

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

DELTAMETHRIN

**LONG-LASTING (INCORPORATED INTO
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.

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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 Specifications of the technical material and the related formulations of the pesticide in accordance with chapters 4 to 9 of the “FAO/WHO Manual on Pesticide Specifications.”

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 “FAO/WHO Manual on Pesticide Specifications” 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. Dates of publication of the earlier versions, if any, are identified in a footnote. 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 [\(http://www.who.int/whopes/quality/en/\)](http://www.who.int/whopes/quality/en/).

PART ONE
SPECIFICATIONS

DELTA METHRIN

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WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

INFORMATION

ISO common names

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

Synonyms

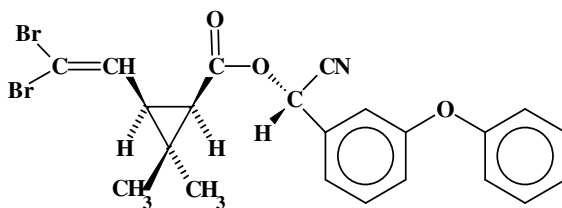
Decamethrin (rejected common name)

Chemical names

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

CA [1*R*-[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 g/mol

CAS Registry number

52918-63-5

CIPAC number

333

EEC number

258-256-6

Identity tests

HPLC retention time; TLC; IR, NMR and mass spectra

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN LONG-LASTING (INCORPORATED INTO POLYETHYLENE) INSECTICIDAL NET

WHO interim specification 333/LN/3 (August 2010*)

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 report (333/2010.1). 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 report (333/2010.1), given in PART TWO, forms an integral part of this publication.

1 Description

The product shall be in the form of netting (Note 1), consisting of 118 denier monofilament polyethylene fibers of different densities, incorporating technical deltamethrin complying with the requirements of WHO specification 333/TC (April 2005) prior to incorporation, together with any necessary other formulants. The product shall appear clean, and shall be free from visible extraneous matter (Note 2), 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 it shall be suitable for use as an insecticidal net with long-lasting activity (Notes 3 & 4).

2 Active ingredient

2.1 Identity tests (CIPAC/4673/m) (Notes 5 & 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 (CIPAC/4673/m) (Notes 5, 6, 7 & 8)

The deltamethrin content shall be declared (1.8 g/kg) and, when determined, the average content shall not differ from that declared by more than $\pm 25\%$.

2.3 Deltamethrin retention index (Note 9)

The average retention index of deltamethrin from the netting, when determined, shall be in the range from 0.95 to 1.00.

* This specification is applicable to long-lasting (incorporated into polyethylene filaments) insecticidal nets. It is not applicable to long-lasting (coated onto filaments) insecticidal nets. The extension number to the specification code permit to distinguish the different net types.

Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: <http://www.who.int/whopes/quality/en/>.

3 Physical properties

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 20, and the lowest value shall be not less than 20.

3.2 Dimensional stability of netting to washing (Note 11)

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

3.3 Bursting strength (Note 12)

The minimum bursting strength of the fabric shall be declared (not less than 400 kPa) 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, CIPAC Handbook J, p.128, 2000)

After storage at $54 \pm 2^\circ\text{C}$ for 2 weeks, the determined average active ingredient content must not be lower than 95% of the average content found before storage. The average retention index of deltamethrin from the netting, when determined, shall be not less than 0.90 (Note 13) and the netting shall continue to comply with the clauses for:

- dimensional stability (3.2);
- bursting strength (3.3).

Note 1 The specification applies to manufactured nets and bulk netting. The nets or netting may be white or colored, for example, yellow, pink, khaki or light brown, blue or dark blue, green or dark green.

Note 2 Occasional short lengths of loose thread present in finished nets are not considered to be extraneous matter.

Note 3 Long-lasting insecticidal netting is expected to retain its insecticidal activity during its life span and through a number of standardized laboratory washes. The clause for deltamethrin retention characteristics (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 4 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 fibers cannot be measured in the netting or the manufactured bed net but it should be identified on the packaging.

Note 5 For complete identification and good quantification, deltamethrin (i.e. the [*S*,1*R*,3*R*]-isomer, otherwise known as the *S*-isomer) must be separated from the [*R*,1*R*,3*R*]-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 The extension of the CIPAC method 333/LN/(M)/3 (CIPAC/4673/m) for determination of deltamethrin in incorporated into polyethylene LN was accepted as provisional CIPAC method in 2009. Prior to its publication in next Handbook, copies of the method may be obtained through the CIPAC website, <http://www.cipac.org/prepubme.htm>.

Note 7 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. Where a final product is made from more than one type of netting, each type of netting should be sampled and tested separately.

Use sharp scissors, or equivalent, to minimize damage to the fibres and fabric and thus avoid any consequential bias in the results of certain tests. Roll up the strips or squares and place them in labelled, new, clean aluminium foil prior to analysis. Samples should be kept cool, avoiding heat sources (including sun heat) 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 deltamethrin declared content is 1.8 g/kg corresponding to 68.4 mg/m². 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 (1977).

Note 9 Currently, CIPAC is developing a wash method for determination of the retention behaviour of long-lasting insecticidal mosquito nets. Prior to the publication in Handbook, copies of the method may be obtained through the CIPAC website, <http://www.cipac.org>. This method is a standardisation 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, World Health Organization, Geneva, 2005. Briefly, the retention index is determined by analyzing net samples in triplicate representing wash points 0 and 4 for total active ingredient content and calculating the average retention index using the equation for a free migration stage behaviour. A retention index of 0.95 indicates that 95 % of the insecticide present in samples washed 3 times is still present after an additional wash step. The retention index applies to the average obtained from triplicate tests performed on samples removed side by side in the length direction from the same net or batch of netting. The net samples have to be stored at 40°C for 2 days between washings.

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. Before counting, the fabric should be conditioned according to ISO 139 (1973) (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.

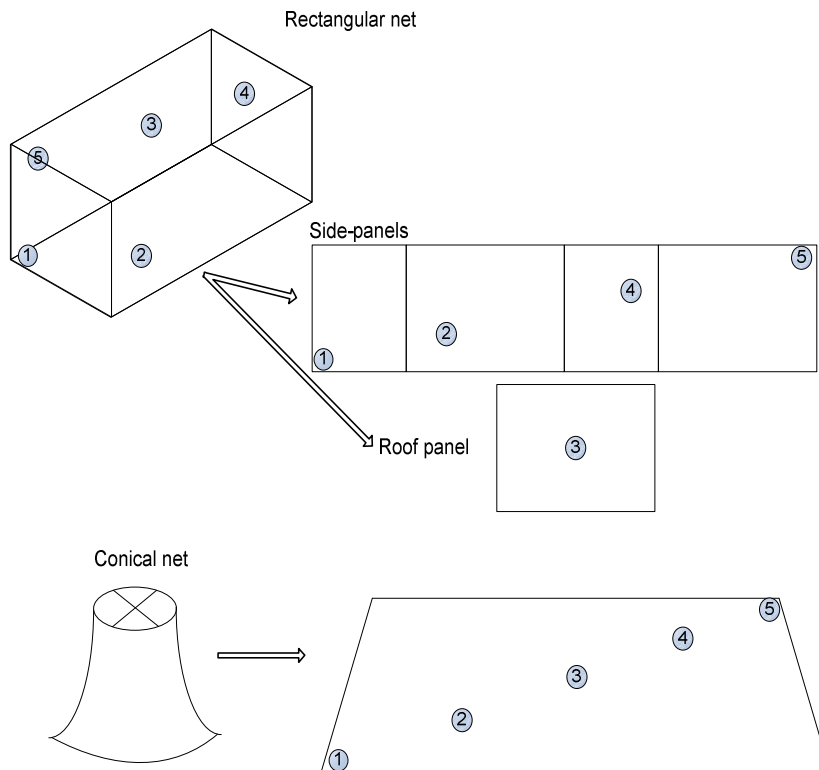
Note 11 Method of preparation, marking and measuring: ISO 3759 (2007). Method of washing: ISO 6330 (2001). Method of calculation: ISO 5077 (1984). Size of test portions: 500 mm²; mark off 350 mm² within the test portion. Test a total of 4 replicate portions, 2 washed in each of 2 separate loads. Type of washing machine: ISO type A (front loading). Washing programme: ISO type 8A (gentle cycle 30°C). Fill the washer with dummy load (with fabric as per ISO standard) up to the standard of 2 to 4 kg. Drying: flat drying.

Note 12 Test method: ISO 13938 part 1 (1999) and ISO 13938 part 2 (1999), with conditioning of the fabric as specified in the ISO standard. The declared minimum 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). Ten 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 one produced by conceptually arranging the panels end to end). The average of the 10 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 Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

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 (INCORPORATED INTO POLYPROPYLENE) INSECTICIDAL NET

WHO interim specification 333/LN/4 (September 2011^{*})

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 report (333/2011). 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 report (333/2011), given in PART TWO, forms an integral part of this publication.

1 Description

The product shall be in the form of netting (Note 1), consisting of 100 denier multi-filament polypropylene fibers, incorporating technical deltamethrin complying with the requirements of WHO specification 333/TC (April 2005), together with any necessary other formulants. The product shall appear clean, and shall be free from visible extraneous matter (Note 2), 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 it shall be suitable for use as an insecticidal net with long-lasting activity (Notes 3 & 4).

2 Active ingredient

2.1 Identity tests (CIPAC/4797/m) (Notes 5 & 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 (CIPAC/4797/m) (Notes 5, 6, 7 & 8)

The deltamethrin content shall be declared (8.5 g/kg for 100 denier yarn) and, when determined, the average 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 Bayer CropScience and commercialised under the trade name LifeNet®. The question 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 was not 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: <http://www.who.int/whopes/quality/en/>.

2.3 Deltamethrin retention index (Note 9)

The average retention index of deltamethrin from the netting, when determined, shall be not less than 0.80 after the first wash and in the range from 0.94 to 0.99 for the subsequent washes (up to 30 washes).

3 Physical properties

3.1 Netting mesh size

When counted by the method given in Note 10, the netting shall have a minimum of 21 complete holes/cm² and an average in the range 21-29 complete holes/cm².

3.2 Dimensional stability of netting to washing (Note 11)

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

3.3 Bursting strength (Note 12)

The minimum bursting strength of the fabric shall be declared (not less than 450 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, CIPAC Handbook J, p.128, 2000)

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

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

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

Note 2 Occasional short lengths of loose thread present in finished nets are not considered to be extraneous matter.

Note 3 A long-lasting insecticidal net is expected to retain its insecticidal activity during its life span and/or through a number of standardized laboratory washes. The clause for deltamethrin retention characteristics (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 4 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 fibers cannot be measured in the netting or the manufactured bed net but it should be identified on the packaging.

Note 5 For complete identification and good quantification, deltamethrin (i.e. the [*S*,1*R*,3*R*]-isomer, otherwise known as the *S*-isomer) must be separated from the [*R*,1*R*,3*R*]-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 The extension of the CIPAC method 333/LN/(M)/3 (CIPAC/4673/m) for determination of deltamethrin in incorporated into polyethylene LN was accepted as provisional CIPAC method in 2009. This method was additionally validated for determination of deltamethrin in incorporated into polypropylene LN (CIPAC/4797/m) and was accepted as provisional CIPAC method in 2011. Prior to its publication in next Handbook, copies of the method may be obtained through the CIPAC website, <http://www.cipac.org/prepubme.htm>.

Note 7 Samples should be assembled from pieces as shown in 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 sun heat) 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 declared value for deltamethrin content in g/kg is equivalent to 340 mg/m² in each case. 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 (1977).

Note 9 Currently (2011), CIPAC is developing a wash method for determination of the retention behaviour of long-lasting insecticidal mosquito nets. Prior to the publication in a Handbook, copies of the method may be obtained through the CIPAC website, <http://www.cipac.org>. This method is a standardisation 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, World Health Organization, Geneva, 2005. Briefly, the retention index is determined by analyzing net samples in triplicate representing wash points 0 and 4 for total active ingredient content and calculating the average retention index per wash using the equation for a free migration stage behaviour. A retention index per wash of 0.94 indicates that 94 % of the insecticide present in samples washed 1 to 3 times is still present after an additional wash step. The retention index applies to the average obtained from triplicate tests performed on samples removed side by side in the length direction from the same net or batch of netting.

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. Before counting, the fabric should be conditioned according to ISO 139 (1973) (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.

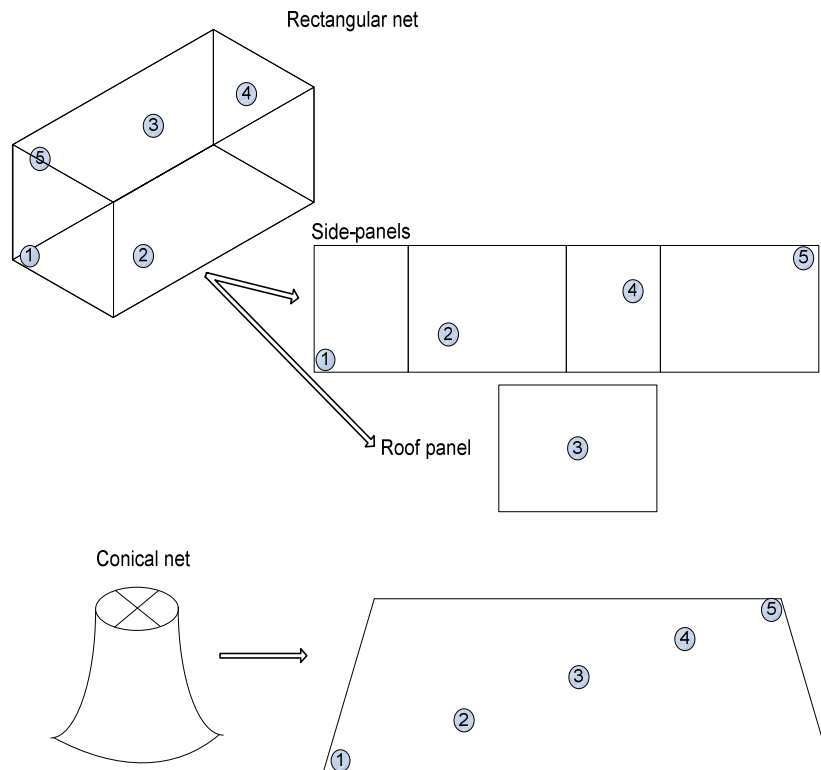
Note 11 Method of preparation, marking and measuring: ISO 3759 (2007). Method of washing: ISO 6330 (2001). Method of calculation: ISO 5077 (1984). Size of test portions: 500 mm x 500 mm; mark off 350 mm x 350 mm within each test portion. Test a total of 4 replicate portions, 2 washed in each of 2 separate loads. Type of washing machine: ISO type A (front loading). Washing programme: ISO type 8A (gentle cycle 30°C). Fill the washer with dummy load (with fabric as per ISO standard) up to the standard of 2 to 4 kg. Drying: flat drying.

Note 12 Test method: ISO 13938 part 1 (1999) and ISO 13938 part 2 (1999), with conditioning of the fabric as specified in the ISO standard. The declared minimum 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 400 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 one produced by conceptually arranging the panels end to end. 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 Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

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.



PART TWO

EVALUATION REPORTS

DELTAMETHRIN

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WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

FAO/WHO EVALUATION REPORT 333/2011

Recommendations

The Meeting recommended the following.

A time-limited interim specification (until September 2014) for deltamethrin long-lasting (incorporated into polypropylene) insecticidal net, proposed by Bayer CropScience and as amended, should be adopted by WHO.

Appraisal

Supporting data and draft specifications for deltamethrin long-lasting (incorporated into polypropylene) insecticidal net (LN), provided by Bayer CropScience, were considered by the Meeting for development of a new WHO specification. Appropriate clauses, limits and methods of testing for certain parameters of this new type of formulation were developed by the company and scientific institutes.

The deltamethrin (incorporated into filaments) LN produced by this manufacturer was tested and evaluated by WHOPES and a time-limited interim recommendation for their use in malaria prevention and control was issued in 2011 (WHO 2011).

The diversity of LN technologies currently requires specification clauses and limits to be tailored to individual products or type of products, as efficacy is strongly dependent on retention / release characteristics of the product. The LN under consideration is a warp knitted fabric in which deltamethrin is incorporated into multi-filament polypropylene fibres of 100 denier at the target dosage of 8.5 g deltamethrin per kg of netting material.

The active ingredient incorporated into the LN is from a source compliant with the existing WHO specification for deltamethrin (Bayer CropScience).

Description clause

The Meeting agreed that the specification should be applied to netting, in bulk, and to finished rectangular and conical bed nets, made from 100 denier multi-filament polypropylene fibers.

Active ingredient content clause

The target dose of deltamethrin (8.5 g/kg) is related to the LN technology and the specific insecticidal activity of the active ingredient, in order to achieve a satisfactory biological activity. The target dose on a fabric area basis (340 mg/m²) 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.

The extension of the CIPAC method 333/LN/(M)/3 (CIPAC/4673/m) for determination of deltamethrin in incorporated into polyethylene LN by high performance liquid chromatography with UV detection (HPLC-UV) was accepted as a provisional CIPAC method in 2009. This method was additionally validated for determination of deltamethrin in incorporated into polypropylene LN (CIPAC/4797/m, as referenced in the specification) and was accepted as provisional CIPAC method in 2011. Bayer CropScience provided also the Meeting with a new method involving extraction by refluxing with xylene, precipitation of the polymer with 2-propanol, filtration and rinsing with acetonitrile, and chromatographic determination by high performance liquid chromatography with UV detection (HPLC-UV). This method was successfully validated and showed comparable results with the provisional CIPAC method.

Special attention needs to be paid to control random variations in the distribution of the insecticide within the net and between nets. The manufacturer provided spatial variation data on 15 nets showing a good within-net homogeneity of the active ingredient content (n= 5, RSD ranging from 2.81 to 7.15%) and also a low between net variability (n=15, RSD = 1.92%). The WHOPEs Phase I and II trials showed also that deltamethrin content complies with the target dose (except for 2 samples which were just below the tolerance lower limit), and that the distribution of deltamethrin within and between nets is homogeneous (WHO 2011).

During the manufacturing process of deltamethrin LN, epimerization of deltamethrin to the (insecticidally inactive) R-alpha isomer may occur. This conversion must be controlled by the manufacturer to avoid losses of active ingredient. This epimer is not a relevant impurity but excessive amount may lead to loss of biological activity. WHOPEs Phase I trial and one WHOPEs Phase II trial showed that deltamethrin R-alpha isomer is less than 10% of the deltamethrin content. Nevertheless, in two of the WHOPEs Phase II trials, the deltamethrin R-alpha isomer content was relatively high (19% of the deltamethrin content) (WHO 2011).

This conversion can also occur if the LN is exposed to excessive heat or UV light during storage or use. The Meeting agreed that the R-alpha isomer should remain designated as a non-relevant impurity and hence remained excluded from the specification. It is however indirectly specified by the content clause in the accelerated storage test, where at least 95% of deltamethrin has still to be present after the test thus limiting the epimerization during storage to a maximum of 5%.

Active ingredient 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 LN, to avoid excessive losses during washing and to provide a reservoir from which the surface is replenished with active ingredient. 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 deltamethrin content and associated biological efficacy of LifeNet® washed up to 60 times (according to the WHO washing procedure). These data showed an exponential decay of the deltamethrin content in function of the number of washes (free-migration stage behaviour) with the exception of the first wash which removes a higher amount of deltamethrin. The regeneration time is less than 24 hours.

Currently (2011), CIPAC is developing a wash method for the determination of the retention behaviour of long-lasting insecticidal mosquito nets. This method is a

further standardisation 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, World Health Organization, Geneva, 2005. Briefly, the retention index is determined by analyzing net samples in triplicate representing wash points 0 and 4 for total active ingredient content and calculating the average retention index using the equation for a free migration stage behaviour (WHO 2008).

The data provided by the manufacturer showed that a deltamethrin retention index of minimum 80% after the first wash and within the range 0.94 to 0.99 for the subsequent washes is adequately supported. WHOPES Phase I data confirmed also these clauses.

Relevant impurities clause

There are no relevant impurities identified in the existing WHO specifications for deltamethrin TC.

Physical properties clauses

The clauses for dimensional stability to washing and bursting strength specify ISO methods. The test method for netting mesh size does not require standardization.

The ± 5 % tolerance for dimensional stability to washing is in agreement with the standard of 5 % given in the LN guideline (FAO/WHO 2010) 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 in a closed glass bottle at 40°C for 8 weeks showing that the determined average deltamethrin content is higher than 95% of the average content found before storage, and that the net still complies with the limit set for the retention index. Moreover the physical properties of the fabric are maintained after the storage stability test. The storage of the LN at 54°C for 14 days showed that the retention index can be lower than the limit specified. The Meeting agreed to include in the specification the testing 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
AQ 009-10 M-413937-01-1	Broda J.	2010	Accelerated storage stability study for 8 weeks at 40°C for deltamethrin LN 0.85A W [Deltamethrin long lasting (incorporated into polypropylene insecticidal mosquito net (LN)]. Report AQ 009-10. BioGenius GmbH, Bergisch-Gladbach, Germany, March 2010.
22357 M-413938-01-1	CRA-W	2010	Determination of deltamethrin in Lifenet [deltamethrin long-lasting (incorporated into polypropylene) insecticidal net (LN)]. Report WHO / RE 22357 / 2010 of the Walloon Agricultural Research Centre, Gembloux, Belgium for WHO, December 10, 2010.
22402 M-413939-01-1	CRA-W	2011	Determination of deltamethrin and its R-alpha isomer in Lifenet® [deltamethrin long-lasting (incorporated into polypropylene) insecticidal net (LN)] : comparative study of 2 analytical methods (extension of CIPAC method 333/LN/(M)/3 and Bayer CropScience method AM013809MF1). Report BAYER / RE 22402 / 2010 of the Walloon Agricultural Research Centre, Gembloux, Belgium for Bayer CropScience, March 11, 2011.
22472 M-413940-01-1 M-413941-01-1 M-413942-01-1	CRA-W	2011	Determination of deltamethrin in LifeNet (deltamethrin long-lasting (incorporated into polypropylene) insecticidal net (LN)). [WHOPEs Phase II testing and evaluation of LifeNet in Benin, India and Tanzania). Reports WHO / RE 22472 / 2011 / 1, 2 & 3 of the Walloon Agricultural Research Centre, Gembloux, Belgium for WHO, May 2011.
22540 M-413943-01-1	CRA-W	2011	Validation of the extension of the CIPAC method 333/LN/(M)/3 (CIPAC/4673/m) for determination of deltamethrin in LifeNet® [deltamethrin long-lasting (incorporated into polypropylene) insecticidal net (LN)]. Report BAYER / RE 22540 / 2011 of the Walloon Agricultural Research Centre, Gembloux, Belgium for Bayer CropScience, June 01, 2011.
	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).
	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).
E-0631-Z-10 M-413953-01-1	Haid H. & Wendtlandt	2010	Determination of selected properties of insecticidal nets according to WHO-instruction (March 2006). Report E-0631-Z-10 from the Institut für Textil- und Verfahrenstechnik (ITV), Central laboratory, Denkendorf, Germany.
E-0212-Z-10 M-413944-01-1	Haid H. & Wendtlandt	2010	Determination of selected properties of insecticidal nets according to WHO-instruction (March 2006). Report E-0212-Z-10 from the Institut für Textil- und Verfahrenstechnik (ITV), Central laboratory, Denkendorf, Germany.
CIPAC/4797/m CIPAC/4798/R	Krautstrunk Gerhard	2011	Validation study for the extension of the scope of CIPAC method 333/LN/(M)/3 (CIPAC/4673) for the determination of deltamethrin in LifeNet® [deltamethrin long-lasting (incorporated into polypropylene) insecticidal net (LN)]. 2011 CIPAC Technical Meeting, CIPAC documents 4797/m and 4798/R.

Study number	Author(s)	Year	Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study
AQ 028-11 M-413946-01-1	Manka S.	2011	Determination of the Retention Index for Deltamethrin LN 0.85B W. Report AQ 028-11. BioGenius GmbH, Bergisch-Gladbach, Germany, March 2011.
AQ 040-11 M-413948-01-1	Manka S.	2011	Storage Stability under Accelerated Conditions. Determination of the Content and Retention Index for Deltamethrin LN 0.85B W stored in Glass Bottles. BioGenius GmbH, Bergisch-Gladbach, Germany, July 2011.
M-364693-01-1	Nentwig G.	2010	Wash resistance of LifeNet® : Wash resistance study of LifeNet® against <i>Anopheles gambiae</i> , susceptible strain KISUMU, according to WHO protocols. Results after 0-60 washes. Report MÜ090818b, BES-03678, M-364693-01-1. Bayer CropScience AG, Monheim, Germany, February 2010.
M-358969-01-1	Odendahl A. & Zitmann W.	2009	Validation of HPLC-method AM013809MF1 – Determination of deltamethrin and its R-alpha isomer in polypropylene matrices – normal phase method – deltamethrin LN 0/85 (8.5 g/kg). Bayer CropScience AG, Development – Formulation Technology, Monheim – Germany, November 2009.
M-366384-01-1	Patty L & Horn K.	2010	LifeNet®. WHOPEs Dossier. Bayer CropScience, March 2010.
M-395535-01-1	Patty L.	2010	LifeNet®. JMPS Dossier. Bayer CropScience, October 2010.
CIPAC/4673/m	Vestergaard- Frandsen	2009	Method extension of CIPAC 333/LN. Determination of deltamethrin in PE by high performance liquid chromatography. 2009 CIPAC Technical Meeting, CIPAC document 4673/m.
CIPAC/4674/R	Vestergaard- Frandsen	2009	Deltamethrin 333/LN. Method extension for polyethylene LN, Validation Data and Statistics. 2009 CIPAC Technical Meeting, CIPAC Document 4674/R.
M-358904-01-1	Zitmann W.	2009	Analytical method AM013809MF1 - Determination of deltamethrin and its R-alpha isomer in polypropylene matrices - Assay HPLC, external standard, normal phase. Bayer CropScience AG, Development – Formulation Technology, Monheim – Germany, November 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	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	2011	Report of the Fourteen WHOPEs Working Group Meeting, WHO/HQ, Geneva, 11-15 April 2011. WHO, Geneva, document WHO/HTM/NTD/WHOPEs/2011.7

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN

FAO/WHO EVALUATION REPORT 333/2010.1

Recommendations

The Meeting recommended the following.

A time-limited interim specification (until August 2013) for deltamethrin long-lasting (incorporated into filaments) insecticidal net, proposed by Intelligent Insect Control and as amended, should be adopted by WHO.

Appraisal

Supporting data and draft specifications for deltamethrin long-lasting (incorporated into filaments) insecticidal net (LN), provided by Intelligent Insect Control, were considered by the Meeting for development of a new WHO specification. Appropriate clauses, limits and methods of testing for certain parameters of this new type of formulation were developed by the company and scientific institutes.

The deltamethrin (incorporated into filaments) LN produced by this manufacturer was tested and evaluated by WHOPES and a time-limited interim recommendation for their use in malaria prevention and control was issued in 2007 (WHO 2008).

A provisional specification guideline for LN formulations was accepted by the JMPS in 2004 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 raschel-warp-knitted fabric in which the active ingredient, deltamethrin, is incorporated into the polymer prior to the spinning process. The yarn is a mixture of high, medium and low density polyethylene monofilament. The manufacturer confirmed that the active ingredient incorporated into the LN is from a source compliant with the existing WHO specification for deltamethrin (Tagros).

Description clause

The Meeting agreed that the specification should be applied to white or coloured raschel-warp-knitted fabrics made from 118 denier monofilament spun from a mixture of high, medium and low density polyethylene yarn and that it should apply equally to made up, ready-to-use nets (rectangular and circular) or to netting in bulk. The supporting data show that the incorporation process (mixing of deltamethrin TC with the high, medium and low density polyethylene) and the subsequent melt-spinning process leads to an increase in the α R-isomer at the expense of deltamethrin, which is a single isomer pyrethroid having α S-configuration. The description clause was therefore slightly modified ("complying with the TC specification prior to incorporation") in order to allow for the higher relative content of

α R-isomer, a non-relevant impurity, as compared to the TC. Initially, a limit for α R-isomer was proposed in the draft specification but the Meeting agreed that it was not necessary and the clause for isomer ratio of the active ingredient was removed.

Active ingredient content clause

The target dose of deltamethrin (1.8 g/kg) is related to the LN technology and the specific insecticidal activity of the active ingredient, in order to achieve a satisfactory biological activity. The target dose on a fabric area basis (68.4 mg/m²) is calculated from measurements of g/kg and fabric density in g/m² which has at least 20 complete holes per cm². 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 control random variations in the distribution of the insecticide over the surface of the net and between nets. The manufacturer provided between- and within-batch data which demonstrated a good homogeneity of the active ingredient content within and between nets (RSD < 5%). The WHOPES Phase I and II data showed also that deltamethrin content complies with the target dose and that the distribution of deltamethrin within and between nets is homogeneous.

Study reports submitted by Intelligent Insect Control to support the specification involved different analytical methods for deltamethrin content. The method involving extraction with hot heptane (existing CIPAC method for permethrin incorporated into filaments) and determination by HPLC with UV detection (existing CIPAC method for deltamethrin coated onto filaments) underestimates the content of insecticide in the LN formulation. Other methods involve extraction by refluxing with xylene and determination by GC-ECD, GC-FID or HPLC-UV or extraction by refluxing with xylene, exchange of solvent to HPLC mobile phase and determination by HPLC-UV. This last method (CIPAC/4673/m) was presented to CIPAC as an extension of the CIPAC method 333/LN/(M)/3 for determination of deltamethrin in incorporated into polyethylene LN by HPLC-UV and was accepted as a provisional CIPAC method in 2009.

Active ingredient retention index clause

An adequate amount of active ingredient must be present on the surface of the LN, for efficacy, whereas the majority must reside within the fibres of the LN, to avoid excessive losses during washing and to provide a reservoir from which the surface is replenished with active ingredient. The nature of the fibre material – a mixture of polyethylenes of different densities – strongly influences the migration of deltamethrin to the surface when the LN is subjected to repeated washing.

Initially the manufacturer provided data for release index which were elaborated with solvent washes using acetone, methanol, hexane or isooctane / dioxane. These data showed release index values (active ingredient surface concentration in the third wash divided by active ingredient surface concentration in the second wash) ranging between 0.75 to 1.02 depending on the solvent used. These results, whatever quite variable due to the method used, indicated nevertheless a quite high retention of deltamethrin in the LN formulation. The Meeting requested the manufacturer to provide retention index data after washing the net with aqueous detergent (instead of solvent) using the WHO/CIPAC method.

Depletion of total active ingredient content by washing (retention index) is now accomplished by analyzing separate washed and unwashed pieces of the same fabric. Currently, CIPAC is developing a wash method for the determination of the retention behaviour of long-lasting insecticidal mosquito nets. This method is a standardisation 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, World Health Organization, Geneva, 2005. Briefly, the retention index is determined by analyzing net samples in triplicate representing wash points 0 and 4 for total active ingredient content and calculating the average retention index using the equation for a free migration stage behaviour.

The manufacturer provided data showing that approximately constant proportions of the remaining deltamethrin are removed from the polymer by successive washings with aqueous detergent (free-migration stage behaviour, WHO 2008). As the diffusion processes in solid materials are significantly slower than in solution, a certain time period (2 days at 40°C) is necessary to re-establish the equilibrium level of the active ingredient on the surface of polymer. Data obtained after 1, 3 and 5 washes showed an average deltamethrin retention index of 0.98 - 0.99 and the Meeting agreed to specify a minimum retention index of 0.95. WHOPES Phase I data supports also this clause.

Relevant impurities clause

There are no relevant impurities identified in the existing WHO specifications for deltamethrin TC. During the manufacturing process of deltamethrin LN, epimerization of deltamethrin to the (insecticidally inactive) α R-isomer may occur. This conversion must be controlled by the manufacturer to avoid losses of active ingredient. Data initially provided by the manufacturer showed that deltamethrin α R isomer content could reach up to 20 % of deltamethrin content. The manufacturer provided further data indicating that the deltamethrin α R-isomer content can be reduced to 10% of the deltamethrin content.

This conversion can also occur if the LN is exposed to excessive heat during storage or use. The Meeting agreed that the α R 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 nets are available in the mesh size 20 complete holes per cm² (136 mesh/inch²). The clauses for dimensional stability to washing and bursting strength specify ISO methods and apply to net in bulk and manufactured nets. The test method for netting mesh size does not require standardization.

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

Storage stability clause

Deltamethrin is normally stable over a very wide temperature range and has low volatility and thus its incorporation into a polymer should provide additional protection to the active ingredient. However, storage of the net (without packaging) in an oven at 54°C for 2 weeks led in a study to a measurable loss of deltamethrin (approximately 8%), although the physical properties of the fabric were maintained. The supporting data showed that the loss of deltamethrin occurs mainly through epimerization to the α R-isomer. The manufacturer provided additional data on the net stored at 54°C for 2 weeks indicating the loss of deltamethrin was less than 5%. The manufacturer and the Meeting finally agreed to include in the specification the standard testing of 54°C for 2 weeks. Data provided for the retention index on the net stored at 54°C for 2 weeks showed a decrease in retention index (average deltamethrin retention index of 0.93-0.97 after 1, 3 and 5 washes), and the Meeting agreed to specify a minimum retention index of 0.90 after the accelerated storage.

ANNEX 1: REFERENCES

Study number	Author(s)	Year	Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study
21353	CRA-W	2006	Determination of deltamethrin in mosquito net samples (32 samples for the WHOPES testing and evaluation of NetProtect. Report WHO / RE 21353 / 2006 of the Walloon Agricultural Research Centre, Gembloux, Belgium for WHO, November 2006.
21469	CRA-W	2007	Deltamethrin content, deltamethrin release characteristics and accelerated storage stability test for NetProtect [deltamethrin long-lasting (incorporated into filaments) mosquito net (LN)]. Report IIC / RE 21469 / 2007 of the Walloon Agricultural Research Centre, Gembloux, Belgium for Intelligent Insect Control, August 2007.
21608	CRA-W	2007	Determination of deltamethrin and deltamethrin R-isomer in NetProtect. Report IIC / RE 21608 / 2007 of the Walloon Agricultural Research Centre, Gembloux, Belgium for Intelligent Insect Control, October 2007.
21609	CRA-W	2007	Determination of deltamethrin in NetProtect (75 samples for the WHOPES testing and evaluation of NetProtect. Report WHO / RE 21609 / 2007 / 1 of the Walloon Agricultural Research Centre, Gembloux, Belgium for WHO, November 2007.
21616	CRA-W	2007	Determination of deltamethrin and deltamethrin R-isomer in NetProtect. Report IIC / RE 21616 / 2007 of the Walloon Agricultural Research Centre, Gembloux, Belgium for Intelligent Insect Control, October 2007.
21672	CRA-W	2008	Determination of deltamethrin and deltamethrin R-isomer in NetProtect: comparison of 2 analytical methods. Report IIC / RE 21672 / 2007 of the Walloon Agricultural Research Centre, Gembloux, Belgium for Intelligent Insect Control, March 2008.
21676	CRA-W	2008	Deltamethrin content, deltamethrin R-isomer content and deltamethrin release characteristics for NetProtect® [deltamethrin long-lasting (incorporated into filaments) insecticidal mosquito net (LN)]. Report IIC / RE 21676 / 2007 of the Walloon Agricultural Research Centre, Gembloux, Belgium for Intelligent Insect Control, August 2008.
CIPAC/4682/m	CRA-W	2009	Determination of deltamethrin and/or piperonyl butoxide in Long-Lasting (incorporated into polyethylene) Insecticidal Mosquito Nets. Analytical method by GC-FID. 2009 CIPAC Technical Meeting, CIPAC Document 4682/m.
CIPAC/4683/R	CRA-W	2009	Determination of deltamethrin and/or piperonyl butoxide in Long-Lasting (incorporated into polyethylene) Insecticidal Mosquito Nets. Validation and performance verification of the analytical method by GC-FID. 2009 CIPAC Technical Meeting, CIPAC Document 4683/R.
22094	CRA-W	2009	Deltamethrin content in samples of masterbatches, socks and PE netting. Report IIC / RE 22094 / 2009 of the Walloon Agricultural Research Centre, Gembloux, Belgium for Intelligent Insect Control, December 2009.
22307	CRA-W	2010	Accelerated storage stability study (deltamethrin content and retention / release index) for NetProtect [deltamethrin long-lasting (incorporated into polyethylene) insecticidal mosquito net (LN)]. Report IIC / RE 22307 / 2010 / 1 of the Walloon Agricultural Research Centre, Gembloux, Belgium for Intelligent Insect Control, July 2010.

	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).
CH:TX:9420056 105	Intelligent Insect Control SGS	2007	Technical data and draft specification submitted by Intelligent Insect Control to WHO for application for WHO specifications, November 2007. Bursting strength, dimensional change after washing, tensile strength, weight per unit area for NetProtect. Report CH:TX:9420056105 for Bestnet Europe Ltd., October 2009.
CIPAC/4673/m	Vestergaard- Frandsen	2009	Method extension of CIPAC 333/LN. Determination of deltamethrin in PE by high performance liquid chromatography. 2009 CIPAC Technical Meeting, CIPAC document 4673/m.
CIPAC/4674/R	Vestergaard- Frandsen	2009	Deltamethrin 333/LN. Method extension for polyethylene LN, Validation Data and Statistics. 2009 CIPAC Technical Meeting, CIPAC Document 4674/R.
	WHO	2005	Guidelines for laboratory and field testing of long-lasting insecticidal mosquito nets. Document WHO/CDS/WHOPES/GCDPP/2005.11. WHO, Geneva, 2005.
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	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.