated onto filaments) insecticidal net (LN), provided by Tianjin Yorkkool International Trading Co., Ltd., were considered by the Meeting for extension of the existing WHO specifications 333/LN/1 (NETTING and NET) (December 2009).

Yorkkool LN is made of 75 denier warp-knitted multi-filament polyester fibres with technical deltamethrin coated onto the polyester netting after the knitting process. The manufacturer provided a written confirmation that deltamethrin TC coated onto the LN was from a source compliant with the existing WHO specification for deltamethrin TC (Heranba).

Yorkkool LN was tested and evaluated by WHOPES who concluded that the bio-efficacy is comparable to the reference product (PermaNet 2.0). WHOPES recommended also the extension of the WHO specifications for deltamethrin (coated) LN to Yorkkool LN, subject to satisfactory assessment of the physical and chemical properties of the product by JMPS (WHO 2009).

Description clause – netting and net

The Meeting concluded that the description of Yorkkool LN made of 75 denier warp-knitted multi-filament polyester fibres treated with technical deltamethrin complies with the existing WHO specifications 333/LN/1 (NETTING and NET).

Active ingredient content clause – netting and net

Yorkkool LN is produced from 75 denier yarns and the target deltamethrin content is 1.8 g/kg, corresponding to 55 mg/m². Data provided by the manufacturer for density and active ingredient content showed that the product complies with the existing WHO specifications 333/LN/1 (NETTING and NET).

Special attention needs to be paid to control random variations in the distribution of the insecticide over the surface of the net and between nets. The manufacturer provided spatial variation data on 5 batches showing a good homogeneity of the active ingredient content within and between nets (within-net RSD = 4.1 to 4.8 %, between-net RSD = 1.1 to 3.1 %). The manufacturer provided also an additional study report with the chemical analysis of 5 individual strips on 2 net samples and showing a good homogeneity of the distribution of deltamethrin over the net (RSD = 0.84% and 1.69 %).

WHOPES Phase I data showed that deltamethrin content in Yorkool LN comply with the target dose of 1.8 g/kg ($\pm 25\%$) and that the between-net variation of deltamethrin content is quite low (RSD = 3.9%) (WHO 2009).

The CIPAC method 333/LN/(M)/3 validated and adopted for deltamethrin coated LN and involving extraction by sonication and shaking with isooctane / dioxane (80/20, v/v) and determination by high performance liquid chromatography with UV detection is fully applicable for Yorkool LN.

Deltamethrin retention index clause - netting

An adequate amount of active ingredient must be present at the surface of the LN, for efficacy, whereas the majority must reside within the coating of the LN, to avoid excessive losses during washing and to provide a reservoir from which the surface is replenished with active ingredient. The depth and quality of coating therefore strongly influence the retention of deltamethrin when the LN is subjected to repeated washing. Depletion of total active ingredient content by washing (retention index) is accomplished by analyzing separate washed and unwashed pieces of the same fabric.

The manufacturer provided data on 3 batches of nets washed up to 30 times (according to the WHO washing method) showing that decreasing proportions of the remaining deltamethrin are removed from the net by successive washings with aqueous detergent (free-migration stage behavior, WHO 2008). The deltamethrin retention index after the first wash ranges from 0.92 to 0.96 and the average deltamethrin retention index for washes 3 to 30 ranges from 0.93 to 0.96. The manufacturer provided also an additional study report showing that the deltamethrin retention index after the first wash (using IEC-A* detergent) is 0.86 and the average deltamethrin retention index for washes 3 to 5 is 0.93.

WHOPES Phase I data showed that the average deltamethrin retention index (0.92) was similar to this one (0.93) of the reference product (PermaNet 2.0) (WHO 2009).

On basis of all these data, the Meeting concluded that the deltamethrin retention index of Yorkool LN complies with the existing WHO specifications 333/LN/1 (NETTING).

Relevant impurities clause - netting

There are no relevant impurities identified in the existing WHO specification for deltamethrin TC. During the coating process of deltamethrin LN, epimerization of deltamethrin to the (insecticidally inactive) 1*R*-isomer may occur. This conversion must be controlled by the manufacturer to avoid significant losses of active ingredient. This conversion can also occur if the LN is exposed to excessive heat during production, storage or use. A study report provided by the manufacturer and WHOPES Phase I data showed that deltamethrin 1*R*-isomer content in Yorkool LN is < 0.01 g/kg of netting material.

Physical properties clauses

The manufacturer provided a study report showing that Yorkool LN fully comply with the clauses of the existing WHO specifications 333/LN/1 (NETTING and NET) for netting mesh size, dimensional stability of netting to washing and bursting strength.

Storage stability clause

Although deltamethrin in bulk is stable over a very wide temperature range and has very low volatility, in the LN it apparently behaves differently. The manufacturer provided data after storage at 54°C for 2 weeks and after storage at 40°C for 8 weeks showing that the loss of deltamethrin is less than 5% (2.9% and 0% respectively) and the retention index remains unchanged (deltamethrin retention index after the first wash = 0.93 and 0.92 respectively, and average deltamethrin retention index for washes 3 to 5 = 0.94 and 0.94 respectively). The manufacturer provided data showing that the dimensional stability to washing and the bursting strength remains unchanged after storage at 40°C for 8 weeks. The Meeting concluded that Yorkool LN comply with the existing WHO specifications 333/LN/1 (NETTING) for stability at 40°C for 8 weeks. The first proposer (Vestergaard Frandsen) was asked to change the accelerated storage stability test to the standard test of 54°C for 2 weeks, but confirmed the need to maintain for their products the accelerated storage stability test of 40°C for 8 weeks.

ANNEX 1. REFERENCES

| Study number | Author(s) | Year | Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study |
|------------------|-----------------|------|---|
| | FAO/WHO | 2006 | Manual on development and use of FAO and WHO specifications for pesticides. March 2006 revision of the 1 st edition. FAO, Rome and WHO, Geneva, March 2006 (internet publications). |
| 21818 | CRA-W | 2008 | Determination of deltamethrin in Yorkool LN [deltamethrin long-lasting (coated on polyester) insecticidal mosquito net (LN)] : spatial variation study. Report YORKOOL / RE 21818 / 2008 of the Walloon Agricultural Research Centre, Gembloux, Belgium for Tianjin Yorkool International Trading Co., Ltd., August 2008. |
| 22029 | CRA-W | 2009 | Determination of deltamethrin in Yorkool LN and PermaNet 2.0 [deltamethrin long-lasting (coated on polyester) insecticidal mosquito net (LN)]. Report WHO / RE 22029 / 2009 of the Walloon Agricultural Research Centre, Gembloux, Belgium for WHO, July 2009. |
| 22087 | CRA-W | 2010 | Physical and chemical properties and accelerated storage stability for Yorkool LN [deltamethrin long-lasting (coated onto polyester) insecticidal mosquito net (LN)]. Report YORKOOL / RE 22087 / 2009 of the Walloon Agricultural Research Centre, Gembloux, Belgium for Tianjin Yorkool International Trading Co., Ltd., February 2010. |
| | Tianjin Yorkool | 2008 | Technical data submitted by Tianjin Yorkool International Trading Co., Ltd. to WHO for application for WHOPES evaluation of Yorkool LN, July 2008. |
| | Tianjin Yorkool | 2009 | Technical data submitted by Tianjin Yorkool International Trading Co., Ltd. to WHO for extension of LN specifications, October 2009. |
| | Tianjin Yorkool | 2010 | Certificate of deltamethrin technical supply to Yorkool for LN manufacture, February 2010. |
| TSNT0021 2245 | Wang A. | 2009 | Dimensional stability to washing, bursting strength, weight per unit area, netting mesh size and flammability of Yorkool LN. Report TSNT00212245 of Intertek, Tianjin, China for Tianjin Yorkool International Trading Co., Ltd., September 2009. |
| | WHO | 2005 | Guidelines for laboratory and field testing of long-lasting insecticidal mosquito nets. Document WHO/CDS/WHOPES/GCDPP/2005.11. WHO, Geneva, 2005. |
| | WHO | 2007 | Report of the Tenth WHOPES Working Group Meeting, WHO/HQ, Geneva, 11-14 December 2006. WHO, Geneva, document WHO/CDS/NTD/WHOPES/2007.1 |
| | WHO | 2008 | Report of the Eleventh WHOPES Working Group Meeting, WHO/HQ, Geneva, 10-13 December 2007. WHO, Geneva, document WHO/HTM/NTD/WHOPES/2008.1. |
| | WHO | 2009 | Report of the Thirteenth WHOPES Working Group Meeting, WHO/HQ, Geneva, 28-30 July 2009. WHO, Geneva document WHO/HTM/NTD/WHOPES/2009.5 |

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

FAO/WHO EVALUATION REPORT 333/2009.2

Recommendations

The Meeting recommended the following.

- (i) A time-limited interim specification (until December 2012) for deltamethrin long-lasting (coated) insecticidal net proposed by Tana Netting Co. Ltd., as amended, should be adopted by WHO.
- (ii) Future proposals for extension of this specification to apparently equivalent LN formulations should be supported by evidence to show whether or not the test method and limit for active ingredient retention characteristics are appropriate for the additional products.

Appraisal

Supporting data and draft specification for deltamethrin LN (coated type), provided by Tana Netting Co. Ltd., were considered by the JMPS for development of a new WHO specification in 2009. Appropriate clauses, limits and methods of testing were proposed by the company.

The manufacturer confirmed that the formulation of the active ingredient coated onto the LN was from a source compliant with the existing WHO specification for deltamethrin SC.

Description clause

The Meeting and manufacturer agreed that the specification should be applied to white or coloured fabrics made from 75 or 100 denier poly-filament polyester yarn and that it should equally apply to made-up, ready-to-use nets (rectangular and circular) or to netting in bulk.

Active ingredient content clause

With the aim of achieving similar levels of efficacy, the target dose of deltamethrin for all weights of fabric is similar on an area basis (80 mg/m²) but it differs when expressed as g/kg. The mg/m² value is calculated from measurements of g/kg and fabric density in g/m². The Meeting agreed that the declared and tolerance values should be based on g/kg, with the corresponding mg/m² value being defined in a note to the specification.

Special attention needs to be paid to describe and control random variations in the distribution of the insecticide in the net. Despite that the within net variability study provided by the manufacturer was performed on separated pieces of net that were pooled and analysed as a single sample, results suggest that the within net variation of the active ingredient is acceptable. Moreover the analysis of 5 different nets from 5 batches (total 25 nets) showed that the deltamethrin content is within the proposed tolerance ($\pm 25\%$). WHOPES Phase I data showed also a good homogeneity of deltamethrin content among the nets (RSD ranged from 5.5 to 11.5%). Nevertheless,

of six unwashed nets tested in the phase II trials, two had a high within net variation of the deltamethrin content (RSD > 20%). WHO has recommended to the manufacturer to monitor the variability of deltamethrin content to ensure it remains in conformity with proposed limits (WHO 2009).

The analytical method used by the manufacturer involves extraction with acetonitrile / tetrahydrofuran / 2-propanol / water and chromatographic determination by reversed phase High Performance Liquid Chromatography with UV detection. An extension of the CIPAC method 333 to LN (coated type) was adopted by CIPAC in 2006 and published in the CIPAC Handbook M in 2009, and involves extraction with isooctane / dioxane (80/20, v/v) and determination by normal phase high performance liquid chromatography with UV Detection. The manufacturer confirmed later that the CIPAC method is applicable for their product and provided validation data to support this statement.

Deltamethrin retention index clause

An adequate amount of active ingredient must be present at the surface of the LN, for efficacy, whereas the majority must reside within the coating of the LN, to avoid excessive losses during washing and to provide a reservoir from which the surface is replenished with active ingredient. The coating system of the considered LN glues the particles to the surface of the fibre. There is no need for migration to the surface of a layer as all particles are bio-available on the surface. It is assumed that few particles are removed during washing of the net, the binder layer being basically not washed off.

Depletion of total active ingredient content by washing (retention index) is accomplished by analyzing separate washed and unwashed pieces of the same fabric. The manufacturer provided data on nets washed up to 40 washes (according to the WHO washing procedure) showing that decreasing proportions of the remaining deltamethrin are removed from the net by successive washings with aqueous detergent (free-migration stage behaviour), and proposed a minimum retention index per wash of 0.94. Considering the WHOPES Phase I data but also data provided by the manufacturer, the Meeting proposed the range 0.94-0.99 to be adopted as retention index instead of the minimum 0.94 in order to avoid an excessive retention of deltamethrin.

Relevant impurities clause

There are no relevant impurities identified in the existing WHO specifications for deltamethrin SC. During the coating process of deltamethrin LN, epimerization of deltamethrin to the (insecticidally inactive) 1R isomer may occur. This conversion must be controlled by the manufacturer to avoid losses of active ingredient. This conversion can also occur if the LN is exposed to excessive heat during storage or use. The Meeting agreed that the 1R isomer should remain designated as a non-relevant impurity and hence remain excluded from the specification. It is however indirectly specified by the content clause in the accelerated storage test, where at least 95% of deltamethrin is still present after the test thus limiting the epimerization to a maximum of 5%.

Physical properties clauses

The clauses for physical properties are based on ISO methods, with the exception of netting mesh size which do not require standardisation and deltamethrin retention index, which relates to the active ingredient.

The 5% tolerance for dimensional stability to washing is in agreement with the 5% standard given in the LN guideline (FAO/WHO 2006) and was supported by test results.

Storage stability clause

Although deltamethrin in bulk is stable over a very wide temperature range and has very low volatility, in the LN it apparently behaves differently. The manufacturer provided data after storage at 54°C for 2 weeks showing that the loss of deltamethrin is less than 5% and the retention index remains unchanged. The Meeting and manufacturer agreed to include into the specification the storage stability test of 54°C for 2 weeks.

ANNEX 1. REFERENCES

| Reference and year | Title of report or publication details |
|--------------------|---|
| FAO/WHO 2006 | Manual on development and use of FAO and WHO specifications for pesticides, March 2006 revision of the 1 st edition. FAO, Rome, March 2006; WHO, Geneva, March 2006 (internet publications). |
| Tana Netting 2009 | Draft specifications and supporting data for DawaPlus 2.0 LN, January 2009. |
| Tana Netting 2009 | Additional data for DawaPlus 2.0 LN (bursting strength and validation report for deltamethrin content), August 2009. |
| WHO 2005 | Guidelines for laboratory and field testing of long-lasting insecticidal mosquito nets. Document WHO/CDS/WHOPES/GCDPP/2005.11. World Health Organization, Geneva, 2005. |
| WHO 2005 | Technical consultation on specifications and quality control of netting materials for mosquito nets (untreated and treated). 29 November–02 December 2005. WHO Headquarters, Geneva, Switzerland. |
| WHO 2007 | Report of the Tenth WHOPES Working Group Meeting, WHO/HQ, Geneva, 11-14 December 2006. Geneva, World Health Organization, document WHO/CDS/NTD/WHOPES/2007.1 |
| WHO 2008 | Report of the Eleventh WHOPES Working Group Meeting, WHO/HQ, Geneva, 10-13 December 2007. Geneva, World Health Organization, document WHO/HTM/NTD/WHOPES/2008.1. |
| WHO 2009 | Report of the Thirteenth WHOPES Working Group Meeting, WHO/HQ, Geneva, 28-30 July 2009. Geneva, World Health Organization document WHO/HTM/NTD/WHOPES/2009.5 |

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

FAO/WHO EVALUATION REPORT 333/2009.1

Recommendations

The Meeting recommended the following.

- (i) The WHO specification for deltamethrin long-lasting (coated) insecticidal net (August 2006) should be withdrawn.
- (ii) A time-limited interim specification (until December 2012) for deltamethrin long-lasting (coated) insecticidal netting and net proposed by Vestergaard Frandsen, as amended, should be adopted by WHO.
- (iii) Future proposals for extension of this specification to apparently equivalent LN formulations should be supported by evidence to show whether or not the test method and limit for active ingredient retention characteristics are appropriate for the additional products.

Appraisal

Supporting data and draft specifications for a new deltamethrin long-lasting (coated) mosquito net (LN), PermaNet 2.0 Extra, provided by Vestergaard Frandsen, were considered by the JMPS for development of new WHO specifications in 2009. Appropriate clauses, limits and methods of testing were proposed by the company.

PermaNet 2.0 Extra was tested and evaluated by WHOPES and a time-limited interim recommendation for its use in malaria prevention and control was issued (WHO 2009). PermaNet 2.0 Extra is made of warp-knitted multi-filament polyester fibres, using the same knitting and coating technology as that of PermaNet 2.0, for which a WHO specification was published in August 2006. The major differences with the latter are the side netting having a reinforced lower panel and a higher target dose of deltamethrin.

Bearing in mind the manufacturing processes of PermaNet 2.0 and PermaNet 2.0 Extra being similar and in order to keep the number of specifications as small as possible while maintaining applicability of limits and transparency of evaluation, the specification for netting (the fabric) and net (the finished products) were separated into the respective specifications. The specifications therefore relate to both LN products. Certain clauses apply to yarn or netting in bulk only (content of active ingredient, retention index, some physical properties) and other apply to the finished product like description and some physical properties.

The manufacturer confirmed that the active ingredient coated onto the LN was from a source compliant with the existing WHO specification for deltamethrin TC.

Description clause - netting

The Meeting and manufacturer agreed that the specification should be applied to white or coloured fabrics made from 75 or 100 denier multi-filament polyester yarn.

Description clause - net

The Meeting and manufacturer agreed that the specification should be applied to white or coloured fabrics complying with the specification for deltamethrin coated type netting used to produce ready to use nets (rectangular and circular). In contrast to the netting, the finished net may have strengthened borders of 70 cm, where more yarn is used in the knitting process. The weight of the fabric is concurrently increased from 30 to 40 g/m². These strengthened borders provide higher durability as expressed in increased bursting strength (see physical properties) but have the same content of deltamethrin expressed in g/kg.

Active ingredient clause - netting

As the fabrics are produced from yarns with different denier, the content of deltamethrin is dependent on the weight of the fabric per m² to achieve a similar level of efficacy. The Meeting agreed that the declared and tolerance values should be based on g/kg.

PermaNet 2.0: the target dose is 1.8 and 1.4 g deltamethrin per kg of net with 75 and 100 denier respectively, corresponding to 55 mg/m² for both denier.

PermaNet 2.0 Extra: the target dose is 2.8 and 2.1 g deltamethrin per kg of net for upper side panel and roof (75 denier with weight of 30 g/m² ± 10% and 100 denier with weight of 40 g/m² ± 10%, respectively) and lower side panels (75 denier with weight of 40 g/m² ± 10% and 100 denier with weight of 52 g/m² ± 10%, respectively), corresponding to 85 mg/m² in the body and 115 mg/m² in the strengthened border.

The mg/m² value is calculated from measurements of g/kg and fabric density in g/m².

Special attention needs to be paid during sampling process to describe and control random variations in the distribution of the insecticide over the surface of the net. The manufacturer provided data to show that the analysis of single 100 cm² pieces sampled over the net provided acceptable precision (RSD <11% in one experiment). The analysis of 5 different batches showed that the deltamethrin content is within the proposed tolerance (± 25%). The WHOPES Phase I and II testing of PermaNet 2.0 Extra showed also an acceptable within and between net homogeneity of the deltamethrin content (WHO 2009).

The analytical method for determination of deltamethrin in coated LN was validated as an extension of the existing CIPAC method for deltamethrin, adopted by CIPAC in 2006 and is published in Handbook M (August 2009).

Relevant impurities clause - netting

There are no relevant impurities identified in the existing WHO specifications for deltamethrin TC. During the coating process of deltamethrin LN, epimerization of deltamethrin to the (insecticidally inactive) 1R isomer may occur. This conversion must be controlled by the manufacturer to avoid significant losses of active ingredient. This conversion can also occur if the LN is exposed to excessive heat during storage or use. The Meeting agreed that the 1R isomer should remain designated as a non-relevant impurity and hence remain excluded from the specification. It is however indirectly specified by the content clause in the accelerated storage test, where at least 95 % of deltamethrin is still present after the test thus limiting the epimerization to a maximum of 5%.

Deltamethrin retention index clause - netting

An adequate amount of active ingredient must be present at the surface of the LN, for efficacy, whereas the majority must reside within the coating of the LN, to avoid excessive losses during washing and to provide a reservoir from which the surface is replenished with active ingredient. The depth and quality of coating therefore strongly influence the retention of deltamethrin when the LN is subjected to repeated washing. The manufacturer provided data showing that approximately decreasing proportions of the remaining deltamethrin are removed from the polymer by successive washings with aqueous detergent (free-migration stage behaviour). As the diffusion processes in solid materials are significantly slower than in solution, a certain time period is necessary to re-establish the equilibrium level of the active ingredient on the surface of polymer.

Depletion of total active ingredient content by washing (retention index) is most easily accomplished by analysis of separate washed and unwashed pieces of the same fabric. However, this may be expected to introduce additional sampling (i.e. sub sampling) error into the measurement because, unlike most other formulation types, LN products cannot be mixed thoroughly prior to testing. As the diffusion behaviour within the coating polymer appears to be simple, it may be thought that the influence of the additional sub sampling error could be minimized by a test involving repetitive washing but the available data did not support this approach. The manufacturer's data from single and multi wash tests showed little difference in the dispersion of results for retention index per wash, indicating that other variables may be more important than sub sampling error. The manufacturer proposed an acceptable range of retention index – minimum 0.87, maximum 0.97 – determined after the second and following washes of the net. WHOPEs Phase I data supported also this clause. The range of retention index was accepted by the Meeting.

Physical properties clause - netting

The clauses for physical properties are based on ISO methods, with the exception of netting mesh and deltamethrin retention index, which relates to the active ingredient.

The 5% tolerance on dimensional stability to washing was in agreement with the 5% standard given in the LN guideline (FAO/WHO 2006).

Storage stability clause - netting

Although deltamethrin in bulk is stable over a very wide temperature range and has very low volatility, in the LN it apparently behaves differently. The manufacturer stated that deltamethrin in the LN has better stability at 40 or 47°C than at 54°C and its concentration remains almost unchanged after 2 years at 40°C. At 54°C for 14 days, about 10% of the deltamethrin was lost, mainly due to conversion to the R isomer. Above 80°C, deltamethrin is rapidly and completely lost from the LN, apparently due to volatilization. At 40°C for 8 weeks, the loss of deltamethrin was minimal (less than 2% conversion to R isomer) and the physical properties of the fabric were maintained. The Meeting accepted the need to specify the use of the alternative test regime.

ANNEX 1. REFERENCES

| Reference and year | Title of report or publication details |
|--------------------|---|
| FAO/WHO 2006 | Manual on development and use of FAO and WHO specifications for pesticides, March 2006 revision of the 1 st edition. FAO, Rome, March 2006; WHO, Geneva, March 2006 (internet publications). |
| Vestergaard 2008 | Draft specifications and supporting data for PermaNet 2.5, October 2008. |
| Vestergaard 2009 | RI 2-3 data package for PermaNet 2.0, July 2009. |
| WHO 2005 | Guidelines for laboratory and field testing of long-lasting insecticidal mosquito nets. Document WHO/CDS/WHOPES/GCDPP/2005.11. World Health Organization, Geneva, 2005. |
| WHO 2005 | Technical consultation on specifications and quality control of netting materials for mosquito nets (untreated and treated). 29 November–02 December 2005. WHO Headquarters, Geneva, Switzerland. |
| WHO 2007 | Report of the Tenth WHOPES Working Group Meeting, WHO/HQ, Geneva, 11-14 December 2006. Geneva, World Health Organization, document WHO/CDS/NTD/WHOPES/2007.1 |
| WHO 2008 | Report of the Eleventh WHOPES Working Group Meeting, WHO/HQ, Geneva, 10-13 December 2007. Geneva, World Health Organization, document WHO/HTM/NTD/WHOPES/2008.1. |
| WHO 2009 | Report of the Twelfth WHOPES Working Group Meeting, WHO/HQ, Geneva, 8-11 December 2008. Geneva, World Health Organization, document WHO/HTM/NTD/WHOPES/2009.1. |

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

FAO/WHO EVALUATION REPORT 333/2006.1

Recommendations

The Meeting recommended that:

- (i) the specification for deltamethrin LN (coated type) proposed by Vestergaard-Frandsen, as amended, should be adopted by WHO;
- (ii) future proposals for extension of this specification to apparently equivalent LN formulations should be supported by evidence to show whether or not the test method and limit for active ingredient release characteristics are appropriate for the additional products.

Appraisal

Supporting data and draft specifications for deltamethrin LN, provided by Vestergaard-Frandsen, were considered by the JMPS for development of a new WHO specification in 2004, 2005 and 2006. Appropriate clauses, limits and methods of testing for certain parameters of this new type of formulation were also developed by the company over this period.

Deltamethrin-treated long-lasting insecticidal nets (LN) were tested/evaluated by WHOPEs and an interim recommendation for their use in malaria prevention and control was issued (WHO 2004). A provisional specification guideline for LN formulations was accepted by the 2004 JMPS and published by WHO. The guideline for LN was subsequently amended, taking into account the recommendations of a WHO consultation on mosquito nets (WHO 2005) and published in the revised manual (FAO/WHO 2006). However, the apparent diversity of LN technologies currently requires specification clauses and limits to be tailored to individual products. The LN under consideration is a warp-knitted fabric in which the active ingredient resides mainly within a coating applied to yarn filaments. The yarn is a poly-filament type, because with this type of LN it is important to maximize surface area, rather than yarn volume, per unit area of fabric.

The manufacturer confirmed that the active ingredient incorporated into the LN was from a source compliant with the existing WHO specification for deltamethrin TC.

Description clause

The Meeting and manufacturer agreed that the specification should be applied to white or coloured fabrics made from 75, 100 or 150 denier yarn and that it should apply equally to made up, ready-to-use nets (rectangular and circular) or to netting in bulk.

Active ingredient content clause

With the aim of achieving similar levels of efficacy, the target dose of deltamethrin for all weights of fabric is similar on an area basis (55 mg/m^2) but it differs when expressed as g/kg . The mg/m^2 value is calculated from measurements of g/kg and fabric density in g/m^2 . The Meeting agreed that the declared and tolerance values should be based

on g/kg, with the corresponding mg/m² value being defined in a Note to the specification.

The Meeting observed that random variations in the distribution of deltamethrin may influence the variation in measured values. The manufacturer initially provided between- and within-batch data based on analysis of single 100 cm² pieces but variations in deltamethrin distribution made it difficult to interpret individual results. Subsequently, larger samples were prepared from material taken from multiple positions, cut into approximately 2 x 2 cm pieces, mixed and sub-sampled for analysis. The manufacturer then showed that analysis of portions equivalent to 100 cm² provided a precision similar to that of portions which were 3 or 5 times larger but otherwise produced similarly. This procedure provided good precision (RSD <2% in one experiment).

The analytical method for determination of the deltamethrin in LN was validated as an extension of the existing CIPAC method for deltamethrin and adopted by CIPAC in 2006.

Relevant impurities clause

There are no relevant impurities identified in the existing WHO specification for deltamethrin TC. During the production of deltamethrin LN, a small proportion of conversion to the *R*-isomer can occur and this must be controlled by the manufacturer to avoid potentially significant losses of active ingredient. The isomerization can also occur if the LN is exposed to excessive heat during storage or use. The Meeting agreed that the *R*-isomer should remain designated as a non-relevant impurity and hence remain excluded from the specification.

Deltamethrin retention index clause

An adequate amount of active ingredient must be present on the surface of the LN, for efficacy, but the majority must reside within the coating of the LN, to avoid excessive losses during washing and to provide a reservoir from which the surface is replenished with active ingredient. The depth and quality of coating therefore strongly influence the retention of deltamethrin when the LN is subjected to repeated washing. The manufacturer provided data showing that approximately constant proportions of the remaining deltamethrin are removed from the polymer by successive washings with aqueous detergent. Broadly, the coating behaves rather like a solid solution of deltamethrin, with diffusion within the coating occurring much more slowly than the rate at which the deltamethrin can be removed from its surface, emulsified by aqueous detergent. Thus, following rapid depletion of the surface deltamethrin by washing, a short "curing" period at room temperature (or 2 h at 40°C) is required, to re-establish an equilibrium level of the active ingredient on the surface of polymer.

Depletion of total active ingredient content by washing (retention index) is most easily accomplished by analysis of separate washed and unwashed pieces of the same fabric. However, this may be expected to introduce additional sampling (i.e. sub-sampling) error into the measurement because, unlike most other formulation types, LN products cannot be mixed thoroughly prior to testing. As the diffusion behaviour within the polymer appears to be simple, it may be thought that the influence of the additional sub-sampling error could be minimized by a test involving repetitive washing but the available data did not support this approach. The manufacturer's data from single- and multi-wash tests showed little difference in the dispersion of results for

retention index per wash, indicating that other variables may be more important than sub-sampling error.

A single-wash test for determination of retention index was therefore developed by the manufacturer and validated by collaborative study, through CIPAC in 2006. The method was subsequently modified to calculate retention index as the average of triplicate determinations, to enhance repeatability and hence reproducibility of results.

Physical properties clauses

The clauses for physical properties mostly specify ISO methods, with the exception of netting mesh size, which does not require standardization, and deltamethrin retention index, which relates to the active ingredient. Where the ISO standard provides alternative methods, the option to be used is specified in a Note to the specification.

The Meeting accepted the manufacturer's explanation that the test for bursting strength obviated the need for a separate clause for tearing strength.

The Meeting noted that the $\pm 10\%$ tolerance on dimensional stability to washing was higher than the standard 5% given in the LN guideline (FAO/WHO 2006). The manufacturer explained that the manufacturing process is such that dimensional stability and deltamethrin retention index are inversely related. The Meeting therefore agreed that the 10% tolerance was an acceptable compromise.

Storage stability clause

Although deltamethrin in bulk is stable over a very wide temperature range and has very low volatility, in the LN it behaves differently. The manufacturer stated that deltamethrin in the LN has better stability at 40-47°C than at 54°C and its concentration remains almost unchanged after 2 years at 40°C. At 54°C for 14 days, about 15% of the deltamethrin was lost, mainly due to conversion to the *R*-isomer. Above 80°C, deltamethrin is rapidly and completely lost from the LN, apparently due to volatilization. At 40°C for 8 weeks, the loss of deltamethrin was minimal ($\leq 0.5\%$ conversion to *R*-isomer) and the physical properties of the fabric were maintained. The Meeting accepted the need to specify use of the alternative test regime.

**SUPPORTING INFORMATION
FOR
EVALUATION REPORT 333/2006.1**

Uses

The LN is intended for personal protection and disease vector control.

The formulation and its characteristics

The deltamethrin LN formulation characterized by the proposed specification is registered for use in Indonesia, Ethiopia, India, Kenya, Nigeria and Nicaragua and registration is in progress in Mexico, USA, Sri Lanka, Mali, Benin, Ghana, Brazil, Columbia, Malaysia, Peru, Columbia, Tanzania and Vietnam. The product is a fabric, made of warp-knitted multi-filament polyester fibres bearing a bonded layer of polymer containing deltamethrin.

The netting is available in three fabric densities, 30, 40 and 60 g/m² corresponding to the use of 75, 100 and 150 denier yarns, and may be white or coloured.

The netting is normally sold made up into ready-to-use bed nets, which are distributed in plastic bags, to minimize contamination with filth or water. The specification applies to rectangular and circular bed nets, as well as to the netting in bulk (which may be incorporated into other products).

ANNEX 1: REFERENCES

| Reference | Full reference |
|--------------|---|
| FAO/WHO 2006 | Manual on development and use of FAO and WHO specifications for pesticides, March 2006 revision of the 1 st edition. FAO, Rome, March 2006; WHO, Geneva, March 2006 (internet publications). |
| WHO 2004 | Report of the Seventh WHOPES Working Group Meeting, WHO/HQ, Geneva, 2-4 December 2003. Geneva, World Health Organization, document WHO/CDS/WHOPES/2004.8. |
| WHO 2005 | Technical consultation on specifications and quality control of netting materials for mosquito nets (untreated and treated). 29 November–02 December 2005. WHO Headquarters, Geneva, Switzerland. |