

FAO SPECIFICATIONS AND EVALUATIONS
FOR PLANT PROTECTION PRODUCTS

BETA-CYFLUTHRIN

(1RS, 3RS; 1RS, 3SR)-3-(2,2-dichloro-vinyl)-2,2-dimethyl-cyclopropane-carboxylic acid (RS)-cyano-(4-fluoro-3-phenoxy-phenyl)-methyl ester

1999



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

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Disclaimer¹

FAO specifications are developed with the basic objective of ensuring that pesticides complying with them are satisfactory for the purpose for which they are intended so that they may serve as an international point of reference. The specifications do not constitute an endorsement or warranty of the use of a particular pesticide for a particular purpose. Neither do they constitute a warranty that pesticides complying with these specifications are suitable for the control of any given pest, or for use in a particular area. Owing to the complexity of the problems involved, the suitability of pesticides for a particular application must be decided at the national or provincial level.

Furthermore, the preparation and use of pesticides complying with these specifications are not exempted from any safety regulation or other legal or administrative provision applicable thereto. FAO shall not be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of the preparation, transportation, sale or use of pesticides complying with these specifications.

Additionally, FAO wishes to alert users of specifications to the fact that improper field mixing and/or application of pesticides can result in either a lowering or complete loss of efficacy. This holds true even where the pesticide complies with the specification. Accordingly, FAO can accept no responsibility for the consequences of improper field mixing and/or application.

FAO is not responsible for ensuring that any product claimed to comply with FAO specifications actually does so.

¹ This disclaimer applies to all specifications published by FAO. Furthermore it does not undertake to insure anyone who utilizes this Manual or the specifications against liability for infringement of any Letters Patent nor assume any such liability.

INTRODUCTION

FAO establishes and publishes specifications* for technical pesticides and related formulations of plant protection products, 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.

Since 1999 the development of FAO specifications has followed the **New Procedure**, described in the 5th edition of the “Manual on the development and use of FAO specifications for plant protection products” (FAO Plant Production and Protection Page No. 149). This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package required for evaluation, the procedures to be applied in the evaluation process by FAO and the Experts of the “FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent.”

FAO Specifications now only apply to the products of manufacturers whose data have been evaluated as satisfactory and to whose products the specifications are thus known to be appropriate. Consequently from the year 2000 onwards the publication of FAO specifications under the **New Procedure** has changed. Every specification document consists now of two parts, namely the specifications and the evaluation report(s):

Part One: The Specifications of the technical material and the related formulations of the plant protection product, in accordance with the requirements of chapters 4, 5 and 6 of the 5th edition of the “Manual on the development and use of FAO specifications for plant protection products”.

Part Two: The Evaluation Report(s) of the plant protection product, reflecting the evaluation of the data package carried out by FAO and the Panel of Experts, and providing the justification for any deviation in the specifications from requirements of the 5th edition of the Manual. The data have been provided by the manufacturer(s) according to the requirements of Appendix A, Annex 1, of the 5th edition of the “Manual on the development and use of FAO specifications for plant protection products”. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical pesticide has been evaluated.

FAO 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 methods of synthesis. FAO may extend the scope of the specifications to notionally similar products, if the Panel of Experts has been satisfied that the additional products are equivalent to those which formed the basis of the reference specification.

* Footnote: The publications are available on the Internet under (<http://www.fao.org/waicent/faoinfo/agricult/agp/>) or as hardcopy from the Plant Protection Information Officer.

BETA-CYFLUTHRIN

INFORMATION

Common name

beta-cyfluthrin (ISO)

Chemical names (stereochemistry unstated)

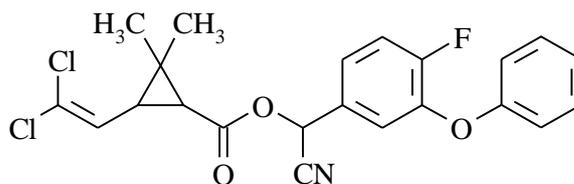
IUPAC

3-(2,2-dichloro-vinyl)-2,2-dimethyl-cyclopropane-carboxylic acid cyano-(4-fluoro-3-phenoxy-phenyl)-methyl ester

CA

Cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, cyano (4-fluoro-3-phenoxyphenyl)methyl ester

Structural formula



Molecular formula

$C_{22}H_{18}Cl_2FNO_3$

Relative molecular mass

434.3

CAS Registry number

68359-37-5 (unstated stereochemistry)

CIPAC code number

482

BETA-CYFLUTHRIN TECHNICAL MATERIAL

482/TC (1999)

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 (482/1999). 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 report (482/1999) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of beta-cyfluthrin together with related manufacturing impurities, in the form of a white to yellowish powder, free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 Identity tests (CIPAC 482/TC/M/2)

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

2.2 Beta-cyfluthrin content (CIPAC 482/TC/M/3)

The beta-cyfluthrin content shall be declared (not less than 965 g/kg) and, when determined, the mean measured content shall not be lower than the declared minimum content.

2.3 Ratio of Isomers (CIPAC 482/TC/M/3)

Beta-cyfluthrin is a mixture of four diastereoisomers (Note 1) and their ratio, expressed as a percentage of the sum of the four diastereoisomers, shall be:

diastereoisomer I	(1R,3R, α R + 1S,3S, α S = 1:1; cis):	maximum 2.0 %
diastereoisomer II	(1R,3R, α S + 1S,3S, α R = 1:1; cis):	30.0 – 40.0 %
diastereoisomer III	(1R,3S, α R + 1S,3R, α S = 1:1; trans):	maximum 3.0 %
diastereoisomer IV	(1R,3S, α S + 1S,3R, α R = 1:1; trans):	57.0 – 67.0 %

3 Physical properties

3.1 Acidity (CIPAC MT 31)

Maximum: 2 g/kg calculated as H₂SO₄.

Note 1 Retention time in HPLC increases from diastereoisomer I to IV.

BETA-CYFLUTHRIN EMULSIFIABLE CONCENTRATE

482/EC (1999)

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 (482/1999). 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 report (482/1999) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of technical beta-cyfluthrin, complying with the requirements of FAO specification 482/TC (1999), 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 (CIPAC 482/EC/M/2)

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

2.2 Beta-cyfluthrin content (CIPAC 482/EC/M/3)

The beta-cyfluthrin content shall be declared (g/kg or g/l at 20 ± 2 °C, Note 1) and, when determined, the content measured shall not differ from that declared by more than the following amounts:

Declared content in g/kg or g/l at 20 °C	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	

3 Relevant impurities

3.1 Water (CIPAC MT 30)

Maximum: 2.0 g/kg

4 Physical properties

4.1 pH range (CIPAC MT 75)

pH range: 4.5 to 7.0

4.2 Emulsion stability and re-emulsification (CIPAC MT 36.1.1) (Note 2)

The formulation, when diluted at 30 ± 2 °C (Note 3) 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: 0 ml
2.0 h	"Cream", maximum: 1 ml "Free oil", maximum: 0 ml
24 h	Re-emulsification: complete
24.5 h	"Cream", maximum: 0 ml "Free oil", maximum: 0 ml
Note: Tests after 24 h are required only where results at 2 h are in doubt	

4.3 Persistent foam (CIPAC MT 47.2) (Note 4)

Maximum: 10 ml after 1 min.

5 Storage stability

5.1 Stability at 0 °C (CIPAC MT 39.3)

After storage at 0 ± 2 °C for 7 days, no solid and/or liquid which separates shall be visible.

5.2 Stability at elevated temperature (CIPAC 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 5) and the formulation shall continue to comply with the clauses for: pH range (4.1) and emulsion stability and re-emulsification (4.2).

Note 1 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 2 This test will normally only be carried out after the heat stability test, 5.2.

Note 3 Unless another temperature is specified.

Note 4 The test should be carried out at the highest application concentration.

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.

BETACYFLUTHRIN AQUEOUS SUSPENSION CONCENTRATE

482/SC (1999)

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 (482/1999). 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 report (482/1999) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of a suspension of fine particles of technical beta-cyfluthrin, complying with the requirements of FAO specification 482/TC (1999), 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 (CIPAC 482/SC/M/2)

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

2.2 Beta-cyfluthrin content (CIPAC 482/SC/M/3)

The beta-cyfluthrin content shall be declared (g/kg or g/l at 20 ± 2 °C, Note 2) and, when determined, the content measured shall not differ from that declared by more than the following amounts:

Declared content in g/kg or g/l at 20 °C	Tolerance
up to 25	± 15 % 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: In each range the upper limit is included	

3 Physical properties

3.1 Mass per millilitre at 20 °C (CIPAC MT 3.3)

If required, the range of the mass per millilitre (g/ml) at 20 ± 2 °C shall be declared.

3.2 pH range (CIPAC MT 75.3)

pH range: 4.0 to 5.5 (undiluted)

3.3 Pourability (CIPAC MT 148)

Maximum residue: 3 %

3.4 Spontaneity of dispersion (CIPAC MT 160) (Note 3)

A minimum of 90 % of the beta-cyfluthrin content found under 2.2 shall be in suspension after 5 min in CIPAC Standard Water D at 30 ± 2 °C (Note 4).

3.5 Suspensibility (CIPAC MT 161) (Note 3)

A minimum of 95 % of the beta-cyfluthrin content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2 °C (Note 4).

3.6 Wet sieve test (CIPAC MT 59.3) (Note 5)

Maximum: 0.1 % of the formulation shall be retained on a 75 µm test sieve.

3.7 Persistent foam (CIPAC MT 47.2) (Note 6)

Maximum: 30 ml after 1 min.

4 Storage stability

4.1 Stability at 0 °C (CIPAC MT 39.3)

After storage at 0 ± 2 °C for 7 days, the formulation shall continue to comply with suspensibility (3.5) and wet sieve test (3.6), as required.

4.2 Stability at elevated temperature (CIPAC MT 46.3)

After storage at 54 ± 2 °C for 14 days, the determined average active ingredient content must not be lower than 98 % relative to the determined average content found before storage (Note 7) and the formulation shall continue to comply with the clauses for: pH range (3.2), pourability (3.3), spontaneity of dispersion (3.4), suspensibility (3.5), and wet sieve test (3.6), as required.

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 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 the chemical assay method. In case of dispute, the chemical method shall be the referee method.

Note 4 Unless other temperatures and/or times are specified.

Note 5 This test detects coarse particles (e.g. caused by crystal growth) or agglomerates (crust formation) or extraneous materials which could cause blockage of spray nozzles or filters in the spray tank.

Note 6 The mass of sample to be used in the test should be specified at the application 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.

BETA-CYFLUTHRIN

EVALUATION REPORT 482/1999

Explanation

An evaluation of proposed new specifications for an active ingredient protected under patent in the USA until 16.06.2006 (No. 4 782 174, 1988).

Beta-cyfluthrin is currently under review by the European Commission, according to Regulation 3600/92/EEC. It has not been evaluated by the FAO/WHO JMPR.

The draft specifications and the supporting data were provided by Bayer AG in 1999.

Uses

Beta-cyfluthrin is an insecticide, acting as a contact and stomach poison. It combines a rapid knock-down effect with long lasting efficacy. It is not systemic in plants. It is used in agriculture, horticulture (field and protected crops) and viticulture. It is also used against migratory locusts and grasshoppers and in public health and hygiene.

Identity

ISO common name

beta-cyfluthrin (accepted)

Synonyms

none

Chemical names

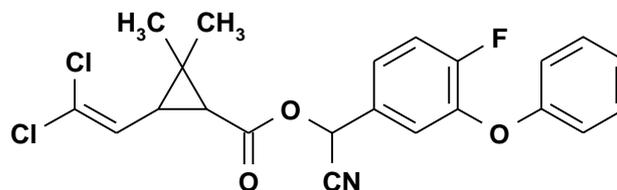
IUPAC

3-(2,2-dichloro-vinyl)-2,2-dimethyl-cyclopropane-carboxylic acid cyano-(4-fluoro-3-phenoxy-phenyl)-methyl ester (unstated stereochemistry)

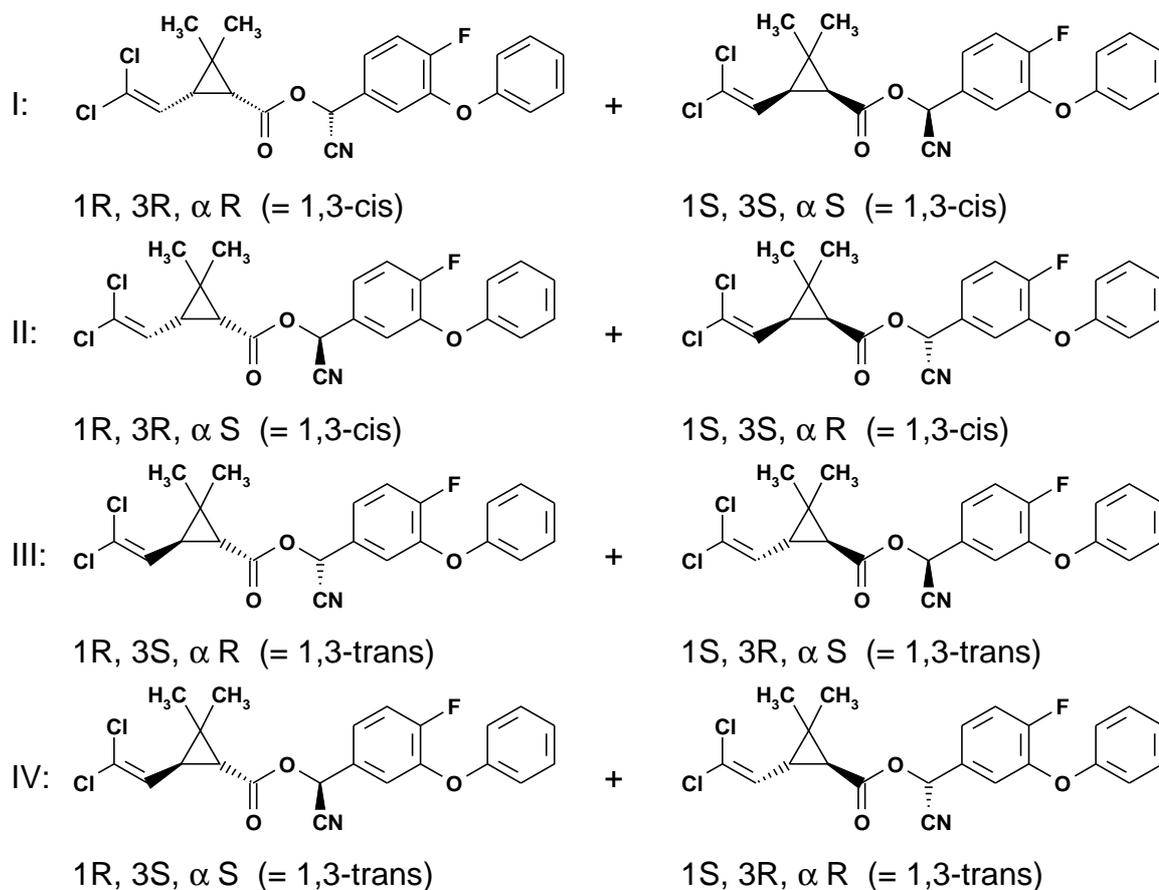
CA

Cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, cyano (4-fluoro-3-phenoxyphenyl) methyl ester (unstated stereochemistry)

Structural formula



Beta-cyfluthrin is a mixture, predominantly of two diastereoisomers, II and IV. The diastereoisomers I and III are present in low proportion (< 5 %).



Molecular formula

$C_{22}H_{18}Cl_2FNO_3$

Relative molecular mass

434.3

CAS Registry numbers

68359-37-5 (unstated stereochemistry)

86560-92-1 (diastereoisomer I)

86560-93-2 (diastereoisomer II)

86560-94-3 (diastereoisomer III)

86560-95-4 (diastereoisomer IV)

CIPAC number

482

Identity tests

CIPAC Method Handbook H (1998), Beta-Cyfluthrin 482/TC/M/2, pp 44-45. HPLC retention time and chromatographic pattern; thin-layer chromatography*; IR (KBr)*; 1H -NMR (200 MHz, CD_2Cl_2).

* Note: beta-cyfluthrin and cyfluthrin cannot be distinguished by these tests.

Physico-chemical properties of the pure active ingredient

<i>Vapour pressure</i>	Diastereoisomer II (purity 97.4 %): 1.4×10^{-8} Pa at 20 °C (by extrapolation). Diastereoisomer IV (purity 98.9 %): 8.5×10^{-8} Pa at 20 °C (by extrapolation). Method: OECD 104 / EC A4. The vapour pressure of beta-cyfluthrin is very low.																														
<i>Melting point</i>	Diastereoisomer II (purity 99.2 %): 80.71 °C. Diastereoisomer IV (purity 99.8 %): 106.19 °C. Method: EC A1.																														
<i>Solubility in water</i>	Diastereoisomer II (purity 97.5%): 2.1 µg/l at 20 °C. Diastereoisomer IV (purity 95.9%): 1.2 µg/l at 20 °C. The pH was not declared. Method: OECD 105/EC A6. Beta-cyfluthrin is of very low solubility in water.																														
<i>Octanol/water partition coefficient</i>	Diastereoisomer II (purity 97.5%): $\log P_{OW} = 6.18$ at 22 °C. Diastereoisomer IV (purity 95.9%): $\log P_{OW} = 6.18$ at 22 °C. The pH was not declared. Method: OECD 107 / EC A8. Beta-cyfluthrin is lipophilic with a tendency for bioaccumulation.																														
<i>Hydrolysis characteristics</i>	<p>The material used was a mixture of 4 diastereoisomeric pairs (purity 99.0 %). Under all conditions tested diastereoisomers II and IV isomerized partially to diastereoisomers I and III, respectively, before degradation by hydrolysis became significant. Isomerization rates were not determined. Therefore, it was only possible to determine half-lives for the degradation of the sums of diastereoisomers I and II and diastereoisomers III and IV.</p> <table border="1"> <thead> <tr> <th></th> <th>20 °C</th> <th>25 °C</th> </tr> </thead> <tbody> <tr> <td>pH 4</td> <td></td> <td></td> </tr> <tr> <td>diastereoisomers I + II</td> <td>> 1 yr</td> <td>> 1 yr</td> </tr> <tr> <td>diastereoisomers III + IV</td> <td>> 1 yr</td> <td>> 1 yr</td> </tr> <tr> <td>pH 7</td> <td></td> <td></td> </tr> <tr> <td>diastereoisomers I + II</td> <td>270 d</td> <td>120 d</td> </tr> <tr> <td>diastereoisomers III + IV</td> <td>160 d</td> <td>75 d</td> </tr> <tr> <td>pH 9</td> <td></td> <td></td> </tr> <tr> <td>diastereoisomers I + II</td> <td>42 h</td> <td>21 h</td> </tr> <tr> <td>diastereoisomers III + IV</td> <td>33 h</td> <td>17 h</td> </tr> </tbody> </table> <p>Method: OECD 111 / C7. Beta-cyfluthrin is very stable to hydrolysis at pH 4, stable at pH 7 but readily hydrolysed at pH 9.</p>		20 °C	25 °C	pH 4			diastereoisomers I + II	> 1 yr	> 1 yr	diastereoisomers III + IV	> 1 yr	> 1 yr	pH 7			diastereoisomers I + II	270 d	120 d	diastereoisomers III + IV	160 d	75 d	pH 9			diastereoisomers I + II	42 h	21 h	diastereoisomers III + IV	33 h	17 h
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Chemical composition and properties of the technical material (TC and TK)

Confidential information on the manufacturing process and the impurity profile (5 batch analysis data and maximum content of all impurities present at or above 1 g/kg) was presented by the Proposer and is held on file by FAO.

Declared minimum content

minimum 965 g/kg (total of isomers I - IV).

Ratio of diastereoisomers, as a proportion of the sum

diastereoisomer I, maximum 2.0 %
diastereoisomer II, 30.0 – 40.0 %
diastereoisomer III, maximum 3.0 %
diastereoisomer IV, 57.0 – 67.0 %.

Relevant impurities and maximum limits for them

none of the impurities reported in the analytical profile of batches was considered relevant.

Hazard summary

The evaluation is based partly on beta-cyfluthrin and partly on cyfluthrin. In general both substances have the same toxicological profile. Depending on different administration vehicles, beta-cyfluthrin has approximately 2 to 5 times higher acute toxicity than cyfluthrin.

Toxicological profile of the technical material based on acute oral, dermal and inhalation toxicity; skin and eye irritation, skin sensitization

Acute oral toxicity

Rat, male (fasted)	LD ₅₀	11 mg/kg body weight (water/Cremophor EL)
Rat, male (fasted)	LD ₅₀	380 mg/kg body weight (PEG 400)
Rat, female (fasted)	LD ₅₀	651 mg/kg body weight (PEG 400)
Mouse, male (fasted)	LD ₅₀	91 mg/kg body weight
Mouse, female (fasted)	LD ₅₀	165 mg/kg body weight
Dog, male (fasted)	LD ₅₀	> 5000 mg/kg body weight
Dog, female (fasted)	LD ₅₀	> 5000 mg/kg body weight

Acute oral toxicity depends on the nature of the vehicle employed.

Acute dermal toxicity

The dermal toxicity of beta-cyfluthrin is very low (rat LD₅₀ > 5000 mg/kg body weight).

Acute inhalation toxicity

Rat (aerosol: a.i. in ethanol/PEG 400)	LC ₅₀ (4 h):	81 – 100 mg/m ³
Rat (dust)	LC ₅₀ (4 h):	532 – 967 mg/m ³

Skin irritation

New Zealand White rabbits tolerated the application of beta-cyfluthrin without exhibiting any manifestation of irritation.

Eye irritation

The treatment produced slight irritation of the conjunctivae of New Zealand White rabbits. However, the changes were reversible within 2 days of application.

Skin sensitisation

No evidence of a skin sensitising potential has been found in the maximisation test on guinea pigs according to the Magnusson and Kligman protocol.

Toxicological profile of the technical material based on repeated administration (from subacute to chronic) and studies such as reproductive and development toxicity, genotoxicity, carcinogenicity, etc.

Sub-acute/sub-chronic toxicity

Groups of rats were treated orally by gavage with beta-cyfluthrin at doses of 0, 0.25, 1, 4 or 16 mg/kg body weight/day for 4 weeks. Treatment up to 1 mg/kg body weight/day was tolerated without adverse signs.

Rats were exposed to beta-cyfluthrin aerosols for 4 weeks (6 h per day, 5 days per week). Concentrations up to 0.2 mg/m³ air were tolerated without adverse effects.

Groups of rats and dogs received beta-cyfluthrin in their feed for 13 weeks. Concentrations up to 125 mg/kg respectively 60 mg/kg feed were tolerated by male and female rats respectively male and female dogs without effects.

Chronic toxicity

Long-term feeding studies were conducted with cyfluthrin on rats, mice and dogs. The following concentrations were tolerated without effects:

Rat (24 months)	50 mg/kg feed (ppm)*
Mouse (23 months)	200 mg/kg feed (ppm)*
Dog (12 months)	160 mg/kg feed (ppm)*

* applied to the diastereoisomers ratio in cyfluthrin.

Carcinogenicity

In a.m. chronic feeding studies with rats and mice, no evidence of oncogenic potential of cyfluthrin was found. Cyfluthrin studies are regarded as representative for beta-cyfluthrin.

Reproduction

Groups of 10 male and 20 female rats received cyfluthrin via the feed throughout an entire experimental period (3 successive generations, 2 matings each). Concentrations up to 50 mg/kg feed had no effect on the fertility and did not induce malformations in the young.

Developmental toxicity

Groups of inseminated rats and rabbits were treated with cyfluthrin in daily oral doses. No primary embryotoxic or teratogenic effects were observed.

Genotoxicity

The mutagenic potential of beta-cyfluthrin was studied in various in-vitro and in-vivo test systems. None of the test systems used revealed any evidence of mutagenic and/or genotoxic potential of beta-cyfluthrin.

Neurotoxicity

In sub-chronic studies with cyfluthrin on rats and chickens no signs of delayed neurotoxicity were observed on either the clinical or the histological level.

Ecotoxicological profile

Acute toxicity to fish

In laboratory flow-through studies the following results (LC₅₀, 96 h) were obtained:

Golden orfe (<i>Leuciscus idus melanotus</i> , 20 – 22 °C):	331 ng/l
Rainbow trout (<i>Oncorhynchus mykiss</i> , 12 – 13 °C):	89 ng/l

Acute toxicity to *Daphnia*

The acute toxicity of beta-cyfluthrin technical to water fleas was determined under flow-through conditions. The 48-hour EC₅₀ value for *Daphnia magna* exposed to beta-cyfluthrin at 20 °C was approximately 0.3 µg a.i./l.

Effects on algal growth

The effects of beta-cyfluthrin technical on the growth of the green alga, *Scenedesmus subspicatus*, were determined in a 96-hour laboratory study under static test conditions using test concentrations of 1 and 10 µg a.i./l nominal concentration at 23 °C. Because of the low water solubility of this compound it was impossible to test higher concentrations. The EC₅₀ for the growth rate was determined to be > 10 µg a.i./l. The no-observed-effect-concentration was >10 µg a.i./l. No toxic signs were observed at 10 µg a.i./l, the highest concentration tested.

Effects on aquatic ecosystems

In studies with beta-cyfluthrin in natural and artificial ponds a pronounced but transient depression of populations of crustaceans was observed. Due to the rapid disappearance of the compound from the water phase (low water solubility and extremely high adsorption to organic material), recovery of the crustacean population is also rapid. No adverse effects on flora and other fauna of the ecosystem, fish included, were observed.

Effects on earthworms

The acute toxicity of beta-cyfluthrin to earthworms was determined to be LC₅₀ > 1000 mg/kg dry weight soil, i.e. beta-cyfluthrin can be regarded as non toxic to earthworms.

Effects on bees

The acute toxicity of beta-cyfluthrin to bees was determined to be LD₅₀ < 0.025 µg/bee, i.e. beta-cyfluthrin must be regarded as toxic to bees.

Effects on birds

Beta-cyfluthrin is practically non-toxic to birds, as indicated by an acute TEL (threshold effect level) of > 2000 mg a.i./kg b.w. for bobwhite quail. The TEL for bobwhite quail of cyfluthrin is in the same range. The short term TEC (threshold effect concentration) for cyfluthrin was determined to be 2200 mg a.i./kg diet for bobwhite quail and 3200 mg a.i. /kg diet for mallard duck.

WHO (IPCS) evaluation

IPCS has not evaluated beta-cyfluthrin.

WHO IPCS hazard classification

moderately hazardous, class II.

FAO/WHO JMPR evaluation

FAO/WHO JMPR has not evaluated beta-cyfluthrin.

Formulations

Main formulation types available in the market

EC, SC.

Main countries where the formulations are registered and sold

Both formulation types are registered and sold in many countries all over the world.

Methods of analysis and testing

Chemical analysis method for active ingredient (identity tests included)

CIPAC Method, Handbook H (1998), Beta-cyfluthrin 482/TC/M/-, pp 43-51. Beta-cyfluthrin is determined by normal phase HPLC, using UV detection at 235 nm with external standardisation.

Physical testing methods

Test methods used to determine the physico-chemical properties of the active ingredient were OECD and EU, while those used for the formulations were CIPAC, corresponding to those indicated in the specifications.

Physical properties

The physical properties, the methods for testing them and the limits proposed for the EC and the SC formulations, comply with the recommendations of the FAO Manual, 5th edition.

Containers and packaging

No special requirements were identified for containers and packaging:

Expression of the active ingredient

The active ingredient is expressed as beta-cyfluthrin in g/kg or g/l for liquid formulations at 20±2°C.

Appraisal

The data submitted are in accordance with the requirements of the FAO Manual, 5th edition, and support the specifications.

Beta-cyfluthrin is an isomeric mixture consisting predominantly of 2 diastereoisomeric pairs (II + IV) of enantiomers. Melting points of enantiomer pairs II and IV are 80.71°C and 106.19°C respectively. Beta-cyfluthrin is very slightly volatile and very slightly soluble in water. It is hydrolytically very stable at pH 4, stable at pH 7 but readily hydrolysed at pH 9. It is a lipophilic compound with a tendency for bioaccumulation.

It is formulated as emulsifiable concentrates (EC) and suspension concentrates (SC).

The Meeting was provided with commercially confidential information on the manufacturing process and batch analysis data on impurities present at or above 1 g/kg, which were declared to be identical to those submitted for registration in Germany.

The acute oral toxicity of beta-cyfluthrin is rather high, the dermal toxicity very low, while the acute inhalation toxicity is higher as an aerosol than in the form of a dust.

There is no evidence of genotoxic potential, delayed neurotoxicity, carcinogenic potential or effects on reproduction.

Based on toxicity data and exposure estimates, the risks to birds and mammals are considered low. Acute and chronic toxicity studies show that the technical material and formulations of beta-cyfluthrin are highly toxic to fish and aquatic invertebrates and moderately toxic to algae. It is classified as presenting a high risk to honey bees and other arthropod species. Its effects on earthworms and other soil macro- or micro-organisms are considered to be small.

Recommendations

The Meeting recommended that the specifications for TC, EC, SC proposed by Bayer should be adopted as FAO specifications.

References

Food and Agriculture Organization of the United Nations (1999), Manual on Development and Use of FAO Specifications for Plant Protection Products, 5th edition, FAO Plant production and protection paper 149, FAO, Rome.

W. Dobrat and A. Martijn, Eds. (1998), CIPAC Handbook H, Collaborative International Pesticides Analytical Council, Harpenden, UK.

W. Dobrat and A. Martijn, Eds. (1995), CIPAC Handbook F, Collaborative International Pesticides Analytical Council, Harpenden, UK.