Directorate of National Vector Borne Disease Control Programme

Technical Specification of Synthetic Pyrethroids (wdp) under NVBDCP

A. WHO Specification for Public Health Insecticide/Pesticide

1. Deltamethrin -333/WP
2. Cyfluthrin - 385/WP
3. Lambdacyhalothrin - 463/WP
4. EtofenpProx – 471/WP
5. Alphacypermethrin – 454/WP
6. Bifenthrin – 415/WP (interim)

B. The Central Insecticide Board (CIB) has approved the following Insecticides for Public Health use.

1. Deltamethrin 2.5% (wdp)
2. Cyfluthrin 10% (wdp)
3. Lambdacyhalothrin 10% (wdp)
4. Alphacypermethrin 5% (wdp)
5. Bifenthrin 10% WP

EtofenpProx is not registered under CIB

The details of the description, active ingredient, physical properties, wet sieve test, wettability, persistent foam, storage stability as per WHO specification is enclosed at **Annexure** for each insecticide(s) mentioned at B above.

The committee also looks into the conversion formula i.e calculations for comparison of requirement vis-a-vis cost due to variation in their active ingredient.

Conversion Formula (Calculations for Comparison)

Sr. No.	Insecticide (wdp)	Requirement/million population (MT)	Dosages per square metre of active ingredient
1.	Deltamethrin 2.5% WP	60.00MT	20 mg/m^2
2.	Cyfluthrin 10% WP	18.75 MT	20 mg/m^2
3.	Lambdacyhalothrin 10% WP	18.75 MT	25 mg/ m^2
4.	Alphacypermethrin 5% WP	37.5 MT	25 mg/ m^2
5.	Bifenthrin 10% WP	18.75 MT	25mg/ m^2

The dose spray remains un-altered in NVBDCP considering the respective dose of Cyfluthrin, Lambdacyhalothrin and Bifenthrin which are available in high concentration i.e. 10% WDP. The quantity would be 3.2 times more if the strength is reduced to 2.5%.

60 MT: 18.75 MT (for 1 million Population)
3.2 : 1

Similarly, Alphacypermthrin which is available in high concentration i.e. 5% WDP. The quantity would be 1.6 times more if the strength is reduced to 2.5%.

60 MT: 37.50. MT (for 1 million Population)
1.6 : 1

Similarly the cost of different insecticides may be calculated based on same mathematical formula as mentioned above. For example

Deltamethrin	2.5%	- Rs. 7,80,000	= Rs. 7,80,000
Cyfluthrin	10%	- Rs. 24,96,000 Divided by 3.2	= Rs. 7,80,000
Lambdacyhalothrin	10%	-Rs. 24,96,000 Divided by 3.2	= Rs. 7,80,000
Bifenthrin	10%	-Rs. 24,96,000 Divided by 3.2	= Rs. 7,80,000
Alphacypermethrin	5%	-Rs.4,87,500 Divided by 1.6	= Rs. 7,80,000

(the price is indicative one & here its use is only for calculation purposes/comparison of rates).

The Technical Specification of Synthetic Pyrethroid (wdp) under NVBDCP approved by Technical Specification Committee in the meeting held on 26.09.2011

ANNEXURE 2

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

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, 333/2006.2*). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TCfrom 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, 333/2006.2*), 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 formulants. 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.

 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 ± 2°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 ± 2°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).

Note 1 There are no relevant impurities to be controlled in products of the manufacturers identified in
evaluation reports 333/2004, 333/2005 and 333/2006.2. 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 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.

CYFLUTHRIN WETTABLE POWDER (WP)

WHO Specification 385/WP (November 2004□)

*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 (*385/2003*). 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 specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation reports (*385/2003*) as PART TWO forms an integral part of this publication.*

1 **Description**

The material shall consist of an homogeneous mixture of technical cyfluthrin, complying with the requirements of FAO/WHO specification 385/TC (2003), together with filler(s) and any other necessary formulants. It shall be in the form of a fine beige powder, free from visible extraneous matter and hard lumps.

Where the material is packaged in sealed water-soluble bags (Note 1), the material shall consist of a defined quantity of cyfluthrin wettable powder, complying with the requirements of WHO specification 385/WP, contained in a sealed water-soluble bag.

2 **Active ingredient**

2.1 **Identity tests** (CIPAC 385/TC/M/2, CIPAC Handbook H, p 107, 1998, Note 2)

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 **Cyfluthrin content** (CIPAC 385/WP/M/3, CIPAC Handbook H, p 113, 1998)

The cyfluthrin content shall be declared (100 g/kg) and, when determined, the average content measured shall not differ from that declared by more than the tolerance given below.

Declared content in g/kg Tolerance
100 ± 10% of the declared content

3 **Relevant impurities**

3.1 **Water** (MT 30.5, CIPAC Handbook J, p 120, 2000)

Maximum: 35 g/kg.

4 **Physical properties**

4.1 **pH range** (1% dispersion) (MT 75.3, CIPAC Handbook J, p 131, 2000)
pH range: 6.0 to 7.5.
 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/.

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

Maximum: 5% retained on a 40 µm test sieve.
Maximum: 4% retained on a 75 µm test sieve.
Maximum: 2% retained on a 100 µm test sieve.

4.3 **Suspensibility** (MT 15.1, CIPAC Handbook F, p 45, 1995; or MT 177, CIPAC Handbook F, p 445, 1995) (Notes 3, 4 and 5)

A minimum of 70% of the cyfluthrin content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2°C. In the case of water-soluble bag packaging, the provisions of clause 6.2 should be applied.

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

Maximum: 10 ml after 1 min.
In the case of water-soluble bag packaging, the provisions of clause 6.3 should be applied.

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 ± 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 7) and the formulation shall continue to comply with the clauses for:

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

In the case of water-soluble bag packaging, the package should be enclosed in a watertight sachet, box or any other container at 54°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, and theformulation shall continue to comply with the clauses for:

- pH range (4.1);
- wet sieve test (4.2);
- dissolution of the bag (6.1);
- suspensibility (6.2);
- persistent foam (6.3).

None of the bags tested should show signs of leakage or rupture during normal handling, before and after storage.

6 **Material packaged in a sealed water-soluble bag** (see Notes 8, 9 and 10)

6.1 **Dissolution of the bag** (MT 176, CIPAC Handbook F, p 440, 1995)

The dissolution of the bag shall be tested on a sample of the emptied and

cleaned bag, taken according to the procedure described in Note 9, together with an appropriate proportion of the WP.
Flow time of the suspension: maximum 160 seconds.

6.2 **Suspensibility** (MT 15.1, CIPAC Handbook F, p 45, 1995; or MT 177, CIPAC Handbook F, p 445, 1995) (Notes 3, 4 and 5)

The suspensibility shall be tested on a suspension containing the WP and the bag material in the actual ratio of application, prepared according to the procedure described in Note 10.

A minimum of 70% shall be in suspension after 30 minutes in CIPAC Standard Water D at 30 ± 2°C.

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

The persistent foam shall be tested on a suspension containing the WP and the bag in the actual ratio of application, prepared according to the procedure described in Note 10.
Maximum: 10 ml after 1 min.

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

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

Note 1 For record keeping purposes, the suffix "SB" should be added to the formulation code (WPSB).

Note 2 Complete identification of cyfluthrin requires confirmation that the diastereoisomers are present in the appropriate ratio (refer to specification 385/TC, 2003, clause 2.3).

Note 3 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 methods MT 15.1 or MT 177.

Note 4 This test will normally only be carried out after the heat stability test 5.1.

Note 5 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".

Note 6 The mass of sample to be used in the test should be at the highest rate of use recommended
by the supplier.

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.

Note 8 Sub-sampling

Lay the bag on a bench and carefully open one side of the bag with a cutter, taking care not to damage the seals.
Transfer the contents of the bag into a suitable flask. This material shall be used to carry out the tests for:

- active ingredient identity (2.1);
- active ingredient content (2.2);
- water content (3.2);
- pH range (4.1);
- wet sieve test (4.2);
- wettability (4.5);
- dissolution of the bag (6.1);
- suspensibility (6.2);
- persistent foam (6.3).

The bag is then opened on three sides, completely cleaned from adhering powder by brushing or suction and weighed to the nearest 0.01 g. It shall be used to carry out the dissolution test (6.1). Aliquots of an aqueous solution of the bag material shall be used in the suspensibility (6.2) and persistent foam (6.3) tests.

In the case of delay of the above tests, the bag shall be stored in a watertight container (glass bottle or equivalent) to avoid any change in its properties.

Note 9 The sampling of the bag for the dissolution test should be as follows:

Lay the empty cleaned bag in its original configuration (double layer). Delineate and then cut up a test sample including part of the upper seal (5 cm) and symmetrically including the vertical seal (10 cm). If the size of the bag is less than this dimension, use the whole bag .Carry out the dissolution test immediately to avoid any modification of the sample.

Note 10 The procedure for adding the bag material to the solution for the suspensibility and the persistent foam tests should be as follows:

Prepare a stock solution of the bag material (1 mg/ml) by weighing approximately a 100 mg sample (n mg) of the bag (excluding sealed parts) to the nearest mg. Dissolve this sample by

stirring in the standard water used for the tests to give a final volume of n ml. Store the stock solution in a stoppered bottle before use.

Calculate the volume (V ml) of the stock solution of the bag to be added to the test suspension of the wettable powder, according to the following equation:
V(ml) = X x 1000B
W
where: B (g) = weight of the emptied and cleaned bag;
W (g) = nominal weight of the WP contained in the bag;
X (g) = weight of the WP sample used in the test.

LAMBDA-CYHALOTHRIN WETTABLE POWDER

WHO Specification 463/WP (2003□)

*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 (*463/2003, 463/2006*). It should be applicable to relevant products of these manufacturers, and those of any other formulators who use only TC from the evaluated source. 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 (*463/2003 , 463/2006*), as PART TWO, form an integral part of this publication.*

1 **Description**

The material shall consist of an homogeneous mixture of technical lambdacyhalothrin, complying with the requirements of WHO specification 463/TC
(2003), together with filler(s) and any other necessary formulants. It shall be in the form of a fine powder free from visible extraneous matter and hard lumps. Where the material is packaged in sealed water soluble bags (Note 1), the material shall consist of a defined quantity of a lambda-cyhalothrin wettable powder, complying with the requirements of WHO specification 463/WP, contained in a sealed water soluble bag.

2 **Active ingredient**

2.1 **Identity tests** (CIPAC 463/WP/M-, CIPAC Handbook E, 1992)

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

2.2 **Lambda-cyhalothrin content** (CIPAC 463/WP/M-, CIPAC Handbook E,
1992)

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

Declared content in g/kg Permitted tolerance

up to 25 ± 15% of the declared content

above 25 up to 100 ± 10% of the declared content

Note: in each range the upper limit is included.

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

3 **Physical properties**

3.1 **pH range** (MT 75.2)

pH range: 5.5 to 9.0.

3.2 **Wet sieve test** (MT 59.3)

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

3.3 **Suspensibility** (MT 184) (Notes 2 and 3)

A minimum of 50 % of the lambda-cyhalothrin content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2°C (Note 4). In the case of water soluble bag packaging, the provisions of clause 5.2 should be applied.

3.4 **Persistent foam** (MT 47.2) (Note 5)

Maximum: 60ml after 1 min.

In the case of water soluble bag packaging, the provisions of clause 5.3 should be applied.

3.5 **Wettability** (MT 53.3)

The formulation shall be completely wetted in 1 min, without swirling.

4 **Storage stability**

4.1 **Stability at elevated temperature** (MT 46.3)

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 6) and the formulation shall continue to comply with the clauses for:

- pH range (3.1);
- wet sieve test (3.2);
- suspensibility (3.3);
- wettability (3.5).

In the case of water soluble bag packaging, the package should be enclosed in a watertight sachet, box or any other container, at 30°C for 18 weeks. 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 clauses for:

- pH range (3.1);
- wet sieve test (3.2);
- dissolution of the bag (5.1);
- suspensibility (5.2);
- persistent foam (5.3).

None of the bags tested should show signs of leakage or rupture during normal handling, before and after storage.

5 **Material packaged in a sealed water soluble bag** (Note 7)

5.1 **Dissolution of the bag** (MT 176) (Note 8)

The dissolution of the bag shall be tested on a sample of the emptied and cleaned bag taken according to the procedure described in Note 8, together with an appropriate proportion of the WP. Flow time of the suspension: maximum 30 sec.

5.2 **Suspensibility** (MT 184) (Notes 2 and 3)

The suspensibility shall be tested on a suspension containing the WP and the bag material in the actual ratio of application, prepared according to the procedure described in Note 9.

A minimum of 50% shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2°C (Note 4).

5.3 **Persistent foam** (MT 47.2) (Note 5)

The persistent foam shall be tested on a suspension containing the WP and the bag in the actual ratio of application, prepared according to the procedure described in Note 9.
Maximum: 60ml after 1 min.

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Note 1 For record keeping purposes, the suffix "SB" should be added to the formulation code (WPSB).
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 184.
Note 3 This test will normally only be carried out after the heat stability test 4.1.
Note 4 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".
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.
Note 7 Sub-sampling
Lay the bag on a bench and carefully open one side of the bag with a cutter, taking care not to damage the seals. Transfer the contents of the bag into a suitable flask. This material shall be used to carry out the tests for:
- active ingredient identity (2.1);
- active ingredient content (2.2);
- pH range (3.1);
- wet sieve test (3.2);
- wettability (3.5);
- dissolution of the bag (5.1);
- suspensibility (5.2);
- persistent foam (5.3).

The bag is then opened on three sides, completely cleaned from adhering powder by brushing or suction and weighed to the nearest 0.01 g. It shall be used to carry out the dissolution test (5.1). Aliquots of an aqueous solution of the bag material shall be used in the suspensibility (5.2) and persistent foam (5.3) tests. In the case of delay of the above tests, the bag shall be stored in a watertight container (glass bottle or equivalent) to avoid any change in its properties.

Note 8 The sampling of the bag for the dissolution test should be as follows:

Lay the empty cleaned bag in its original configuration (double layer). Delineate and then cut up a test sample including part of the upper seal (5 cm) and symmetrically including the vertical seal (10 cm). If the size of the bag is less than this dimension, use the whole bag. Carry out the dissolution test immediately to avoid any modification of the sample. Note 9 The procedure for adding the bag material to the solution for the suspensibility and the persistent foam tests should be as follows: Prepare a stock solution of the bag material (1 mg/ml) by weighing approximately a 100 mg sample (n mg) of the bag (excluding sealed parts) to the nearest mg. Dissolve this sample by stirring in the standard water used for the tests to give a

final volume of n ml. Store the stock solution in a stoppered bottle before use. Calculate the volume (V ml) of the stock solution of the bag to be added to the test suspension of the wettable powder according to the following equation: V(ml) = X *x* 1000B W
where: B (g) = weight of the emptied and cleaned bag;
W (g) = nominal weight of the WP contained in the bag;
X (g) = weight of the WP sample used in the test.

ALPHA-CYPERMETHRIN WETTABLE POWDER

WHO specification 454/WP (April 2006□)

*This specification, which is PART ONE of this publication, is based on evaluations of data submitted by the manufacturers whose names are listed in the evaluation reports (*454/2005, 454/2007*). It should be applicable to relevant products of these manufacturers, 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 (*454/2005, 454/2007*), as PART TWO, form an integral part of this publication.*

1 **Description**

The material shall consist of a homogeneous mixture of technical alphacypermethrin, complying with the requirements of WHO specification 454/TC (April 2006), together with filler(s) and any other necessary formulants. It shall be in the form of a freely flowing fine powder, free from visible extraneous matter and hard lumps.

2 **Active ingredient**

2.1 **Identity tests** (454/WP/M/2, CIPAC Handbook H, p.18, 1998)

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 **Alpha-cypermethrin content** (454/WP/M/3, CIPAC Handbook H, p.18, 1998)

The alpha-cypermethrin content shall be declared (100 g/kg) and, when determined, the average measured content shall not differ from that declared by more than ±10%.

3 **Physical properties**

3.1 **pH range** (MT 75.3, CIPAC Handbook J, p.131, 2000)

pH range: 4 to 8.

3.2 **Wet sieve test** (MT 185, CIPAC Handbook K, p.149, 2003)

Maximum: 2% of the formulation shall be retained on a 75 µm test sieve.
3.3 **Suspensibility** (MT 184 CIPAC Handbook K, p.142, 2003) (Notes 1 & 2)
□ 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/.

A minimum of 70% of the alpha-cypermethrin content found under 2.2 shall be in the suspension after 30 min in CIPAC standard water D at 30 ± 2°C.

3.4 **Wettability** (MT 53.3.2, CIPAC Handbook F, p.164, 1995)
The formulation shall be completely wetted in 1 min with swirling.

3.5 **Persistent foam** (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 3)
Maximum: 60 ml after 1min.

4 **Storage stability**

4.1 **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 4), and the formulation shall continue to comply with the clauses for:

- pH range (3.1),
- wet sieve test (3.2),
- suspensibility (3.3),
- wettability (3.4).

Note 1 The formulation should be tested at the highest and lowest rates of use recommended by the supplier, provided it does not exceed the conditions given in method MT184.

Note 2 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler gravimetric methods may be used on a routine basis provided that these methods have been shown to give results equal to those of chemical assay. In case of dispute, the chemical method shall be the "referee method".

Note 3 The mass of sample to be used in the test should be specified at the highest rate recommended by the supplier.

Note 4 Analysis of the formulation, before and after the storage stability test, should be carried out concurrently (i.e. after storage) to reduce the analytical error.

BIFENTHRIN
WETTABLE POWDER

Interim specification WHO/IS/WP/415/2001

CAUTION*: The use of hard water may create suspensibility problems.*

1. Specification

1.1 Description

The material shall consist of an homogeneous mixture of technical bifenthrin, complying with the requirements of WHO specification WHO/IS/TC/415/2001, in a form of a fine, free flowing powder that wets out readily on stirring into water, together with filler(s) and any other necessary formulants. It shall be in form of a fine off-white to tan powder free from visible extraneous matter and hard lumps.

1.2 Chemical and physical requirements

The material, sampled from any part of the consignment (see method WHO/M/1.R1) shall comply with the requirements of section 1.1 and with the following requirements.

1.2.1 Bifenthrin *content (g/kg basis)*

The content of bifenthrin (g/kg basis), determined by the method described in section 2.1, shall not differ from the declared content by more than the following amount:

Declared content	***Permitted Tolerance***
Above 25 up to 100 g/kg	± 10% of the declared content
Above 100 up to 250 g/kg	± 6% of the declared content

Higher declared contents are not currently available

The average content of all samples taken shall not be lower than the declared content.

1.2.2 Water

The water content determined by the method described in WHO/M/7.R.1 (equivalent to CIPAC method MT 30.5, CIPAC Handbook J, p. 120), shall not be higher than 30.0 g/kg.

1.2.3. *Wet sieving*

Not less than 98% of the powder shall pass through a 75 ∝m sieve and not less than 95% of the powder shall pass through a 60 ∝m sieve, when tested by the CIPAC method MT 59.3 (CIPAC Handbook F, p.179).

1.2.4 *Suspensibility*

In WHO hard standard water. When tested by the CIPAC method MT 15.1 (CIPAC Handbook F, p.45), a minimum of 60 % of the bifenthrin content found under 1.2.1 shall be in suspense on after 30 minutes in WHO standard hard water (WHO method WHO/M/29) at 30 + 2^0C. Alternatively, if the buyer requires other standard waters to be used, then this shall be specified when ordering.

1.2.5 *pH range & Acidity*

The pH of the material, when determined by the CIPAC method MT 75 (CIPAC Handbook F, p.205), shall be in the range 8.00 to 10.0.

The acidity of the material, when determined by the CIPAC method MT 31 (CIPAC Handbook F, p.96), shall not be higher than 0.5 g/kg calculated as H2SO4.

1.2.6 *Persistent foam*

The persistent foam of the material at the top of a 250 mL of suspension prepared in standard hard water, shall not exceed 15 mL when tested by the CIPAC method MT 47.2 (CIPAC Handbook F, p.152) after 1 minute.

1.2.7 *Wettability*

In WHO standard hard water (WHO/M/29).The wettability of the material, when determined by the CIPAC method MT 53.3 (CIPAC Handbook F, p.164), shall not be higher than 3 minutes.

1.2.8 *Heat stability*

The powder after treatment as described in section 2.2 must comply with the requirements of sections 1.2.1, 1.2.3, 1.2.4 and 1.2.7 of this specification.

1.3 Packing and marking of packages

The bifenthrin wettable powder shall be packed in suitable clean bulk packs, as specified in the order.

All packages shall bear, durably and legibly marked on the containers, the following:

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2 The product should be tested at the highest and lowest rates of use recommended by the supplier, provided this is consistent with the conditions given in the method.

Manufacturer's name
Bifenthrin wettable powder
Bifenthrin……g/kg
Batch number or reference number, and date of test
Net weight of contents
Date of formulation
Instruction for use

and the following minimum cautionary notice:

Bifenthrin is a pyrethroid that acts predominantly on the central nervous system; high dosages have been found to cause tremor and clonic convulsions in experimental animals. A high concentration in air may be irritant to the eyes and contact with the concentrated product may induce a temporary tingling sensation, particularly on the face. It may be hazardous if swallowed. Do not inhale spray mist. Avoid skin contact; wear protective gloves, clean protective clothing, and a face mask (surgical type) when handling the product. Wash hands and exposed skin thoroughly after using.

Keep containers out of reach of children and well away from foodstuffs and animal feed and their containers. If poisoning occurs, call a physician. Treatment is symptomatic.

Bifenthrin is toxic to aquatic wildlife. Avoid accidental contamination of water.

Methods of determining chemical and physical properties

2.1 Bifenthrin content

2.1.1 Outline of method

This test method describes the analysis of wettable powder formulations.

Improved column technology and method optimization have yielded a method which give results equivalent or superior to previous methods.

Bifenthrin is determined by comparison to an internal standard, octacosane. A test solution containing a known concentration of octacosane is utilized by comparing instrument response (peak area) of the internal standard to the relative response of bifenthrin, taking into account the amount of sample being analyzed.

2.1.2 Apparatus

Analytical Balance. Capable of accurately weighing to 0.1 mg or equivalent.

Centrifuge.
Gas Chromatograph. Capable of operating over the range 100 to 300°C, fittedwith a flame ionization detector and data collection system and if possible an autosampler.

Graduated Cylinder. 500 mL.
Reciprocating Shaker.
Vials, Minimum 40 mL capacity, with poly-lined cap.
Volumetric Pipette.
Magnetic Stirrer and stir bar.

Column. Megabore DB-210, 30 meter length, 0.53 mm internal diameter, film thickness 1 □m; maximum temperature (isothermal) 200 □C. Available from J&W Scientific, or equivalent.

2.1.3 Reagents

Octacosane, Eastman Kodak Chemical Co or equivalent.
Heptane.
Acetone.
Bifenthrin, Analytical Standard Grade, available from FMC Corporation, Agricultural Chemical Group, Princeton, NJ, USA.

2.1.4 Analytical instrument parameters

Gas Chromatograph parameters (all conditions may be adjusted to optimize results):

Oven Temperature:	205 □C
Injection Port Temperature:	240 □C
Detector Temperature:	300 □C

Data Station Parameters (all parameters may be modified to optimize results):

Run Time:	8 minutes
Chart Speed:	0.5 cm/min
Zero:	5% full scale

2.1.5 Determination of response factor "RF'

Weigh 0.1 g of the analytical standard, to the nearest 0.001g, and place into a vial.

Prepare an internal standard stock solution by weighting 2.5 g octacosane, to the nearest 0.01 g, and placing it into a bottle with a capacity of at least 1000 mL. To this add 700 mL of heptane and 175 mL of acetone, which have been measured bya graduated cylinder. Mix well using a magnetic stirrer.

Pipette 40 mL of the internal standard stock solution to the vial containing the analytical standard; mix on reciprocating shaker until dissolved.

Inject 1 □L of the standard solution into the gas chromatograph.

Obtain several chromatograms and measure the peak areas of the internal standard and bifenthrin.

Calculate response factor by the following formula:

$$Rf = \frac{A_{is} \times WT_{std} \times P_{std}}{A_{std} \times WT_{is} \times P_{is}}$$

Where: A_{is} = Area internal standard

A_{std} = Area bifenthrin
WT_{std} = Weight of standard
WT_{is} = Weight of internal standard
P_{std} = Purity of bifenthrin standard
Pis = Purity of internal standard

2.1.6 *Sample preparation*

Bifenthrin wettable formulations: weight a sufficient amount of sample to obtain 0.1 g bifenthrin into a vial; add 40 mL of internal standard stock solution and mix on reciprocating shaker for 30 minutes.

Inject 1 µL portions of the sample solutions, obtaining three replicate injections for each. Run a standard injection series after every three or four samples.

Calculate percent (%) active ingredient bifenthrin by the following formula:

$$\% = \frac{A_{spl} \times WT_{is} \times RF \times 100}{A_{is} \times WTspl}$$

Where: A_{spl} = Area of bifenthrin in sample
WT_{is} = Internal standard weight
RF = Response Factor
A_{is} = Area of internal standard peak
WT_{spl} = Sample weight

2.2 Heat stability treatment

54 + 2°C for 14 days (CIPAC method MT 46.1, CIPAC Handbook F, p.149), unless other temperatures and times are requested (FAO Manual on the development and use of FAO specifications for plant protection products, no.149, p.33).

After completion of the heat stability treatment, the samples should not be exposed to heat, bright sunshine, or atmospheric humidity.

If required the test should be conducted in the commercial type pack.