WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES

LINDANE¹

1,2,3,4,5,6-hexachlorocyclohexane



¹ Lindane is a grade of HCH (BHC) containing not less than 990 g/kg gamma-HCH isomer.

TABLE OF CONTENTS

LINDANE

	Page
DISCLAIMER	3
PART ONE	
SPECIFICATIONS FOR LINDANE	
LINDANE INFORMATION	5
LINDANE TECHNICAL MATERIAL (AUGUST 2009)	6
LINDANE DUSTABLE POWDER (AUGUST 2009)	7
LINDANE WETTABLE POWDER (AUGUST 2009)	9
LINDANE EMULSIFIABLE CONCENTRATE (AUGUST 2009)	11
PART TWO	
EVALUATIONS OF LINDANE	

2009	FAO/WHO EVALUATION REPORT ON LINDANE	11
2009	FAO/WHO EVALUATION REPORT ON LINDANE	14

Disclaimer¹

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

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

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

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

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

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

¹ This disclaimer applies to all specifications published by WHO.

PART ONE

SPECIFICATIONS

LINDANE

	Page
LINDANE INFORMATION	5
LINDANE TECHNICAL MATERIAL (AUGUST 2009)	6
LINDANE DUSTABLE POWDER (AUGUST 2009)	7
LINDANE WETTABLE POWDER (AUGUST 2009)	9
LINDANE EMULSIFIABLE CONCENTRATE (AUGUST 2009)	11

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

LINDANE

INFORMATION

ISO common name

lindane (BSI, E-ISO, (*m*) F-ISO, ESA) (for material containing ≥99% gamma stereoisomer)

Synonyms

gamma-HCH (BSI) gamma-BHC or gamma-HCH (E-ISO, (*m*) F-ISO) gamma benzene hexachloride (ESA, EPA, BAN, USA) gamma-HKhTsH (USSR)

Chemical names

IUPAC $1\alpha, 2\alpha, 3\beta, 4\alpha, 5\alpha, 6\beta$ -hexachlorocyclohexane (gamma stereoisomer)

CA $(1\alpha, 2\alpha, 3\beta, 4\alpha, 5\alpha, 6\beta)$ -hexachlorocyclohexane (gamma stereoisomer)

Structural formula



Molecular formula

 $C_6H_6CI_6$

Relative molecular mass

290.8

CAS Registry number

58-89-9

CIPAC number

488

EEC number

200-401-2

Identity tests

GC retention time, mass spectrum (from GC-MS)

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

LINDANE TECHNICAL MATERIAL

Full specification WHO/SIT/3.R7 (August 2009*)

1 **Description**

The material shall consist of lindane (gamma-HCH) together with related manufacturing impurities, in the form of white or near-white granules, flakes or powder, free from visible extraneous matter and added modifying agents and with no more than a faint odour.

2 Active ingredient

2.1 **Identity tests** (4γ/EW/M/2, CIPAC Handbook 1C, p. 2135, 1985) (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 Lindane (gamma-HCH) content

(4/TC/M3/3, CIPAC Handbook 1C, p. 1977, 1985)

The lindane (gamme-HCH) content shall be declared (not less than 988 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

3 Relevant impurities

3.1 Alpha-HCH $(1\alpha, 2\alpha, 3\beta, 4\alpha, 5\beta, 6\beta$ -hexachlorocyclohexane, CAS No. 319-84-6) (488/TC/M3/4, CIPAC Handbook G, p. 105, 1995)

Maximum: 0.5% of the lindane content found under 2.2.

- 3.2 Water content (MT 30.5, CIPAC Handbook J, p. 120, 2000) Maximum: 1 g/kg.
- 3.3 Acetone insolubles (MT 27, CIPAC Handbook F, p. 88, 1995) Maximum: 1 g/kg.

4 Physical properties

4.1 Acidity (MT 191, CIPAC Handbook L, p. 143, 2006)
Maximum acidity: 1.5 g/kg calculated as H₂SO₄.

Note 1 The identity criteria used in the CIPAC method for lindane EW are also applicable for lindane TC.

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

LINDANE DUSTABLE POWDER

Full specification WHO/SIF/17.R8 (August 2009*)

1 **Description**

The material shall consist of a homogeneous mixture of technical lindane (gamma-HCH), complying with the requirements of WHO specification WHO/SIT/3.R7 (August 2009), together with carriers and any other necessary formulants. 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** (4γ/EW/M/2, CIPAC Handbook 1C, p. 2135, 1985) (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 Lindane (gamma-HCH) content

(4/DP/M2/3, CIPAC Handbook 1C, p. 1978, 1985)

The lindane (gamme-HCH) content shall be declared (g/kg) and, when determined, the average measured content shall not differ from that declared by more than \pm 10%.

3 Relevant impurities

3.1 Alpha-HCH $(1\alpha, 2\alpha, 3\beta, 4\alpha, 5\beta, 6\beta$ -hexachlorocyclohexane, CAS No. 319-84-6) (488/WP/M2/5, CIPAC Handbook G, p. 108, 1995)

Maximum: 0.5% of the lindane content found under 2.2.

4 **Physical properties**

4.1 Acidity or alkalinity (MT 191, CIPAC Handbook L, p. 143, 2006)

Maximum acidity: 1 g/kg calculated as H₂SO₄.

Maximum alkalinity: 2 g/kg calculated as NaOH.

4.2 **Dry sieve test** (MT 59.1, CIPAC Handbook F, p. 177, 1995) (Note 2)

Maximum: 2% retained on a 150 μ m test sieve. The residue remaining on the sieve shall be free from grittiness.

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

5 Storage stability

5.1 **Stability at elevated temperature**

(MT 46.3, CIPAC Handbook J, p. 128, 2000)

After storage at $54 \pm 2^{\circ}$ 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 3) and the formulation shall continue to comply with the clauses for:

- acidity or alkalinity (4.1);
- dry sieve test (4.2).

- <u>Note 2</u> This test will normally only be carried out after the heat stability test, 5.1.
- <u>Note 3</u> 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.

Note 1 The identity criteria used in the CIPAC method for lindane EW are also applicable for lindane DP.

LINDANE WETTABLE POWDER

Full specification WHO/SIF/2.R9 (August 2009*)

1 **Description**

The material shall consist of a homogeneous mixture of technical lindane (gamma-HCH), complying with the requirements of WHO specification WHO/SIT/3.R7 (August 2009), together with filler(s) and any other necessary formulants. It shall be in the form of a fine, free-flowing, white to cream-colored powder, free from visible extraneous matter and hard lumps.

2 Active ingredient

2.1 **Identity tests** (4γ/EW/M/2, CIPAC Handbook 1C, p. 2135, 1985) (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 Lindane (gamma-HCH) content

(4/WP/M2/3, CIPAC Handbook 1C, p. 1979, 1985)

The lindane (gamme-HCH) 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
above 250 up to 500	± 5% of the declared content
above 500	± 25 g/kg
Note: the upper limit is included in each range	

3 Relevant impurities

3.1 Alpha-HCH $(1\alpha, 2\alpha, 3\beta, 4\alpha, 5\beta, 6\beta$ -hexachlorocyclohexane, CAS No. 319-84-6) (488/WP/M2/5, CIPAC Handbook G, p. 108, 1995)

Maximum: 0.5% of the lindane content found under 2.2.

4 **Physical properties**

 4.1 Acidity or alkalinity (MT 191, CIPAC Handbook L, p. 143, 2006) Maximum acidity: 2 g/kg calculated as H₂SO₄.

Maximum alkalinity: 2 g/kg calculated as NaOH.

4.2 Wet sieve test (MT 185, CIPAC Handbook K, p. 149, 2003) (Note 2) Maximum: 2% retained on a 75 μm test sieve.

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

4.3 **Suspensibility** (MT 184, CIPAC Handbook K, p. 142, 2003) (Notes 2 & 3)

A minimum of 50% of the lindane content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at $30 \pm 2^{\circ}C$ (Note 4).

4.4 **Persistent foam** (MT 47.2, CIPAC Handbook F, p. 152, 1995) (Note 3)

Maximum: 10 mL after 1 min in CIPAC Standard Water A.

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

The formulation shall be completely wetted in 2 min in CIPAC Standard Water D without swirling.

5 Storage stability

5.1 **Stability at elevated temperature**

(MT 46.3, CIPAC Handbook J, p. 128, 2000)

After storage at $54 \pm 2^{\circ}$ 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 5) and the formulation shall continue to comply with the clauses for:

- acidity or alkalinity (4.1);
- wet sieve test (4.2);
- suspensibility (4.3).
- <u>Note 1</u> The identity criteria used in the CIPAC method for lindane EW are also applicable for lindane WP.
- Note 2 This test will normally only be carried out after the heat stability test, 5.1.
- Note 3 The formulation will be tested at the use rate of 5 g/L of lindane (gamma-HCH).
- <u>Note 4</u> Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric and solvent extraction determination may be used on a routine basis provided that these methods have been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".
- <u>Note 5</u> 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.

LINDANE EMULSIFIABLE CONCENTRATE

Full specification WHO/SIF/5.R9 (August 2009*)

1 **Description**

The material shall consist of technical lindane (gamma-HCH), complying with the requirements of WHO specification WHO/SIT/3.R7 (August 2009), 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** (4γ/EW/M/2, CIPAC Handbook 1C, p. 2135, 1985) (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 Lindane (gamma-HCH) content

(4/EC/M2/3, CIPAC Handbook 1C, p. 1980, 1985)

The lindane (gamme-HCH) content shall be declared (g/kg or g/l at $20 \pm 2^{\circ}$ 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 ± 2°C	Tolerance
above 250 up to 500	± 5% of the declared content
above 500	± 25 g/kg
Note: the upper limit is included in each range	

3 Relevant impurities

3.1 Alpha-HCH $(1\alpha, 2\alpha, 3\beta, 4\alpha, 5\beta, 6\beta$ -hexachlorocyclohexane, CAS No. 319-84-6) (488/TC/M3/4, CIPAC Handbook G, p. 105, 1995)

Maximum: 0.5% of the lindane content found under 2.2.

3.2 **Water content** (MT 30.5, CIPAC Handbook J, p. 120, 2000) Maximum: 1.5 g/kg.

4 **Physical properties**

 4.1 Acidity or alkalinity (MT 191, CIPAC Handbook L, p. 143, 2006) Maximum acidity: 0.5 g/kg calculated as H₂SO₄.
Maximum alkalinity: 0.5 g/kg calculated as NaOH.

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

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

The formulation, when diluted at $30 \pm 2^{\circ}$ 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", maximum: 1 mL
2.0 h	"Cream", maximum: 2 mL "Free oil", none
24 h	Re-emulsification complete
24.5 h	"Cream", maximum: 2 mL "Free oil", none
Note: tests after 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: 60 mL after 1 min in CIPAC Standard Water A.

5 Storage stability

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

After storage at 0 \pm 2°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 $54 \pm 2^{\circ}$ 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 or alkalinity (4.1);
- emulsion stability and re-emulsification (4.2).

- <u>Note 2</u> 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 The formulation will be tested at 5% dilution.
- <u>Note 4</u> The mass of sample to be used in the test should correspond to the highest rate of use recommended by the supplier.
- <u>Note 5</u> 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.

<u>Note 1</u> The identity criteria used in the CIPAC method for lindane EW are also applicable for lindane EC.

PART TWO

EVALUATION REPORTS

LINDANE

		Page
2009	FAO/WHO evaluation report	
	based on review of specifications by JMPS	14

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

LINDANE

FAO/WHO EVALUATION REPORT 488/2009

Recommendations

The Meeting recommended the following.

- (i) The existing WHO specifications for lindane WHO/SIT/3.R6 (TC, December 1999), WHO/SIF/17.R7 (DP, December 1999), WHO/SIF/2.R8 (WP, December 1999) and WHO/SIF/5.R8 (EC, December 1999) should be withdrawn.
- (ii) The revised WHO specifications for lindane TC, DP, WP and EC, as proposed by JMPS, should be adopted by WHO and published under the category of old specifications.

Appraisal

The Meeting considered the review of the existing WHO specifications for lindane (gamma-HCH): WHO/SIT/3.R6 (TC, December 1999), WHO/SIF/17.R7 (DP, December 1999), WHO/SIF/2.R8 (WP, December 1999) and WHO/SIF/5.R8 (EC, December 1999). The revised specifications include the following changes by comparison with the old specifications.

General considerations

- The updated specifications for lindane TC, DP, WP and EC were written according to the format requirements (specification guidelines) of the FAO/WHO Manual (March 2006 revision of the first edition).
- Information on lindane (gamme-HCH) was added in the revised specifications.
- The methods for lindane (gamma-HCH) content extensively written in the old specifications were referenced in the revised specifications to the existing CIPAC methods.
- While maintaining the clauses and their respective limits, the methods for physicochemical properties referenced in the old specifications were updated in the revised specifications according to the current CIPAC methods.
- The information on packing and marking of packages of the old specifications were withdrawn in the revised specifications because this information is available in the Appendix A of the FAO/WHO Manual.

Lindane technical material (TC)

- The clause of melting point of the old specification was replaced in the revised specification by the clause of identity tests referring to the CIPAC method for lindane EW.

Lindane dustable powder (DP)

- A clause of identity tests referring to the CIPAC method for lindane EW was added in the revised specification.

- The clause of dustability of the old specification was deleted because no material (hand duster) is available as described in the CIPAC method MT 34. This method is obsolete.

Lindane wettable powder (WP)

- A clause of identity tests referring to the CIPAC method for lindane EW was added in the revised specification.
- For the suspensibility, persistent foam and wettability tests, the WHO standard hard and soft waters mentioned in the old specification were replaced in the revised specification by the CIPAC Standard Water D and A respectively.

Lindane emulsifiable concentrate (EC)

- A clause of identity tests referring to the CIPAC method for lindane EW was added in the revised specification.
- For the emulsion stability and persistent foam tests, the WHO standard hard and soft waters mentioned in the old specification were replaced in the revised specification by the CIPAC Standard Water D and A respectively.
- For the emulsion stability test, the method WHO/M/29 (with examination after only 2 h) of the old specification was replaced in the revised specification by the CIPAC method MT 36.1.1 (with examination at 0 h, 0.5 h, 2.0 h, 24 h and 24.5 h). The clause of maximum 2 ml cream at 2.0 h in the old specification was maintained in the revised specification. The clause limits at 0 h, 0.5 h, 24 h and 24.5 h were defined in the revised specification on basis of the model adopted in the existing WHO specifications for lambda-cyhalothrin EC and temephos EC.
- For the stability at 0°C, the default value of "not more than 0.3 mL for the volume of solid and/or liquid which separates" was adopted in the revised specification.
- The clause for flash point was deleted in the revised specification.

Although the specifications were revised according to the guidelines of the FAO/WHO Manual (March 2006 revision of the first edition), the Meeting agreed to publish them under the category of old specifications because no new data were provided by the manufacturers and evaluated by the JMPS.