

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

**PERMETHRIN
(40:60 *cis:trans* isomer ratio)**

**LONG-LASTING (INCORPORATED INTO
FILAMENTS) INSECTICIDAL NET**

3-phenoxybenzyl (1*RS*,3*RS*;1*RS*,3*SR*)-3-(2,2 dichlorovinyl)-
2,2-dimethyl-cyclopropane carboxylate



**World Health
Organization**

TABLE OF CONTENTS

	Page
DISCLAIMER	3
INTRODUCTION	4
PART ONE	
SPECIFICATIONS FOR PERMETHRIN	
40:60 <i>cis:trans</i> PERMETHRIN INFORMATION	6
40:60 <i>cis:trans</i> PERMETHRIN LONG-LASTING (INCORPORATED INTO FILAMENTS) INSECTICIDAL NET (APRIL 2014)	8
PART TWO	
EVALUATIONS OF PERMETHRIN	
2013 FAO/WHO EVALUATION REPORT ON PERMETHRIN LONG-LASTING (INCORPORATED INTO FILAMENTS) INSECTICIDAL NET	13
ANNEX 1: REFERENCES	15
2006 FAO/WHO EVALUATION REPORT ON PERMETHRIN LONG-LASTING (INCORPORATED INTO FILAMENTS) INSECTICIDAL NET	16
SUPPORTING INFORMATION	19
ANNEX 1: REFERENCES	21

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

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

¹ This disclaimer applies to all specifications published by WHO.

INTRODUCTION

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

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

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

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

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

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

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

* Footnote: The publications are available on the Internet under (<http://www.who.int/whopes/quality/en/>).

PART ONE
SPECIFICATIONS

	Page
PERMETHRIN	
40:60 <i>cis:trans</i> PERMETHRIN INFORMATION	6
40:60 <i>cis:trans</i> PERMETHRIN LONG-LASTING (INCORPORATED INTO FILAMENTS) INSECTICIDAL NET (APRIL 2014)	8

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

40:60 *cis:trans* PERMETHRIN

INFORMATION

ISO common names

permethrin (E-ISO), permethrine (F-ISO)

Synonyms

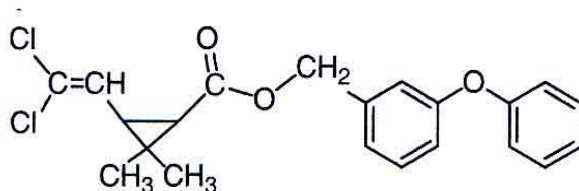
none

Chemical names

IUPAC: 3-phenoxybenzyl (1*RS*,3*RS*;1*RS*,3*SR*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate

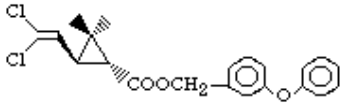
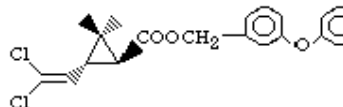
CA: (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate

Structural formula

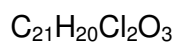


Two pairs of diastereomers (each consisting of a racemic pair of enantiomers; see below) are present in a ratio of approximately 40:60

SI No	Name of isomer	Structure	Proportions
1	1 <i>R</i> , <i>cis</i>	<p>(2) (1<i>R</i>, <i>cis</i>)</p>	sum ≈ 40%
2	1 <i>S</i> , <i>cis</i>	<p>(4) (1<i>S</i>, <i>cis</i>)</p>	

3	1R, <i>trans</i>	 <p>(1) (1R, <i>trans</i>)</p>	sum ≈ 60%
4	1S, <i>trans</i>	 <p>(3) (1S, <i>trans</i>)</p>	

Molecular formula



Relative molecular mass

391.3

CAS Registry number

52645-53-1

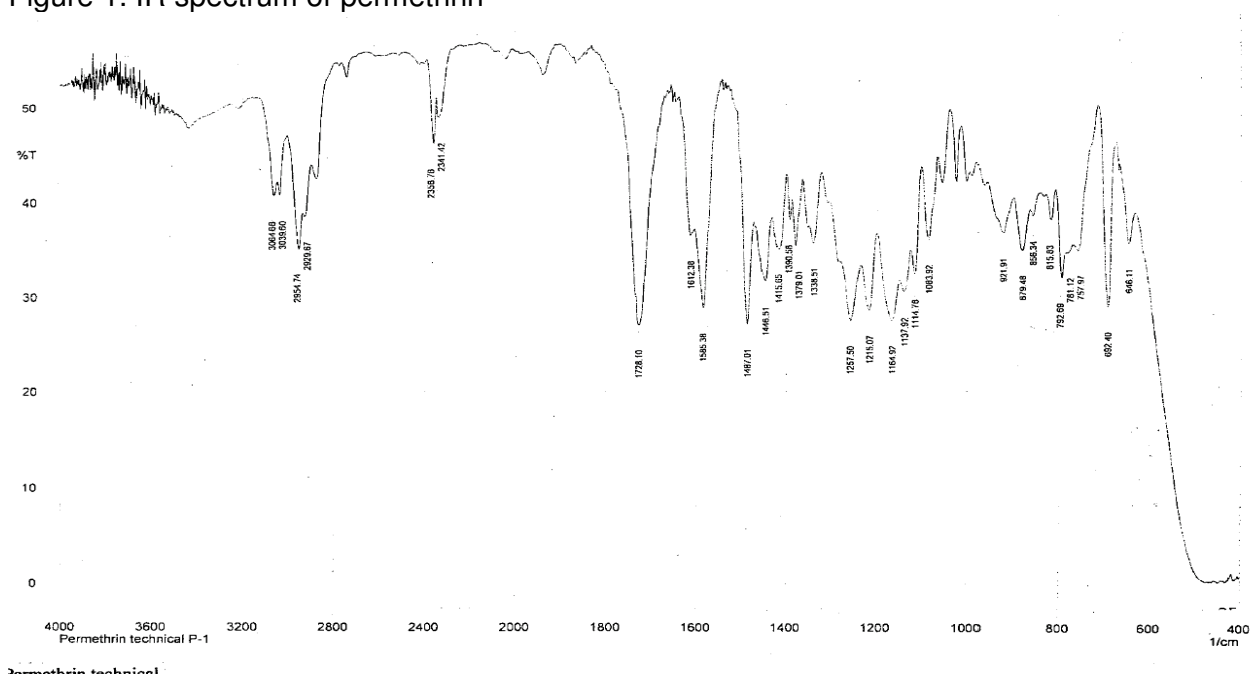
CIPAC number

331

Identity tests

GC retention time, IR spectrum

Figure 1. IR spectrum of permethrin



WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

40:60 *cis:trans* PERMETHRIN LONG-LASTING (INCORPORATED INTO FILAMENTS) INSECTICIDAL NET

WHO specification 331/LN (April 2014*)

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 (331/2006, 331/2013). 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 (331/2006, 331/2013), given in PART TWO, form an integral part of this publication.

1 Description

The product shall be in the form of netting (Note 1), consisting of 150 denier mono-filament, polyethylene fibres, incorporating technical permethrin complying with the requirements of WHO specification 331/TC (October 2013) 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 (331/LN/M/2, CIPAC Handbook M, p. 158, 2009) (Note 5)

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

2.2 Permethrin content (331/LN/M/3, CIPAC Handbook M, p. 159, 2009) (Notes 5 & 6)

The permethrin content shall be declared (20 g/kg) and, when determined, the average content shall not differ from that declared by more than $\pm 25\%$.

2.3 Permethrin isomer ratio (331/LN/M/3, CIPAC Handbook M, p. 159, 2009)

The ratio of [1*RS*,3*RS*]:[1*RS*,3*SR*] (*cis:trans*) permethrin isomers shall be in the range of 50:50 to 30:70.

* This specification is applicable to long-lasting insecticidal nettings and nets produced by Sumitomo Chemical Co., Ltd and commercialised under the trade name Olyset. 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/>.

2.4 Permethrin wash resistance index (MT 195, Notes 5 & 7)

The wash resistance index of permethrin from the netting, when determined, shall be within the range 97% to 101%.

3 Physical properties

3.1 Netting mesh size (Note 5)

When counted by the method given in Note 8, the average number of complete holes/cm² shall be not less than 5.28 holes/cm² and the lowest value shall be not less than 5 holes/cm².

3.2 Dimensional stability of netting to washing (Notes 5 & 9)

Not more than 10% shrinkage/expansion in both dimensions.

3.3 Bursting strength (Notes 5 & 10)

The minimum bursting strength of the fabric shall be declared (not less than 350 kPa) and, when determined, the average shall be not less than that declared.

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

4 Storage stability

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

After storage at $54 \pm 2^\circ\text{C}$ for 2 weeks, the determined average active ingredient content shall not be lower than 95%, relative to the determined average content found before storage (Note 11) and the product shall continue to comply with the clauses for:

- isomer ratio (2.3);
- wash resistance index (2.4);
- dimensional stability (3.2);
- bursting strength (3.3).

Note 1 The specification applies to manufactured nets and bulk netting, which may be rectangular or conical in design. The netting may be white or coloured, for example, green or blue.

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

Note 3 Long-lasting insecticidal netting is expected to retain its insecticidal activity during its life span and through a number of washes. The clause for permethrin wash resistance index (2.4) is based on a model washing regime and compliance with the limit does not guarantee that activity will be retained through any particular number of washes performed according to local practice.

Note 4 Flammability of the product is not part of the specification but it should be measured by the manufacturer, according to 16CFR Part 1610, and the result presented on the package. The linear density (denier) of the fibres cannot be measured in the manufactured net, but should be identified on the packaging.

Note 5 Samples should be taken according to Figure 1 or on a convenient diagonal across the width of bulk material. Samples must be sufficiently large to conduct all tests required and representative of the net or netting. Except where seams are to be tested, do not test material within 10 cm of seams or selvages.

Use sharp scissors, or equivalent, to minimize damage to the fibres and fabric and thus avoid any consequential bias in the results of certain tests. Roll up the strips or squares and place them in labelled, new, clean aluminium foil prior to analysis. Samples should be kept cool, avoiding heat sources (including sun heat) or freezing, and analyzed/tested with minimum delay. Representative portions (sub-samples) for testing should be taken as described in each test method.

Test portion and replication requirements for physical test methods are defined in the methods or Notes referenced.

Note 6 The permethrin 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 7 The CIPAC method MT 195 for determination of wash resistance index of LN was adopted as full CIPAC method in 2013. Prior to the publication in a Handbook, copies of the method may be obtained through the CIPAC website, <http://www.cipac.org/cipacpub.htm>

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

The content of permethrin in the net pieces before and after washing should be determined by the method 331/LN/M/3, CIPAC Handbook M, p.159, 2009. Wash resistance index values higher than 100% up to 101% are acceptable due to the uncertainty of measurement of the CIPAC method MT 195.

Note 8 In the absence of a simple or standard method to determine the size of holes, which may have complex shapes, in highly flexible fabrics, mesh size is determined by counting the number of holes in a square of the fabric. Counting may be done directly on the fabric or indirectly by taking a picture/photocopy the fabric. Indirect methods may ease counting and provide a permanent record. Before counting, the fabric should be conditioned according to ISO 139 (1973) (4 h, 20°C, 65% relative humidity).

Use a template to define the square of netting, taking care not to stretch or distort the fabric. The template should be a 1-2 mm thick rigid sheet, in/on which an accurately calibrated ($\pm 1\%$ in each dimension) square (e.g. 1 x 1 in or 5 x 5 cm) has been cut/marked. If a template is not available and a ruler must be used, great care is required to ensure that the area counted is square. Where practicable, one edge of the square to be counted should be aligned with a row of complete holes in the fabric. Incomplete holes $\geq 1/2$ are counted as complete holes, whereas those $< 1/2$ are not counted. Count 5 replicate squares in pieces taken according to Note 5, calculate the average and note the lowest value.

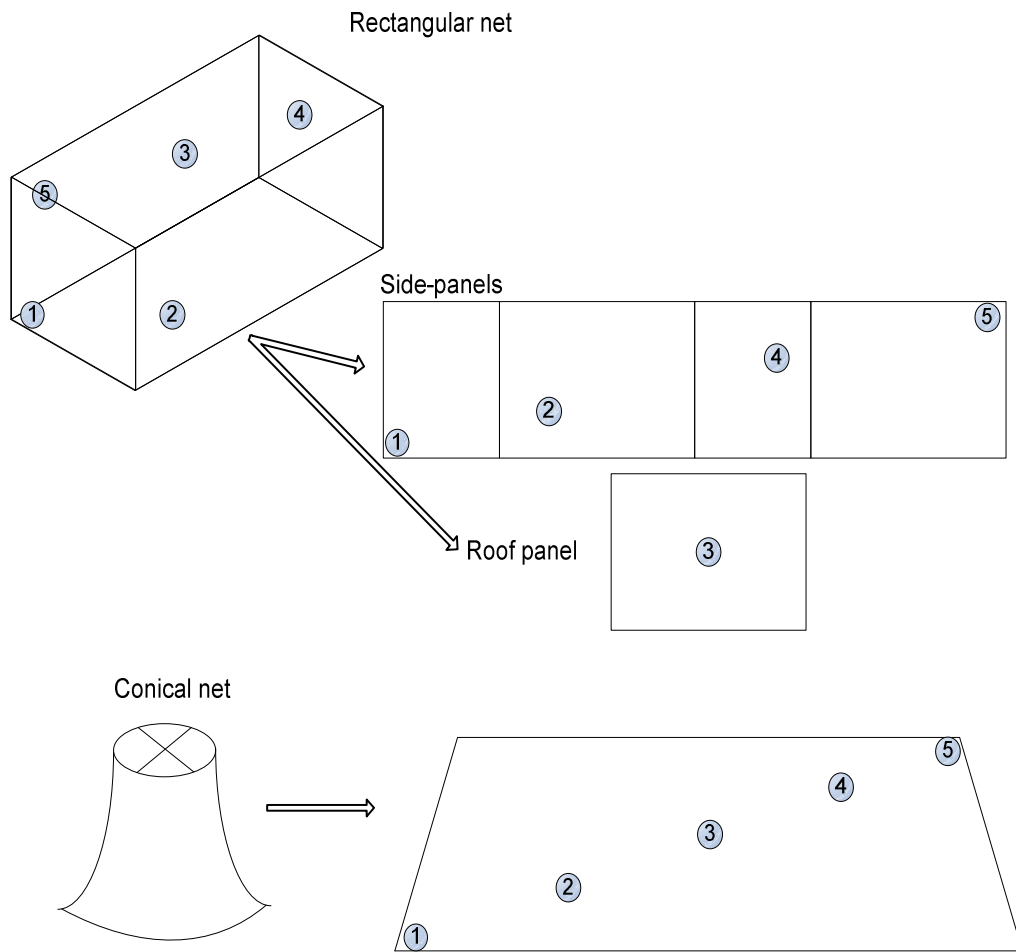
Note 9 Method of preparation, marking and measuring: ISO 3759 (2007). Method of washing: ISO 6330 (2001). Method of calculation: ISO 5077 (1984). Size of test portions: 500 x 500 mm; mark off 350 x 350 mm within each test portion. Test a total of 4 replicate portions, 2 washed in each of 2 separate loads. Type of washing machine: ISO type A (front loading). Washing program: ISO type 8A (gentle cycle 30°C). Fill the washer with dummy load (with fabric as per ISO standard) up to the standard of 2 to 4 kg. Drying: flat drying.

Note 10 Test method: ISO 13938 part 1 (1999) and ISO 13938 part 2 (1999), with conditioning of the fabric as specified in the ISO standard. The declared minimum bursting strength, and testing for compliance with it, should be based on tests of 7.3 cm² areas of fabric. Proposed specifications based on tests of 50 cm² area must be supported by data showing the suitability of the proposed value and its relationship to minimum of 250 kPa (which is based on 7.3 cm² area). Five replicate tests should be conducted on samples taken as described in Note 5. The average of the 5 measurements is calculated.

The method to test seam bursting strength is identical to that used to test the fabric, except that 5 replicate tests should be made, with the seam centered on the test head. Up to 5 seams may be tested but, if there are <5 seams, replicate measurements should be made on 1 or more seams, to provide a total of 5 measurements.

Note 11 Samples of the product taken before and after the storage stability test should be analyzed concurrently in order to reduce the analytical error.

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



PART TWO
EVALUATION REPORTS

PERMETHRIN

Page

2013	FAO/WHO evaluation report based on data submitted by Sumitomo Chemical Co., Ltd (LN)	13
	Annex 1: References	15
2006	FAO/WHO evaluation report based on data submitted by Sumitomo Chemical Co., Ltd (LN)	16
	Annex 1: Supporting information	19
	Annex 2: References	21

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

PERMETHRIN

FAO/WHO EVALUATION REPORT 331/2013

Recommendations

The Meeting recommended the following:

- (i) The WHO specification 331/LN for permethrin long-lasting (incorporated into filaments) insecticidal net (LN) updated according to the LN guideline of the November 2010 edition of the FAO/WHO Manual on specifications for pesticides, proposed by Sumitomo Chemical Co., Ltd, as amended, should be adopted by WHO.
- (ii) The wash resistance index tolerance of the WHO specification 331/LN for permethrin long-lasting (incorporated into filaments) insecticidal net (LN) using the new CIPAC washing method MT 195 should be specified with the range of 97% to 101%.
- (iii) The revised specification should get the status of full WHO specification.

Appraisal

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

The Meeting requested Sumitomo Chemical Co., Ltd producing permethrin long-lasting (incorporated into filaments) insecticidal net (LN) to generate wash resistance index data using the new CIPAC washing method and to propose a revised wash resistance index clause based on these data. The manufacturer provided the Meeting with wash resistance index data generated with the CIPAC method MT 195, as well as a draft specification updated according to the LN guideline of the November 2010 edition of the FAO/WHO Manual on specifications for pesticides.

In the study report provided by the manufacturer, the wash resistance index was measured on 8 Olyset® nets from 2 production sites and 4 different batches, 4 nets (white and blue) stored at room temperature and 4 nets (white and blue) stored at 54 °C for 2 weeks. The permethrin content in the net pieces before and after the 4 wash cycles was determined as the sum of the *cis* and *trans* isomers using the

appropriate CIPAC method. Based on the mean and standard deviation of permethrin content before and after 4 wash cycles, the manufacturer proposed to specify a permethrin wash resistance index within the range of 97% to 101%. The wash resistance index does not significantly change after the accelerated storage.

As observed in some data provided by the manufacturer, the measurement of the wash resistance index can sometimes lead to values slightly higher than 100%. It does not mean a too slow release of the active ingredient on the surface of the net, but it is due to the uncertainty of measurement of the CIPAC method MT 195. The Meeting agreed also that in order to meet the objective of the wash resistance index test, a range of values instead of a minimum value should be specified for the wash resistance index. The Meeting and the manufacturer agreed to specify a range of 97% to 101% for the permethrin wash resistance index.

The manufacturer proposed also to specify for permethrin content a tolerance of $\pm 25\%$ instead of ± 3 g/kg, as specified in the existing specification. The Meeting agreed with this proposal because this is in line with the tolerance recommended by FAO/WHO for formulated products with declared content up to 25 g/kg, and with all the tolerances adopted in the other LN specifications.

ANNEX 1: REFERENCES

Study number	Author(s)	Year	Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study
	CIPAC	2012	MT 19X. Wash resistance index of LN, CIPAC method 4827/m.
	CIPAC	2012	MT 19X. Wash resistance index of LN, small scale collaborative trial, CIPAC report 4828/R.
	CIPAC	2013	MT 195. Wash resistance index of LN, available at http://www.cipac.org/cipacpub.htm
	CIPAC	2013	Wash resistance index of LN - Validation of the new CIPAC Washing Method, CIPAC report 4909/R.
	FAO/WHO	2010	Manual on development and use of FAO and WHO specifications for pesticides. Second revision of the 1 st edition. FAO, Rome and WHO, Geneva, November 2010 (internet publications).
	WHO	2005	Guidelines for laboratory and field testing of long-lasting insecticidal mosquito nets. Document WHO/CDS/WHOPES/GCDPP/2005.11. WHO, Geneva, 2005.
	Kozuki Yumiko	2014	Draft specification for 40:60 <i>cis:trans</i> permethrin long-lasting (incorporated into filaments) insecticidal net submitted by Sumitomo Chemical Co., Ltd to JMPS, February 06, 2014.
	Yamada Noriko	2013	Determination of Wash Resistance Index for Olyset® Net. Report HPTR-2013002 of Sumitomo Chemical Co., Ltd for JMPS, October 04, 2013.

WHO SPECIFICATIONS AND EVALUATIONS FOR
PUBLIC HEALTH PESTICIDES
**PERMETHRIN LONG-LASTING (INCORPORATED INTO FILAMENTS)
INSECTICIDAL NET**

EVALUATION REPORT 331/2006

Recommendations

The Meeting recommended the following.

- (i) The existing (2002) WHO interim specification for permethrin LN should be withdrawn.
- (ii) The specification for permethrin LN proposed by Sumitomo, as amended, should be adopted by WHO with interim status.
- (iii) The new interim specification for permethrin LN should be promoted to the status of a full WHO specification, subject to:
 - (a) satisfactory validation and CIPAC adoption of the test method for determination of the release characteristics;
 - (b) development of a WHO full specification for permethrin TC under the new procedure; and
 - (c) confirmation by the manufacturer that the permethrin incorporated into the LN complies with the new full specification for TC.
- (iv) Future proposals for extension of this specification (at interim or full status) 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

Information and a proposed revised specification were provided by Sumitomo in 2005, for review of the existing (2002) interim WHO specification for an LN containing permethrin (nominal *cis/trans* ratio 40:60). The Meeting considered only revision of the technical aspects of the specification, not its interim status. The Meeting noted that subsequent promotion from interim to full specification status would be automatic, subject to fulfilment of the criteria given in the recommendations (above).

Existing FAO and WHO specifications for permethrin TC were developed, separately, under the old procedure and are awaiting review by the JMPS. The existing WHO specification for permethrin TC (WHO/SIT/28.R1), which encompasses both 25:75 and 40:60 *cis/trans* permethrin ratios, was published in 1999.

The existing and proposed specifications are for warp-knitted mono-filament fabric, in which the active ingredient is incorporated into the filaments.

The proposed LN specification had been amended in accordance with the newly published interim guideline specification for LN (FAO/WHO 2006), which reflected improvements in knowledge about various LN products that had occurred since WHO published its first interim guideline for LN specifications. Among the consequential changes, perhaps most significant was in the method and clause for testing the release characteristics of the LN.

Unlike coated-filament fabrics, in which adequate retention of active ingredient during washing is an important criterion (indicating whether or not there is an appropriate quantity or quality of coating polymer), in fabrics where the active ingredient is incorporated into the filaments it is important to ensure adequate but not excessive release of the active ingredient after washing. This is partly because re-equilibration throughout the filament by diffusion takes longer than it does in a thin coating and partly because slow mechanical/conformational changes are also involved². Where the active ingredient is incorporated into filaments, rapid total loss of active ingredient is not likely to occur during washing but, if redistribution to the surface is too slow, the product may be ineffective for an unacceptable period after washing. Alternatively, if the redistribution is too rapid, the surface concentration could become higher than expected, leading to higher losses of active ingredient during washing and possibly increased user exposure to the active ingredient.

The manufacturer had shown that macro-scale distribution of total permethrin is very uniform within the LN (<2% RSD, measured in single 2 g samples withdrawn from material cut into 5-10 mm squares and mixed) (Sumitomo 2005a). The 2 g samples corresponded to approximately 0.04 m² but, being well mixed, they were representative of a much larger quantity of netting. A similar cutting, mixing and sub-sampling procedure cannot be used for the determination of release index. The release characteristics (measurements of "surface concentrations"³ at rinses 2 and 3) are determined as the average result obtained from three separate 5 cm square pieces (a total of 0.0075 m² or 0.375 g) of netting and the results tend to be much less uniform than measurements of total active ingredient content. Analysis of these smaller samples increases the (statistical) sampling error and contributes to the variation in measured release characteristics but the manufacturer concluded that the results were fit for purpose (Sumitomo 2005b).

The manufacturer provided supporting QC data (Sumitomo 2006a) for surface concentration at rinse 2 and release index and stated that the limits (0.15-0.60 and 0.55-1.2, respectively) were based on the average \pm 3 S.D. The Meeting questioned whether the proposed limits for release characteristics would really distinguish between good and bad materials. The product should contain 17-23 g/kg permethrin. In a theoretical worst-case scenario, at 17 g/kg and with a surface concentration at rinse 2 of 0.6 g/kg and a release index of 1.2, the fabric could be exhausted in about 22 washes, which was considered to be an acceptable number. Again theoretically, with surface concentration of 0.15 g/kg and release index of 0.55, although it may

² The filament is not a simple solid solution of active ingredient. The mechanical/conformational changes are slow but more or less irreversible and produce an effect which may be thought of as "sweating/bleeding". This effect can lead to surface concentrations higher than would be produced by simple diffusion alone.

³ "Surface concentrations" measured for the determination of release index should not be confused with the initial surface concentration. What is measured is broadly similar in concept (though difficult to define physically) in both cases but in the former case it is under experimental control, whereas in the latter case it is uncontrolled.

take about 200 washes to exhaust the fabric, the surface concentration may not be high enough for good efficacy. The manufacturer provided data (Sumitomo 2003) showing that good efficacy requires a minimum surface concentration of about 0.15 g/kg. Thus a surface concentration of 0.15 g/kg at rinse 2 would be just sufficient but a release index of 0.55 would imply that lower surface concentrations could occur. The manufacturer stated (Sumitomo 2005c) that combinations of extreme high + high or extreme low + low values for surface concentration at the 2nd wash and release index do not occur in practice and also that the dispersion of results for both parameters decreases with time after manufacture. Thus, in practice, the surface concentration does not decline below levels required for acceptable efficacy until the active ingredient content is becoming exhausted.

The manufacturer provided supporting QC data for permethrin surface concentration and retention index (Sumitomo 2006b), obtained before and after storage of samples at 54°C for 2 weeks, and stated that the proposed limits were based on the average \pm 3 S.D. The data indicated what is achievable in manufacturing practice using the current test method, and the Meeting therefore accepted the proposed limits.

The proposed limit for dimensional stability (\pm 10%) exceeded the standard \pm 5% in the current LN specification guideline (FAO/WHO 2006). The manufacturer stated (Sumitomo 2006c) that any shrinkage can be addressed by stretching the product, which is not harmed in the process. The manufacturer also stated that no complaints had been received from users or buyers. Therefore Meeting accepted the proposed limit.

New CIPAC analytical methods for identification and for the determination of permethrin content and isomer ratio in TC and LN were adopted in 2006, with provisional status, and are thus acceptable for support of a WHO full specification. However, the method for determination permethrin release characteristics was adopted by CIPAC in 2006 with tentative status only, which is not sufficient for support of a WHO full specification.

**SUPPORTING INFORMATION
FOR
EVALUATION REPORT 331LN/2006**

Uses

The LN is used in the form of bed nets to protect users against flying biting insects, especially mosquitoes which may serve as vectors for diseases such as malaria.

The LN is registered and sold in Colombia, Dominican Republic, Honduras, Indonesia, Kenya, Malaysia, Myanmar, Peru, Philippines, Singapore, Sri Lanka, Thailand, Tanzania, and Trinidad.

Formulations

Permethrin is not co-formulated with other pesticides in the LN.

Methods of analysis and testing

New analytical methods for identification and for the determination of permethrin content and isomer ratio in TC and LN were validated by collaborative study (organized by the company under the auspices of CIPAC) and were adopted by CIPAC in 2006, with provisional status.

The method for determination permethrin release characteristics was also the subject of a CIPAC collaborative study (organized by the company under the auspices of CIPAC) and was adopted by CIPAC in 2006, with tentative status.

The test method for storage stability is a full CIPAC method.

As indicated in the specification, the methods for testing physical properties are ISO standards, with the exception of mesh size which involves only measurement with a ruler or grid.

ANNEX 1. REFERENCES

Reference	Year and title of report/communication or publication details
FAO/WHO 2006	Supplement to the Manual on the development and use of FAO and WHO specifications for pesticides. Published on FAO and WHO websites, February 2006.
Sumitomo 2003	2003. Justification for new proposal of specification of Olyset net.
Sumitomo 2005a	2005. Distribution of permethrin.xls. Sampling method for permethrin LLIN.
Sumitomo 2005b	2005. Amended Interim Specification for Olyset Net WHO/IS/NI/331/2005.
Sumitomo 2005c	2005. RE: Amended Interim Specification for Olyset Net WHO/IS/NI/331/2005.
Sumitomo 2006a	2006. SC data.060531xls.xls. Revised interim specification for permethrin LN.
Sumitomo 2006b	2006. RI SC data.xls. Revised WHO interim specification for permethrin LN.
Sumitomo 2006c	2006. FW: Revised interim specification for permethrin LN.