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## Disclaimer<sup>1</sup>

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

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

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

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

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

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

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<sup>1</sup> 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 1st edition of Manual for Development and Use of FAO and WHO Specifications for Pesticides (2002). This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by WHO and the experts of the “FAO/WHO Joint Meeting on Pesticide Specifications” (JMPS).

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

**Part One:** The Specification of the technical material and the related formulations of the pesticide in accordance with chapters 4 to 9 of the 1<sup>st</sup> edition 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/quality/en/>).

**PART ONE**  
**SPECIFICATIONS**

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# WHO SPECIFICATIONS FOR AGRICULTURAL PESTICIDES

## DELTAMETHRIN

### INFORMATION

#### ISO common names

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

#### Synonyms

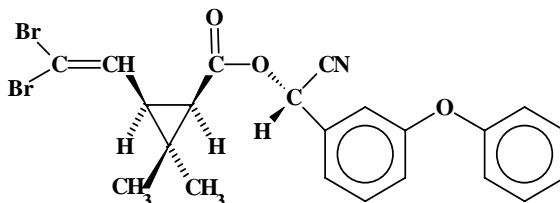
Decamethrin (rejected common name)

#### Chemical names

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

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

#### Structural formula



#### Empirical formula

C<sub>22</sub>H<sub>19</sub>Br<sub>2</sub>NO<sub>3</sub>

#### 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 TECHNICAL MATERIAL

### WHO specification 333/TC (April 2005\*)

*This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (333/2004, 333/2005). It should be applicable to TC produced by these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for TC produced by other manufacturers. The evaluation reports (333/2004, 333/2005), as PART TWO, form an integral part of this publication.*

#### 1 Description

The material shall consist of deltamethrin together with related manufacturing impurities and shall be a white to cream coloured crystalline powder, free from visible extraneous matter and added modifying agents.

#### 2 Active ingredient

##### 2.1 Identity tests (333/TC/M/2, CIPAC Handbook L, p.45, 2006)

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/TC/M/3, CIPAC Handbook L, p.45, 2006)

The deltamethrin content shall be declared (not less than 985 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

#### 3 Relevant impurities (Note 1)

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Note1 There are no relevant impurities to be controlled in products of the manufacturers identified in evaluation reports 333/2004 and 333/2005. However, becisthemic acid chloride [(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxoyl chloride], sometimes spelt bicisthemic acid chloride, can occur as a result of certain manufacturing processes. If this impurity could occur at ≥1 g/kg (of deltamethrin) in the products of other manufacturers, it would be designated as a relevant impurity and a clause would be required to limit its concentration.

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

# WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

## DELTAMETHRIN DUSTABLE POWDER

WHO specification 333/DP (April 2005\*)

*This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (333/2004, 333/2005). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated sources. The specification 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 who use TC from other sources. The evaluation reports (333/2004, 333/2005), as PART TWO, form an integral part of this publication.*

### 1 Description

The material shall consist of a homogeneous mixture of technical deltamethrin, complying with the requirements of WHO specification 333/TC (April 2005), together with carriers and any other necessary formulators. It shall be in the form of a fine, free-flowing powder, free from visible extraneous matter and hard lumps.

### 2 Active ingredient

#### 2.1 Identity tests (333/DP/M/2, CIPAC Handbook L, p.45, 2006)

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/DP/M/3, CIPAC Handbook L, p.45, 2006)

The deltamethrin content shall be declared (g/kg) and, when determined, the average measured content shall not differ from that declared by more than the following tolerance:

Declared content, g/kg	Tolerance
up to 25	± 25% of the declared content
Note: the upper limit is included in the range	

### 3 Relevant impurities (Note 1)

### 4 Physical properties

#### 4.1 pH range (MT 75.3, CIPAC Handbook J, p.131, 2000)

The pH of an aqueous dispersion shall be 4.5 to 7.5.

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

4.2 **Dry sieve test** (MT 59.1, CIPAC Handbook F, p.177, 1995)

Maximum: 2% retained on a 75 µm test sieve.

5 **Storage stability**

5.1 **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% relative to the determined mean content found before storage (Note 2) and the formulation shall continue to comply with the clauses for:

- pH range (4.1);
- dry sieve test (4.2).

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Note 1 There are no relevant impurities to be controlled in products of the manufacturers identified in evaluation reports 333/2004 and 333/2005. However, becisthemic acid chloride [(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxoyl chloride], sometimes spelt bicisthemic acid chloride, can occur as a result of certain manufacturing processes. If this impurity could occur at  $\geq 1$  g/kg (of deltamethrin) in the products of other manufacturers, it would be designated as a relevant impurity and a clause would be required to limit its concentration.

Note 2 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.

# DELTAMETHRIN WETTABLE POWDER

WHO specification 333/WP (September 2005\*)

*This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (333/2004, 333/2005). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated sources. The specification 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 who use TC from other sources. The evaluation reports (333/2004, 333/2005), as PART TWO, form an integral part of this publication.*

## 1 Description

The material shall consist of a homogeneous mixture of technical deltamethrin, complying with the requirements of WHO specification 333/TC (April 2005), together with filler(s) and any other necessary formulators. It shall be in the form of a fine powder free from visible extraneous matter and hard lumps.

## 2 Active ingredient

### 2.1 Identity tests (333/WP/M/2, CIPAC Handbook L, p.45, 2006)

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/WP/M/3, CIPAC Handbook L, p.45, 2006)

The deltamethrin content shall be declared (g/kg) and, when determined, the average measured content shall not differ from that declared by more than the following tolerances:

Declared content, g/kg	Tolerance
up to 25	± 25% of the declared content
above 25 up to 100	± 10% of the declared content
Note: the upper limit is included in each range	

## 3 Relevant impurities (Note 1)

## 4 Physical properties

### 4.1 pH range (MT 75.3, CIPAC Handbook J, p.131, 2000)

The pH of an aqueous dispersion shall be 4.5 to 7.5.

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

4.2 **Wet sieve test** (MT 59.3, CIPAC Handbook F, p.179, 1995)

Maximum: 2% retained on a 75 µm test sieve.

4.3 **Suspensibility** (MT 15.1, CIPAC Handbook F, p.145, 1995) (Notes 2 & 3)

A minimum of 60% of the deltamethrin content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at  $30 \pm 2^\circ\text{C}$  (Note 4).

4.4 **Persistent foam** (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 5)

Maximum: 60 ml after 1 min.

4.5 **Wettability** (MT 53.3, CIPAC Handbook F, p.164, 1995)

The formulation shall be completely wetted in 2 min without swirling.

## 5 Storage stability

5.1 **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% relative to the determined mean content found before storage (Note 6) and the formulation shall continue to comply with the clauses for:

- pH range (4.1);
- wet sieve test (4.2);
- suspensibility (4.3);
- wettability (4.5).

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**Note 1** There are no relevant impurities to be controlled in products of the manufacturers identified in evaluation reports 333/2004 and 333/2005. However, becisthemic acid chloride [(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxoyl chloride], sometimes spelt bicisthemic acid chloride, can occur as a result of certain manufacturing processes. If this impurity could occur at  $\geq 1$  g/kg (of deltamethrin) in the products of other manufacturers, it would be designated as a relevant impurity and a clause would be required to limit its concentration.

**Note 2** The formulation should be tested at the highest and lowest rates of use recommended by the supplier, provided this does not exceed the conditions given in method MT 15.1.

**Note 3** This test will normally only be carried out after the heat stability test, 5.1.

**Note 4** Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, the simpler gravimetric method, MT 168, may be used on a routine basis provided that it has been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".

**Note 5** The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier.

**Note 6** 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.

# WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

## DELTAMETHRIN AQUEOUS SUSPENSION CONCENTRATE

WHO specification 333/SC (April 2005\*)

*This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (333/2004, 333/2005). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated sources. The specification 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 who use TC from other sources. The evaluation reports (333/2004, 333/2005), as PART TWO, form an integral part of this publication.*

### 1 Description

The material shall consist of a suspension of fine particles of technical deltamethrin, complying with the requirements of WHO specification 333/TC (April 2005), in an aqueous phase together with suitable formulants. After gentle agitation the material shall be homogeneous (Note 1) and suitable for further dilution in water.

### 2 Active ingredient

#### 2.1 Identity tests (333/SC/M/2, CIPAC Handbook L, p.45, 2006)

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/SC/M/3, CIPAC Handbook L, p.45, 2006)

The deltamethrin content shall be declared (10 g/kg or g/l at  $20 \pm 2^\circ\text{C}$ , Note 2) and, when determined, the average measured content shall not differ from that declared by more than  $\pm 15\%$ .

### 3 Relevant impurities (Note 3)

### 4 Physical properties

#### 4.1 pH range (MT 75.3, CIPAC Handbook J, p.131, 2000)

The pH of an aqueous dispersion shall be 4.5 to 7.5.

#### 4.2 Pourability (MT 148, CIPAC Handbook F, p.348, 1995)

Maximum "residue": 5%.

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

**4.3 Spontaneity of dispersion** (MT 160, CIPAC Handbook F, p.391, 1995)  
(Note 4)

A minimum of 90% of the deltamethrin content found under 2.2 shall be in suspension after 5 min in CIPAC Standard Water D at  $30 \pm 2^\circ\text{C}$ .

**4.4 Suspensibility** (MT 161, CIPAC Handbook F, p.394, 1995) (Note 4)

A minimum of 90% of the deltamethrin content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at  $30 \pm 2^\circ\text{C}$ .

**4.5 Wet sieve test** (MT 185, CIPAC Handbook K, p.148, 2003)

Maximum: 2% retained on a 75  $\mu\text{m}$  test sieve.

**4.6 Persistent foam** (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 5)

Maximum: 50 ml after 1 min.

## 5 Storage stability

**5.1 Stability at  $0^\circ\text{C}$**  (MT 39.3, CIPAC Handbook J, p.126, 2000)

After storage at  $0 \pm 2^\circ\text{C}$  for 7 days, the formulation shall continue to comply with the clauses for:

- suspensibility (4.4);
- wet sieve test (4.5).

**5.2 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% relative to the determined mean content found before storage (Note 6) and the formulation shall continue to comply with the clauses for:

- pH range (4.1);
- pourability (4.2);
- spontaneity of dispersion (4.3);
- suspensibility (4.4);
- wet sieve test (4.5).

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**Note 1** Before sampling to verify the formulation quality, inspect the commercial container carefully. On standing, suspension concentrates usually develop a concentration gradient from the top to the bottom of the container. This may even result in the appearance of a clear liquid on the top and/or of sediment on the bottom. Therefore, before sampling, homogenize the formulation according to the instructions given by the manufacturer or, in the absence of such instructions, by gentle shaking of the commercial container (for example by inverting the closed container several times). Large containers must be opened and stirred adequately. After this procedure, the container should not contain a sticky layer of non-dispersed matter at the bottom. A suitable and simple method of checking for a non-dispersed sticky layer "cake" is by probing with a glass rod or similar device adapted to the size and shape of the container. All the physical and chemical tests must be carried out on a laboratory sample taken after the recommended homogenization procedure.

**Note 2** Unless homogenization is carried out carefully, it is possible for the sample to become aerated. This can lead to errors in the determination of the mass per millilitre and in calculation of the active ingredient content (in g/l) if methods other than MT 3.3 are used. If

the buyer requires both g/kg and g/l at 20°C, then in case of dispute the analytical results shall be calculated as g/kg.

Note 3 There are no relevant impurities to be controlled in products of the manufacturers identified in evaluation reports 333/2004 and 333/2005. However, becisthemic acid chloride [(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxoyl chloride], sometimes spelt bicisthemic acid chloride, can occur as a result of certain manufacturing processes. If this impurity could occur at  $\geq 1$  g/kg (of deltamethrin) in the products of other manufacturers, it would be designated as a relevant impurity and a clause would be required to limit its concentration.

Note 4 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, the simpler gravimetric method, MT 168, may be used on a routine basis provided that it has been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".

Note 5 The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier.

Note 6 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.

# WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

## DELTAMETHRIN EMULSIFIABLE CONCENTRATE

WHO specification 333/EC (April 2005\*)

*This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (333/2004, 333/2005). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated sources. The specification 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 who use TC from other sources. The evaluation reports (333/2004, 333/2005), as PART TWO, form an integral part of this publication.*

### 1 Description

The material shall consist of technical deltamethrin, complying with the requirements of WHO specification 333/TC (April 2005), dissolved in suitable solvents, together with any other necessary formulants. It shall be in the form of a stable homogeneous liquid, free from visible suspended matter and sediment, to be applied as an emulsion after dilution in water.

### 2 Active ingredient

#### 2.1 Identity tests (333/EC/M/2, CIPAC Handbook L, p.45, 2006)

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/EC/M/3, CIPAC Handbook L, p.45, 2006)

The deltamethrin content shall be declared (g/kg or g/l at  $20 \pm 2^\circ\text{C}$ , Note 1) and, when determined, the average measured content shall not differ from that declared by more than the following tolerances:

Declared content, g/kg or g/l at $20 \pm 2^\circ\text{C}$	Tolerance
up to 25	$\pm 15\%$ of the declared content
above 25 up to 100	$\pm 10\%$ of the declared content
above 100 up to 250	$\pm 6\%$ of the declared content
Note: the upper limit is included in each range	

### 3 Relevant impurities (Note 2)

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

#### 4 Physical properties

##### 4.1 pH range (MT 75.3, CIPAC Handbook J, p.131, 2000)

The pH of an aqueous dispersion shall be 4.5 to 7.5.

##### 4.2 Emulsion stability and re-emulsification (MT 36.1.1, CIPAC Handbook F, p.108, 1995) (Note 3)

The formulation, when diluted at  $30 \pm 2^\circ\text{C}$  with CIPAC Standard Waters A and D, shall comply with the following:

Time after dilution	Limits of stability
0 h	Initial emulsification complete
0.5 h	Cream: none
2.0 h	"Cream", maximum: 1 ml "Free oil": none
24 h	Re-emulsification complete
24.5 h	"Cream": none "Free oil": none.

Note: tests at 24 h are required only where the results at 2 h are in doubt.

##### 4.3 Persistent foam (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 4)

Maximum: 50 ml after 1 min.

#### 5 Storage stability

##### 5.1 Stability at $0^\circ\text{C}$ (MT 39.3, CIPAC Handbook J, p.126, 2000)

After storage at  $0 \pm 2^\circ\text{C}$  for 7 days, the volume of solid and/or liquid which separates shall not be more than 0.3 ml.

##### 5.2 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% relative to the determined average content found before storage (Note 5) and the formulation shall continue to comply with the clauses for:

- pH range (4.1);
- emulsion stability and re-emulsification (4.2).

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**Note 1** If the buyer requires both g/kg and g/l at  $20^\circ\text{C}$ , then in case of dispute the analytical results shall be calculated as g/kg.

**Note 2** There are no relevant impurities to be controlled in products of the manufacturers identified in evaluation reports 333/2004 and 333/2005. However, becisthemic acid chloride [(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxoyl chloride], sometimes spelt bicisthemic acid chloride, can occur as a result of certain manufacturing processes. If this impurity could

occur at  $\geq 1$  g/kg (of deltamethrin) in the products of other manufacturers, it would be designated as a relevant impurity and a clause would be required to limit its concentration.

Note 3 This test will normally only be carried out after the heat stability test: 5.2.

Note 4 The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier.

Note 5 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.

# DELTAMETHRIN ULTRA LOW VOLUME LIQUID

WHO specification 333/UL (September 2005\*)

*This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (333/2004, 333/2005). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated sources. The specification 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 who use TC from other sources. The evaluation reports (333/2004, 333/2005), as PART TWO, form an integral part of this publication.*

## 1 Description

The material shall consist of technical deltamethrin, complying with the requirements of WHO specification 333/TC (April 2005), together with any necessary formulants (Note 1). It shall be in the form of a stable homogeneous liquid, free from visible suspended matter and sediment.

## 2 Active ingredient

### 2.1 Identity tests (333/UL/M/2, CIPAC Handbook L, p.45, 2006)

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/UL/M/3, CIPAC Handbook L, p.45, 2006)

The deltamethrin content shall be declared (g/kg or g/l at  $20 \pm 2^\circ\text{C}$ , Note 2) and, when determined, the average measured content shall not differ from that declared by more than the following tolerances:

Declared content, g/kg or g/l at $20 \pm 2^\circ\text{C}$	Tolerance
up to 25	$\pm 15\%$ of the declared content
above 25 up to 100	$\pm 10\%$ of the declared content
Note: the upper limit is included in each range	

## 3 Relevant impurities (Note 3)

## 4 Physical properties (Notes 4 & 5)

### 4.1 pH range (MT 75.3, CIPAC Handbook J, p.131, 2000)

The pH of an aqueous dispersion shall be 4.5 to 7.5.

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

## 5 Storage stability

### 5.1 Stability at 0°C (MT 39.3, CIPAC Handbook J, p.126, 2000)

After storage at  $0 \pm 2^\circ\text{C}$  for 7 days, no separation of solid and/or oily material shall occur.

### 5.2 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% relative to the determined average content found before storage (Note 6) and the formulation shall continue to comply with the clause for:

- pH range (4.1).

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**Note 1** Although it is not included in this specification, the flash point of the product shall comply with national and/or international transport regulations for flammable materials.

**Note 2** If the buyer requires both g/kg and g/l at  $20^\circ\text{C}$ , then in case of dispute the analytical results shall be calculated as g/kg.

**Note 3** There are no relevant impurities to be controlled in products of the manufacturers identified in evaluation reports 333/2004 and 333/2005. However, becisthemic acid chloride [(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxoyl chloride], sometimes spelt bicisthemic acid chloride, can occur as a result of certain manufacturing processes. If this impurity could occur at  $\geq 1$  g/kg (of deltamethrin) in the products of other manufacturers, it would be designated as a relevant impurity and a clause would be required to limit its concentration.

**Note 4** Viscosity can be critically important for successful application of a UL formulation but the requirements are dependent upon both the formulation and the application technique or equipment. For this reason, no clause is provided for kinematic viscosity.

**Note 5** Loss of droplet mass by volatilisation can be critical for UL formulations because, if the losses are significant, the proportion of the spray which drifts from the target, and the distance over which the drift occurs, is likely to increase. The volatilization and additional drift that occur in practice are dependent on the initial droplet size spectrum and the height through which droplets fall, the air temperature and wind speed. In addition, a degree of volatilization which may be unacceptable for one type of application may be of little or no consequence in another case. At present, no method is available to allow measurement of loss by volatilization to be related to the potential increase in drift and therefore no clause is provided for volatility.

**Note 6** 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.

# WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

## DELTAMETHRIN WATER DISPERSIBLE GRANULES

WHO specification 333/WG (April 2005\*)

*This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (333/2004, 333/2005). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated sources. The specification 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 who use TC from other sources. The evaluation reports (333/2004, 333/2005), as PART TWO, form an integral part of this publication.*

### 1 Description

The material shall consist of a homogeneous mixture of technical deltamethrin, complying with the requirements of the WHO specification 333/TC (April 2005), together with carriers and any other necessary formulants. It shall be in the form of granules for application after disintegration and dispersion in water. The formulation shall be dry, free-flowing, essentially non-dusty, and free from visible extraneous matter and hard lumps.

### 2 Active ingredient

#### 2.1 Identity tests (333/WG/M/2, CIPAC Handbook L, p.45, 2006, Note 1)

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/WG/M/3, CIPAC Handbook L, p.45, 2006, Note 1)

The deltamethrin content shall be declared (g/kg) and, when determined, the average measured content shall not differ from that declared by more than the following tolerances:

Declared content, g/kg	Tolerance
up to 25	± 25% of the declared content
above 25 up to 100	± 10% of the declared content
above 100 up to 250	± 6% of the declared content

Note: the upper limit is included in each range

### 3 Relevant impurities (Note 2)

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

#### 4 Physical properties

- 4.1 **Acidity** (MT 31, CIPAC Handbook F, p.96, 1995)  
Maximum acidity: 5 g/kg calculated as H<sub>2</sub>SO<sub>4</sub>.
- 4.2 **Wettability** (MT 53.3, CIPAC Handbook F, p.165, 1995)  
The formulation shall be completely wetted in 1 min without swirling.
- 4.3 **Wet sieve test** (MT 167, CIPAC Handbook F, p.416, 1995)  
Maximum: 1% retained on a 75 µm test sieve.
- 4.4 **Degree of dispersion** (MT 174, CIPAC Handbook F, p.435, 1995)  
Dispersibility: minimum 90% after 2 min stirring.
- 4.5 **Suspensibility** (MT 168, CIPAC Handbook F, p.417, 1995) (Note 3)  
A minimum of 70% shall be in suspension after 30 minutes in CIPAC Standard Water D at 30 ± 2°C.
- 4.6 **Persistent foam** (MT 47.2, CIPAC Handbook F, p.152, 1995)  
Maximum: 40 ml after 1 min.
- 4.7 **Dustiness** (MT 171, CIPAC Handbook F, p.425, 1995) (Note 4)  
Essentially non-dusty.
- 4.8 **Flowability** (MT 172, CIPAC Handbook F, p.430, 1995)  
At least 99% of the formulation shall pass through a 5 mm test sieve after 20 drops of the sieve.

#### 5 Storage stability

- 5.1 **Stability at elevated temperature** (MT 46.3, CIPAC Handbook J, p.128, 2000)

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 95% relative to the determined average content found before storage (Note 5) and the formulation shall continue to comply with the clauses for:

- acidity (4.1);
- wet sieve test (4.3);
- degree of dispersion (4.4);
- suspensibility (4.5);
- dustiness (4.7).

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**Note 1** The collaboratively tested method for analysis of wettable powders (WP) is applicable to water dispersible granules (WG). It is, however, recommended that samples be ground to a powder prior to analysis.

**Note 2** There are no relevant impurities to be controlled in products of the manufacturers identified in evaluation reports 333/2004 and 333/2005. However, becisthemic acid chloride [(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxyl chloride], sometimes spelt bicisthemic acid chloride, can occur as a result of certain manufacturing processes. If this impurity could occur at ≥1 g/kg (of deltamethrin) in the products of other manufacturers, it would be designated as a relevant impurity and a clause would be required to limit its concentration.

Note 3 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, the simpler gravimetric method, MT 168, may be used on a routine basis provided that it has been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".

Note 4 Measurement of dustiness must be carried out on the sample "as received" and, where practicable, the sample should be taken from a newly opened container, because changes in the water content of samples may influence dustiness significantly. The optical method, MT 171, usually shows good correlation with the gravimetric method and can, therefore, be used as an alternative where the equipment is available. Where the correlation is in doubt, it must be checked with the formulation to be tested. In case of dispute the gravimetric method shall be used.

Note 5 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.

# WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

## DELTAMETHRIN EMULSION, OIL IN WATER

WHO specification 333/EW (April 2006\*)

*This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (333/2004, 333/2005). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated sources. The specification 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 who use TC from other sources. The evaluation reports (333/2004, 333/2005), as PART TWO, form an integral part of this publication.*

### 1 Description

The formulation shall consist of an emulsion of technical deltamethrin, complying with the requirements of WHO specification 333/TC (April 2005), in an aqueous phase together with suitable formulants. After gentle agitation, the formulation shall be homogeneous (Note 1) and suitable for dilution in water.

### 2 Active ingredient

#### 2.1 Identity tests (333/EW/M/2, CIPAC Handbook L, p.45, 2006)

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/EW/M/3, CIPAC Handbook L, p.45, 2006)

The deltamethrin content shall be declared (20 g/kg or g/l at  $20 \pm 2^\circ\text{C}$ , Note 2) and, when determined, the mean measured content shall not differ from that declared by more than  $\pm 15\%$ .

### 3 Relevant impurities (Note 3)

### 4 Physical properties

#### 4.1 pH range (MT 75.3, CIPAC Handbook J, p.131, 2000)

The pH of an aqueous dispersion shall be 4.5 to 7.5.

#### 4.2 Pourability (MT 148, CIPAC Handbook F, p.348, 1995)

Maximum "residue": 5%

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

4.3 **Emulsion stability and re-emulsification** (MT 36.1, CIPAC Handbook F, p. 108, 1995) (Note 4)

The formulation, when diluted at  $30 \pm 2^\circ\text{C}$  (Note 5) with CIPAC standard waters A and D, shall comply with the following:

Time after dilution	Limits of stability
0 h	Initial emulsification complete
0.5 h	Cream: none
2.0 h	"Cream": none "Free oil": none
24 h	Re-emulsification complete
24.5 h	"Cream": none "Free oil": none.

Note: tests at 24 h are required only where the results at 2 h are in doubt.

4.4 **Persistent foam** (MT 47.2, CIPAC Handbook F, p. 152, 1995) (Note 6)

Maximum: 20 ml after 1 min.

5 **Storage stability**

5.1 **Stability at  $0^\circ\text{C}$**  (MT 39.3, CIPAC Handbook J, p.126, 2000)

After storage at  $0 \pm 2^\circ\text{C}$  for 7 days, no separation of particulate or oily matter shall be visible after gentle agitation.

5.2 **Stability at elevated temperature** (MT 46.3, CIPAC Handbook J, p.128, 2000)

After storage  $54 \pm 2^\circ\text{C}$  for 14 days the determined average active ingredient content must not be lower than 95%, relative to the determined average content found before storage (Note 7), and the formulation shall continue to comply with the clauses for:

- pH range (4.1),
- emulsion stability and re-emulsification (4.3).

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**Note 1** All physical and chemical tests listed in this specification are to be performed with a laboratory sample taken after the recommended homogenisation procedure.

Before sampling to verify the formulation quality, the commercial container must be inspected carefully. On standing, emulsions may develop a concentration gradient which could even result in the appearance of a clear liquid on the top (sedimentation of the emulsion) or on the bottom (creaming up of the emulsion). Therefore, before sampling, the formulation must be homogenised according to the instructions given by the manufacturer or, in the absence of such instructions, by gentle shaking of the commercial container (for example, by inverting the closed container several times). Large containers must be opened and stirred adequately.

- Note 2 If the buyer requires both g/kg and g/l at 20°C, then in case of dispute the analytical results shall be calculated as g/kg.
- Note 3 There are no relevant impurities to be controlled in products of the manufacturers identified in evaluation reports 333/2004 and 333/2005. However, becisthemic acid chloride [(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxoyl chloride], sometimes spelt bicisthemic acid chloride, can occur as a result of certain manufacturing processes. If this impurity could occur at ≥1 g/kg (of deltamethrin) in the products of other manufacturers, it would be designated as a relevant impurity and a clause would be required to limit its concentration.
- Note 4 This test will normally be carried out only after the test of stability at elevated temperature (5.2).
- Note 5 The formulation should be tested at the highest and lowest rates of use recommended by the supplier.
- Note 6 The test should be carried out at the highest application concentration.
- Note 7 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.

# WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

## DELTAMETHRIN LONG-LASTING (COATED) INSECTICIDAL NET

WHO specification 333/LN (August 2006\*)

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

### 1 Description

The material shall consist of netting (Note 1), formed from knitted poly-filament polyester fibres, treated with technical deltamethrin complying with WHO specification 333/TC (April 2005) together with any necessary stabilizers, plasticizers and other formulants. The product shall appear clean, free from visible extraneous matter (Note 2), free from 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). 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 333/LN/M/2) (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 Total deltamethrin content (CIPAC 333/LN/M/3) (Notes 5, 6, 7 & 8)

The deltamethrin content shall be declared (0.9 g/kg in 150 denier yarn, 1.4 g/kg in 100 denier yarn, 1.8 g/kg in 75 denier yarn) and, when determined, the average content measured shall not differ from that declared by more than  $\pm 25\%$ .

#### 2.3 Deltamethrin release characteristics (CIPAC Handbook, Note 9)

The measured average retention index of deltamethrin shall be not less than 80% (Note 10).

### 3 Relevant impurities (Note 11)

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

## 4 Physical properties

### 4.1 Netting mesh size

When counted by the method given in Note 12, the netting shall have a minimum of 24 complete holes/cm<sup>2</sup> and an average in the range 24-26 complete holes/cm<sup>2</sup>.

### 4.2 Dimensional stability of netting to washing (Note 13)

Dimensional stability (warp and weft): not exceeding  $\pm 10\%$  of the initial dimensions.

### 4.3 Bursting strength (Note 14)

The minimum bursting strength of the fabric shall be declared (not less than 250, 350 or 400 kPa, respectively, for fabric made from 75, 100 or 150 denier yarn) and, when determined, the average shall be not less than that declared.

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

## 5 Storage stability

### 5.1 Stability at elevated temperature (MT 46.3, CIPAC Handbook J, p.128, 2000)

After storage at  $40 \pm 2^\circ\text{C}$  for 8 weeks (Note 15), the determined average active ingredient content must not be lower than 95% of the average content found before storage (Note 16) and the netting shall continue to comply with the clauses for:

- retention index (2.3);
- dimensional stability (4.2);
- bursting strength (4.3).

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**Note 1** The specification applies to netting, in bulk, and to made up bed nets, which may be rectangular or circular in design. The nets or netting may be white or uniformly 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 made up nets 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 through a number of washes. The clause for deltamethrin release 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.

**Note 6** Methods for the identification and determination of deltamethrin content in various formulations are available in CIPAC Handbook L, p.45, 2006. Extension of the method to

LN was adopted by CIPAC in 2006, but the extension is not yet published in a Handbook. Prior to publication of the Handbook, copies of the method for analysis of LN may be obtained through the CIPAC website, <http://www.cipac.org>.

- Note 7** 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. Unless stated otherwise for the test, samples should be assembled from pieces taken from nets as shown in Figure 1. Samples from bulk netting should be assembled from similar pieces taken along a suitable diagonal across the netting. The sizes of pieces should be appropriate to the tests required and sufficient for both pre- and post-storage stability tests. Samples for chemical analysis may be cut into 1-2cm squares and thoroughly mixed, to provide representative test portions (this is not appropriate for tests of some physical properties).
- Note 8** The declared values for deltamethrin content in g/kg are equivalent to 55 mg/m<sup>2</sup> in each case. The deltamethrin content may be declared as both g/kg and mg/m<sup>2</sup> but, in cases of dispute, g/kg values shall be used. If the active ingredient content is also specified as mg/m<sup>2</sup> of netting, the actual content on this basis is calculated from the measured values for active ingredient content in g/kg and mass of net/m<sup>2</sup>. Mass of net/m<sup>2</sup> should be determined according to ISO 3801 (1977).
- Note 9** The test method for determination of deltamethrin retention index was adopted by CIPAC in 2006 but it is not yet published in a Handbook. Prior to publication of the Handbook, copies of the method may be obtained through the CIPAC website, <http://www.cipac.org>.
- Note 10** The minimum of 80% retention index applies to the average obtained from triplicate tests performed on samples removed from the same net or batch of netting.
- Note 11** There are no relevant impurities to be controlled in products of the manufacturer identified in evaluation reports 333/2004 and 333/2005. However, becisthemic acid chloride [(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxoyl chloride], sometimes spelt bicisthemic acid chloride, can occur as a result of certain manufacturing processes. If this impurity could occur at ≥1 g/kg (of deltamethrin) in the products of other manufacturers, it would be designated as a relevant impurity and a clause would be required to limit its concentration.
- Note 12** 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 (±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 practicable, at least one edge of the square to be counted should be aligned with a row of complete holes in the fabric. Count 5 replicate squares in pieces selected according to figure 1, calculate the average and note the lowest value.
- Note 13** Dimensional stability is determined as follows. Method of preparation: ISO 3759 (1995, under revision in 2006). Method of washing: ISO 6330 (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 6A (1 main wash, 3 rinses, 40°C). Fill the washer with dummy load (with fabric as per ISO standard) up to the standard of 2 to 4 kg. Each test portion should be washed in a bag, to avoid stretching of the fabric. Drying: flat drying.
- Note 14** 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 cm<sup>2</sup> areas of fabric. Five replicate tests should be conducted on samples taken according to Figure 1 and the average calculated.

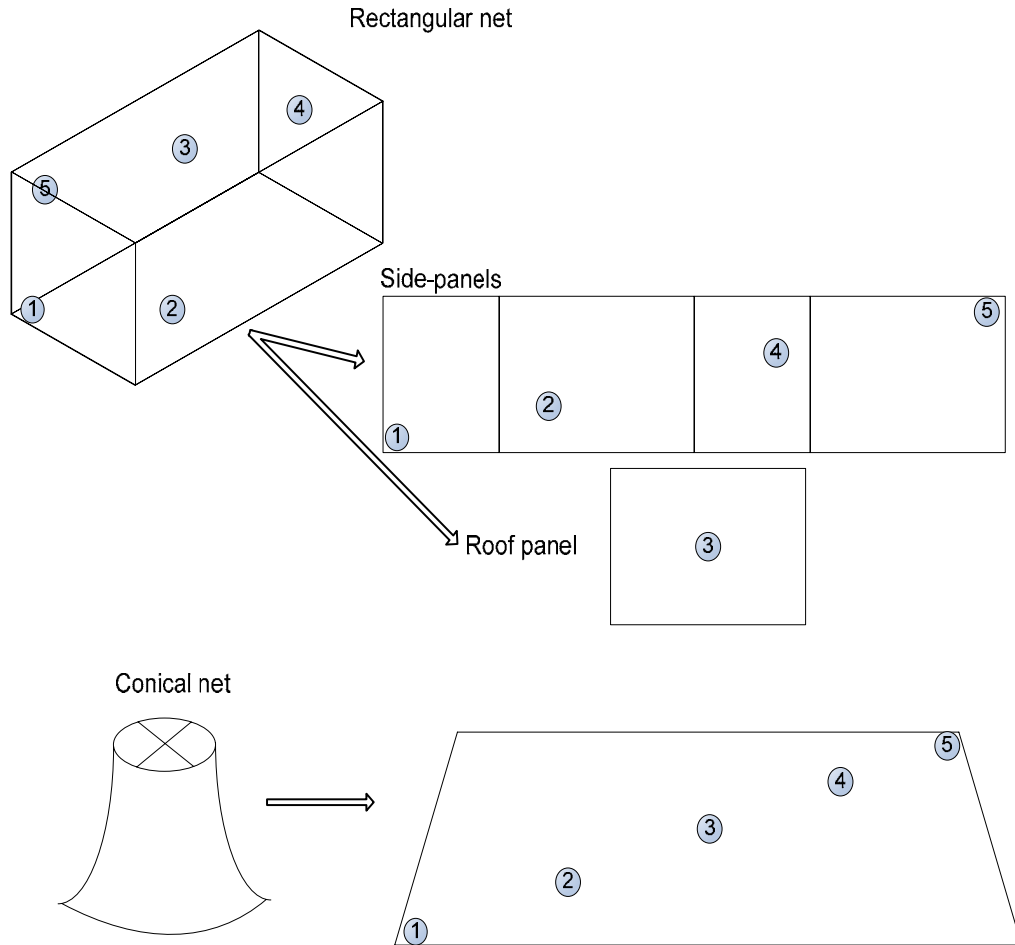
The method for testing seam bursting strength is identical to that used to test the fabric, except that 5 replicate tests should be performed with a seam centred on the test head. Up to 5 seams may be tested, to provide the total of 5 measurements.

**Note 15** 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 16** 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 15cm 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.



## PART TWO

### EVALUATION REPORTS

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# 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 ( $55 \text{ mg/m}^2$ ) but it differs when expressed as g/kg. The  $\text{mg/m}^2$  value is calculated from measurements of g/kg and

fabric density in g/m<sup>2</sup>. The Meeting agreed that the declared and tolerance values should be based on g/kg, with the corresponding mg/m<sup>2</sup> 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 cm<sup>2</sup> 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 cm<sup>2</sup> 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 333B/2006.1**

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**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/m<sup>2</sup> 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 <sup>st</sup> 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.













































