

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

DELTAMETHRIN

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

**(S)- α -cyano-3-phenoxybenzyl (1R,3R)-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

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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

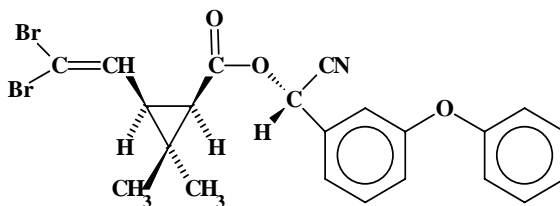
Decamethrin (rejected common name)

Chemical names

IUPAC (S)- α -cyano-3-phenoxybenzyl (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

$C_{22}H_{19}Br_2NO_3$

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 (COATED ONTO FILAMENTS) INSECTICIDAL NETTING

WHO interim specification 333/LN/1 (NETTING) (December 2009*)

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 (333/2006.1, 333/2009.1). 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 (333/2006.1, 333/2009.1), 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 75 or 100 denier multi-filament polyester fibres, treated with 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 shall be suitable for use as an insecticidal net with long-lasting activity (Notes 3 & 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.

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

The deltamethrin content shall be declared 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 Vestergaard Frandsen and commercialized under the trade names PermaNet 2.0 and 2.0 Extra. 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 8)

The measured average retention index of deltamethrin shall be 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.

3 Physical properties

3.1 Netting mesh size

When counted by the method given in Note 9, 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 10)

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

3.3 Bursting strength (Note 11)

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

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 (Note 12), 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:

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

Note 1 The specification applies to netting in bulk. 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 Occasional short lengths of loose thread present in the netting are not considered to be extraneous matter.

Note 3 A long-lasting insecticidal net is expected to retain 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 or decitex) of the fibres cannot be measured in the manufactured net but it should be identified on the packaging.

Note 5 For complete identification and good quantification, deltamethrin (i.e. the [S,1R,3R]-isomer) must be separated from the [R,1R,3R]-isomer (otherwise known as the R-isomer), which is not part of the active ingredient and not a relevant impurity. The isomers may be separated by non-chiral techniques as provided in the CIPAC method for deltamethrin.

Note 6 Each net is expected to conform to the specification and, for the purposes of testing for compliance, material from two or more nets must not be mixed. Samples for testing should be taken in such a way as to be representative of the net or netting material. Unless stated otherwise for the test, samples should be assembled from pieces taken from nets as shown in Figure 1. Samples from bulk netting material should be assembled from similar pieces taken along a suitable diagonal across the netting material. The sizes of pieces should be appropriate to perform the tests required and sufficient for both pre- and post-storage stability tests. Samples for chemical analysis may be cut into 1-2 cm squares and thoroughly mixed, to provide representative test portions (this is not appropriate for tests of some physical properties).

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 (1977).

Note 8 The retention index applies to the average obtained from triplicate tests performed on samples removed from the same net or batch of netting.

Washing should be conducted according to the method given 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 2 and 3 for total deltamethrin content and calculating the amount of insecticide remaining after the additional wash step by expressing the result as a fraction of the amount being present before. A retention index of 0.87 indicates that at least 87 % of the insecticide present in samples washed 2 times is still present after an additional wash step.

Note 9 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 scanning/photocopying 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 rigid sheet, 1-2 mm thick, in or on which an accurately calibrated ($\pm 1\%$ in each dimension) square (e.g. 2 x 2 or 5 x 5 cm) has been cut or 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. If possible, at least one edge of the square to be counted should be aligned with a row of complete holes in the fabric. Count replicate squares in pieces selected according to figure 1 and calculate the average and note the lowest value.

Note 10 Dimensional stability is determined as follows. Method of preparation: ISO 3759 (1995, under revision in 2006). Method of washing: ISO 6330, 8A (2001). Method of calculation: ISO 5077 (1984). Size of test portions: 500 x 500 mm; mark off 350 x 350 mm within the test portion. Test a total of 4 replicate portions, duplicates washed in each of 2 separate loads. Type of washing machine: ISO type A (front loading). Washing programme: ISO type 8A (1 main wash, 3 rinses, 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.

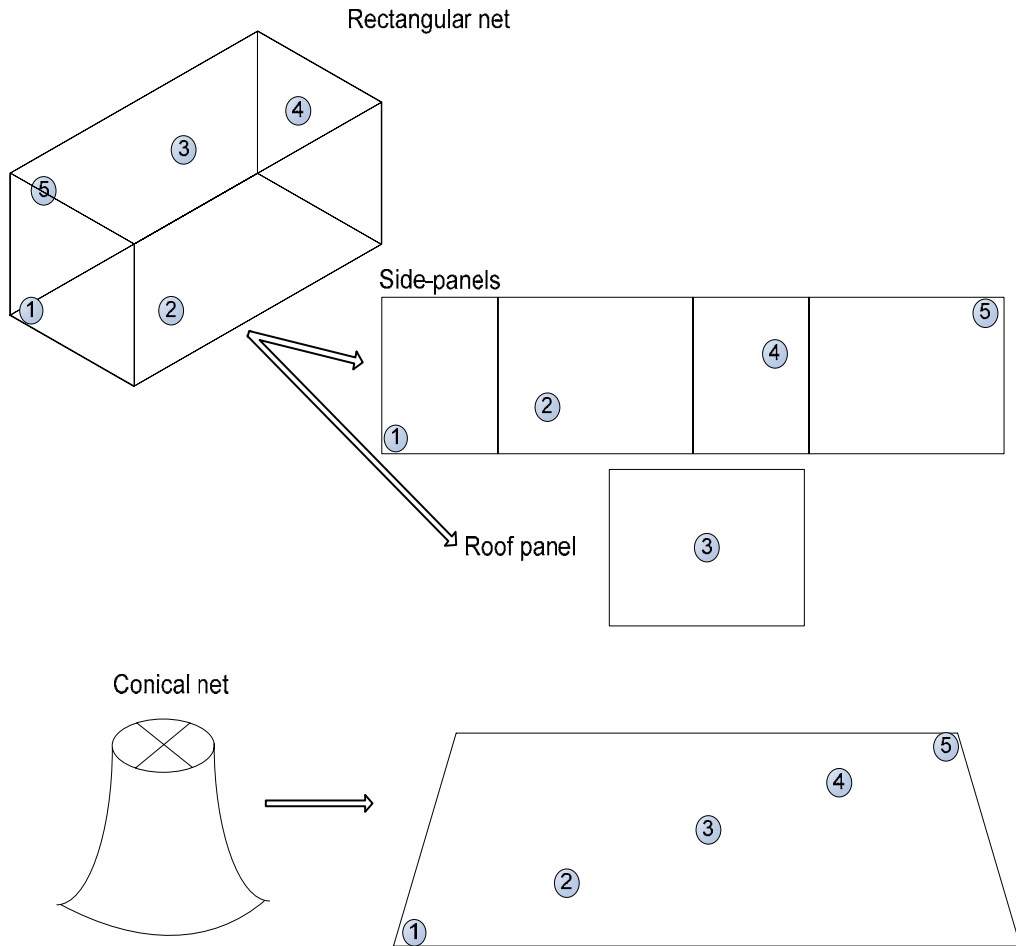
Note 11 ISO 13938 part 1 (1999) and ISO 13938 part 2 (1999), with conditioning of the fabric as specified in the ISO standard. Results should be based tests of 7.3 cm² areas of fabric. Bursting strength is measured separately for the body netting and the strengthened netting. Five replicate tests should be conducted representatively for each part, and the average calculated. The method for testing seam bursting strength is identical to that used to test the fabric, except that 5 replicate tests should be performed with a seam centered on the test head. Up to 5 seams may be tested, to provide the total of 5 measurements.

Note 12 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. The test should be conducted on samples without the presence of packaging material.

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 General method for sampling rectangular and conical nets

The sample should consist of 5 pieces, taken approximately according to the pattern shown in the diagram below. Sufficient material should be taken for all tests and thus the pattern indicated is intended only for general guidance. For most tests, pieces should be taken at least 15 cm from seams or selvages, avoiding folded and creased areas, so as to represent the netting material as fully as possible. To test the bursting strength of seams (clause 3.3), up to 5 seams may be tested, avoiding intersections, to provide a total of 5 measurements.



WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

DELTAMETHRIN LONG-LASTING (COATED ONTO FILAMENTS) INSECTICIDAL NET

WHO interim specification 333/LN/1 (NET) (December 2009*)

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 (333/2006.1, 333/2009.1). 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 (333/2006.1, 333/2009.1), given in PART TWO, forms an integral part of this publication.

1 Description

The product shall be in the form of a finished mosquito net with or without a strengthened 70 cm lower border, complying with the requirements of WHO interim specification for deltamethrin long-lasting (coated onto filaments) insecticidal netting [333/LN/1 (NETTING), December 2009]. The product shall appear clean and shall be free from visible extraneous matter, visible damage 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.

2 Active ingredient

2.1 Deltamethrin content (333/LN/(M)/3, CIPAC Handbook M, p.66, 2009)

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

PermaNet 2.0: 1.8 and 1.4 g/kg, respectively for 75 and 100 denier yarn.

PermaNet 2.0 Extra: 2.8 and 2.1 g/kg, respectively for 75 and 100 denier yarn.

* This specification is applicable to long-lasting insecticidal nettings and nets produced by Vestergaard Frandsen and commercialized under the trade names PermaNet 2.0 and 2.0 Extra. 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/>.

3 Physical properties

3.1 Bursting strength

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

The minimum bursting strength of the fabric in the strengthened 70 cm lower border, if present, shall be declared (not less than 320 or 420 kPa, respectively, for fabric made from 75 or 100 denier yarn) and, when determined, the average shall be not less than that declared.

The average bursting strength of the seams shall be not less than the average for the netting.

DELTAMETHRIN LONG-LASTING (COATED ONTO FILAMENTS) INSECTICIDAL NET

WHO interim specification 333/LN/2 (December 2009*)

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 (333/2009.2). 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 (333/2009.2), 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 75 or 100 denier poly-filament polyester fibres, treated with formulated deltamethrin complying with the requirements of WHO specification 333/SC (April 2005) together with a binder and 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 shall be suitable for use as an insecticidal net with long-lasting activity (Notes 3 & 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.

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

The deltamethrin content shall be declared (2.7 g/kg in 75 denier yarn, 2.0 g/kg in 100 denier yarn) and, when determined, the average measured content shall not differ from that declared by more than $\pm 25\%$.

2.3 Deltamethrin retention index (Note 8)

The measured average retention index of deltamethrin shall be in the range 0.94-0.99.

* This specification is applicable to long-lasting insecticidal nettings and nets produced by Tana Netting Co., Ltd. and commercialized under the trade name DawaPlus 2.0. 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/>.

3 Physical properties

3.1 Netting mesh size

When counted by the method given in Note 9, the netting shall have a minimum of 24 complete holes/cm² and an average in the range 24-26 complete holes/cm².

3.2 Dimensional stability of netting to washing (Note 10)

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

3.3 Bursting strength (Note 11)

The minimum bursting strength of the fabric shall be declared (not less than 250 or 350 kPa, respectively, for fabric made from 75 or 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 $54 \pm 2^{\circ}\text{C}$ for 14 days, the determined average active ingredient content must not be lower than 95% of the average content found before storage (Note 12) and the netting 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 the netting are not considered to be extraneous matter.

Note 3 A long-lasting insecticidal net is expected to retain 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 or decitex) of the fibres cannot be measured in the manufactured net but it should be identified on the packaging.

Note 5 For complete identification and good quantification, deltamethrin (i.e. the [S,1R,3R]-isomer) must be separated from the [R,1R,3R]-isomer (otherwise known as the R-isomer), which is not part of the active ingredient and not a relevant impurity. The isomers may be separated by non-chiral techniques as provided in the CIPAC method for deltamethrin.

Note 6 Each net is expected to conform to the specification and, for the purposes of testing for compliance, material from two or more nets must not be mixed. Samples for testing should be taken in such a way as to be representative of the net or netting material. Unless stated otherwise for the test, samples should be assembled from pieces taken from nets as shown in Figure 1. Samples from bulk netting material should be assembled from similar pieces taken along a suitable diagonal across the netting material. The sizes of pieces should be appropriate to perform the tests required and sufficient for both pre- and post-storage stability tests. Samples for chemical analysis may be cut into 1-2 cm squares and thoroughly mixed, to provide representative test portions (this is not appropriate for tests of some physical properties).

Note 7 The declared values for deltamethrin content in g/kg are equivalent to 80 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 8 The retention index applies to the average obtained from triplicate tests performed on samples removed from the same net or batch of netting.

Washing should be conducted according to the method given 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 2 and 3 for total deltamethrin content and calculating the amount of insecticide remaining after the additional wash step by expressing the result as a fraction of the amount being present before. A retention index of 0.94 indicates that at least 94 % of the insecticide present in samples washed 2 times is still present after an additional wash step.

Note 9 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 scanning/photocopying 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 rigid sheet, 1-2 mm thick, in or on which an accurately calibrated ($\pm 1\%$ in each dimension) square (e.g. 2 x 2 or 5 x 5 cm) has been cut or 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. If possible, at least one edge of the square to be counted should be aligned with a row of complete holes in the fabric. Count replicate squares in pieces selected according to figure 1 and calculate the average and note the lowest value.

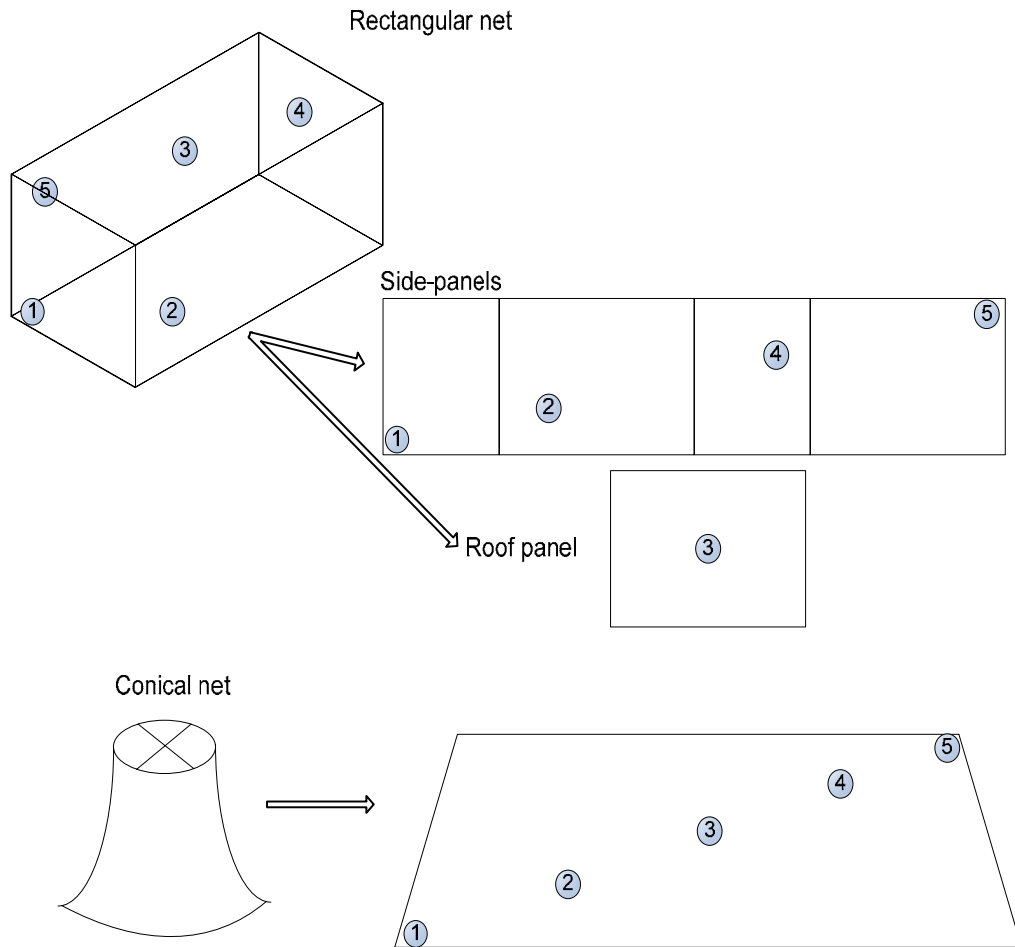
Note 10 Dimensional stability is determined as follows. Method of preparation: ISO 3759 (1995, under revision in 2006). Method of washing: ISO 6330, 8A (2001). Method of calculation: ISO 5077 (1984). Size of test portions: 500 x 500 mm; mark off 350 x 350 mm within the test portion. Test a total of 4 replicate portions, duplicates washed in each of 2 separate loads. Type of washing machine: ISO type A (front loading). Washing programme: ISO type 8A (1 main wash, 3 rinses, 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 11 ISO 13938 part 1 (1999) and ISO 13938 part 2 (1999), with conditioning of the fabric as specified in the ISO standard. Results should be based tests of 7.3 cm² areas of fabric. Bursting strength is measured separately for the body netting and the strengthened netting. Five replicate tests should be conducted representatively for each part, and the average calculated. The method for testing seam bursting strength is identical to that used to test the fabric, except that 5 replicate tests should be performed with a seam centered on the test head. Up to 5 seams may be tested, to provide the total of 5 measurements.

Note 12 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 General method for sampling rectangular and conical nets

The sample should consist of 5 pieces, taken approximately according to the pattern shown in the diagram below. Sufficient material should be taken for all tests and thus the pattern indicated is intended only for general guidance. For most tests, pieces should be taken at least 15 cm from seams or selvages, avoiding folded and creased areas, so as to represent the netting material as fully as possible. To test the bursting strength of seams (clause 3.3), up to 5 seams may be tested, avoiding intersections, to provide a total of 5 measurements.



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EVALUATION REPORTS

DELTAMETHRIN

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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/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/m^2 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 iso-octane / 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. |
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| 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/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 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. |