

WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES

ALPHA-CYPERMETHRIN

A racemic mixture of:

(*S*)- α -cyano-3-phenoxybenzyl-(1*R*,3*R*)-3-(2,2-dichlorovinyl)-
2,2-dimethylcyclopropane-carboxylate and
(*R*)- α -cyano-3-phenoxybenzyl-(1*S*,3*R*)-3-(2,2-dichlorovinyl)-
2,2-dimethylcyclopropane-carboxylate



**World Health
Organization**

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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.

INTRODUCTION

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

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

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

Part One: The Specification of the technical material and the related formulations of the pesticide in accordance with chapters 4 to 9 of the 1st edition of the “FAO/WHO Manual on Pesticide Specifications.”

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

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

Specifications bear the date (month and year) of publication of the current version. Dates of publication of the earlier versions, if any, are identified in a footnote. Evaluations bear the date (year) of the meeting at which the recommendations were made by the JMPS.

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

PART ONE

SPECIFICATIONS

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ALPHA-CYPERMETHRIN

INFORMATION

Common name

alpha-cypermethrin (E-ISO, BSI), alpha-cyperméthrine (F-ISO)

Synonyms

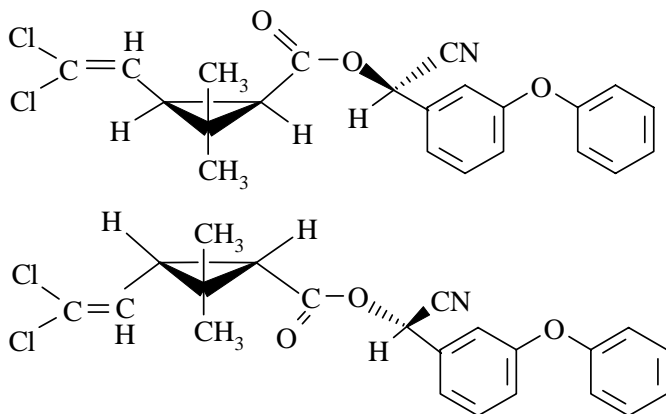
alphamethrin (rejected common name), alfoxylate

Chemical names

IUPAC: a racemic mixture of: (S)- α -cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (R)- α -cyano-3-phenoxybenzyl-(1S,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate

CA: [1 α (S*), 3 α]-(\pm)-cyano(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate

Structural formula



Empirical formula

C₂₂H₁₉Cl₂NO₃

Relative molecular mass

416.3

CAS Registry number

67375-30-8

CIPAC number

454

Identity tests

GC retention time, IR spectrum.

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

ALPHA-CYPERMETHRIN TECHNICAL MATERIAL

WHO specification 454/TC (April 2006*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (454/2005). 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. The evaluation report 454/2005, as PART TWO, forms an integral part of this publication.

1 Description

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

2 Active ingredient

2.1 Identity tests (454/TC/M/2, CIPAC Handbook H, p.15, 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/TC/M/3, CIPAC Handbook H, p.15, 1998)

The alpha-cypermethrin content shall be declared (not less than 930 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

* 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/>.

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

ALPHA-CYPERMETHRIN WETTABLE POWDER

WHO specification 454/WP (April 2006*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (454/2005). 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. The evaluation report 454/2005, as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of a homogeneous mixture of technical alpha-cypermethrin, 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 $\pm 10\%$.

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)

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 $30 \pm 2^\circ\text{C}$.

3.4 Wettability (MT 53.3.2, CIPAC Handbook F, p.164, 1995)

The formulation shall be completely wetted in 1 min with swirling.

* 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/>.

3.5 **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 $54 \pm 2^\circ\text{C}$ for 14 days, the determined average active ingredient content must not be lower than 95%, relative to the determined average content found before storage (Note 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.

WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

ALPHA-CYPERMETHRIN SUSPENSION CONCENTRATE

WHO specification 454/SC (April 2006*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (454/2005). 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. The evaluation report 454/2005, as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of a suspension of fine particles of technical alpha-cypermethrin, complying with the requirements of WHO specification 454/TC (April 2006), 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 (454/SC/M/2, CIPAC Handbook H, p.20, 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/SC/M/3, CIPAC Handbook H, p. 20)

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

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

3 Physical properties

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

pH range: 5 to 8

3.2 Pourability (MT 148, CIPAC Handbook F, p. 348)

Maximum "residue": 3%.

* 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/>.

3.3 Spontaneity of dispersion (MT 160, CIPAC Handbook F, p.391, 1995) (Notes 3 and 4)

A minimum of 60% of the alpha-cypermethrin content found under 2.2 shall be in the suspension after 5 min in CIPAC standard water D at $30 \pm 2^\circ\text{C}$.

3.4 Suspensibility (MT 161, CIPAC Handbook F, p.394, 1995) (Note 3)

A minimum of 60% of the alpha-cypermethrin content found under 2.2 shall be in the suspension after 30 min in CIPAC standard water D at $30 \pm 2^\circ\text{C}$.

3.5 Wet sieve test (MT185, CIPAC Handbook K, p.149, 2003) (Note 5)

Maximum: 2% of the formulation shall be retained on a 75 μm test sieve.

3.6 Persistent foam (MT 47.2, CIPAC Handbook F, p. 152) (Note 6)

Maximum: 60 ml after 1min.

4 Storage stability

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

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

- suspensibility (3.4),
- wet sieve test (3.5).

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

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

- pH range (3.1),
- pourability (3.2),
- spontaneity of dispersion (3.3),
- suspensibility (3.4),
- wet sieve test (3.5).

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 the 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 results equal to those of the chemical assay method. In case of dispute, the chemical method shall be the referee method.

Note 4 The test should be conducted at 0.5% concentration (248.75 ml water, 1.25 ml formulation, corresponding to the maximum recommended concentration for application), instead of the 5% specified in MT 160.

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 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.

**PART TWO
EVALUATION REPORTS**

ALPHA-CYPERMETHRIN

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WHO SPECIFICATIONS FOR PUBLIC HEALTH PESTICIDES

ALPHA-CYPERMETHRIN

FAO/WHO EVALUATION REPORT 454/2005

Recommendations

The Meeting recommended the following.

- (i) That the existing WHO specifications for alpha-cypermethrin TC, SC and WP should be withdrawn.
- (ii) That the specifications for alpha-cypermethrin TC, WP (100 g/kg only) and SC proposed by BASF and Tagros, as amended, should be adopted by WHO.
- (iii) That the specifications for alpha-cypermethrin TC, WP(>100-250 g/kg range), SC, EC and UL proposed by BASF and Tagros, as amended, should be adopted by FAO.

Appraisal

The Meeting considered data on alpha-cypermethrin, submitted by BASF and Tagros, in support of new FAO specifications for TC, SC, EC and UL, and for the review of existing WHO full specifications for TC (WHO/SIT/32, 1999) and SC (WHO/SIF/61, 1999) and the WHO interim specification for WP (WHO/IS/98.1.2.R1, 2000).

Alpha-cypermethrin is not under patent.

Draft specifications and supporting data were provided by BASF Aktiengesellschaft, Germany, and Tagros Chemicals India Ltd, in 2004.

The cypermethrin molecule has 3 chiral centres and cypermethrin exists as 8 different enantiomers, or 4 pairs of diastereoisomers. Alpha-cypermethrin is a racemate of one diastereoisomeric pair: [*S*, 1*R*,3*R*] and [*R*, 1*S*,3*S*]. When analyzed by non-chiral chromatography, cypermethrin may be resolved into 4 peaks, one of which represents alpha-cypermethrin.

The Meeting was presented with information from both manufacturers on the manufacturing process, data from 5-batch analyses, and summary data on toxic hazards. Mass balances were high: 99.0-100.3% (BASF) and 99.70–99.94% (Tagros). The minimum content of alpha-cypermethrin declared by BASF was 930 g/kg, whereas that declared by Tagros was 950 g/kg. Both BASF and Tagros reported unknown impurities, the maximum for the sum of these exceeding 1 g/kg in both cases but the maximum for any individual unknown compound was The BASF data were confirmed as similar to those presented to Belgium, in support of the EU review of alpha-cypermethrin. The Tagros data were confirmed as identical (except for the limit for a solvent impurity) to those presented for registration in Australia.

The Meeting agreed that the impurity profile of BASF should be considered the reference profile, as it was supported by a full data package on hazards. The Tagros TC appeared to be equivalent to that of BASF on the basis of the impurity profiles. However, on the basis of the data provided for skin and eye irritation, the alpha-cypermethrin produced by Tagros (mild irritant) did not appear to be equivalent to that of BASF (non-irritant). A review of the Tagros original study reports by

WHO/PCS secretariat (PCS 2005) concluded that the Tagros TC is not an irritant to either skin or eyes, according to the GHS classification (GHS 2003), and that the two manufacturers' TCs should also be considered equivalent on the basis of the toxicological data. The Meeting agreed with this conclusion.

The Meeting agreed that none of impurities is relevant.

A full CIPAC method is available for the determination of alpha-cypermethrin in the TC and all formulations for which specifications were proposed.

The proposed specifications were broadly in accordance with the requirements of the manual (FAO/WHO 2002) but the Meeting considered certain exceptions.

TC and formulations. Both manufacturers included clauses to specify the minimum amount of total cypermethrin isomers present, in addition to the minimum for alpha-cypermethrin isomers. Similar clauses appeared in the existing WHO specifications for alpha-cypermethrin. While recognising that the low levels of minor cypermethrin isomers present might contribute (minimally) to the overall activity, the Meeting concluded that they are not components of alpha-cypermethrin (as defined by the common name) and that they should be designated as non-relevant impurities and therefore not included in the specification.

TC. The existing WHO specification for alpha-cypermethrin included clauses for hydrocarbon solvent and triethylamine content. Neither manufacturer included these clauses in the proposed specifications and the Meeting accepted that they were not required.

The Meeting agreed that the limit for minimum alpha-cypermethrin content should be that of BASF (930 g/kg).

Formulations. The Meeting questioned the apparently high upper limits given for pH range in the specifications (pH 8 or higher), given the potential for slow hydrolysis of alpha-cypermethrin at pH 9 (half-life of several days at room temperatures). The existing WHO specification for SC (the formulation in which hydrolysis might occur most readily) included an upper limit for pH range of 8.7. The manufacturers confirmed that the active ingredient is stable during storage of products at pH 8 and this limit was therefore agreed by the Meeting.

WP. The clause for wettability proposed by Tagros specified a wetting time limit of 5 min, without swirling. The Meeting acknowledged that pyrethroids have virtually no affinity for water but considered this to be an unacceptably long time. The manufacturer explained that a limit of 1 min, with swirling, was readily achievable and the Meeting accepted this.

The existing WHO specification incorporated a limit of 90 ml for persistent foam but the manufacturers acknowledged that their products comply with the standard maximum of 60 ml (FAO/WHO 2002) and this limit was agreed by the Meeting.

The Meeting noted that the WHO specification for WP is restricted to a 10% formulation, whereas a >100-250 g/kg range is appropriate for FAO specifications.

Tagros stated that their WP is sold in metallized-film sachets but the Meeting did not consider this to require a clause or Note in the specification.

SC. The proposed limits for wet sieve test differed slightly between the manufacturers but they agreed with the Meeting to adopt a limit of 2%.

The Meeting agreed that the limit for pourability of 2.5%, proposed by BASF, should be rounded to 3 ml. The proposed limit for the Tagros product was within this limit.

BASF stated that spontaneity of dispersion should be tested at 0.5% concentration (instead of the usual 5% indicated in method MT 160) because the lower concentration represented both the maximum application rate and a more reasonable test of formulation quality. This requirement for the test did not appear in the existing WHO specification but the existing limit (60% dispersion) was the same as that proposed. The Meeting accepted that testing at the higher concentration was unrealistic in this case and agreed to the proposed deviation from the normal requirement.

The limit proposed by BASF for active ingredient content after storage was lower than that proposed by Tagros but, being within the acceptable range, it was accepted by the Meeting.

EC. Both manufacturers provided limits for method MT 36.1 and MT 173. Following discussions of the methods to be employed, the Meeting and manufacturers agreed that limits should be provided for method MT 36.3 only.

**SUPPORTING INFORMATION
FOR
EVALUATION REPORT 454/2005**

Uses

Alpha-cypermethrin is a non-systemic, broad spectrum, insecticidal pyrethroid, with rapid knockdown activity. It is effective by contact and ingestion against target pests at relatively low application rates. It acts by preventing transmission of nerve impulses, by blocking the passage of sodium ions through channels in nerve membranes, thus preventing signals passing down axons. Typically this intoxication results in a rapid "knockdown" and mortality.

It is used in to control a wide range of chewing and sucking insects (particularly Lepidoptera, Coleoptera and Hemiptera) in fruit (including citrus), vegetables, vines, cereals, maize, beet, oilseed rape, potatoes, cotton, rice, soya beans, forestry and other crops. In public health it is used to control cockroaches, mosquitoes, flies and other insect pests. It is also used in animal health as an ectoparasiticide.

Identity

Common name

alpha-cypermethrin (E-ISO, BSI), alpha-cyperméthrine (F-ISO)

Synonyms

alphamethrin (rejected common name), alfoxylate

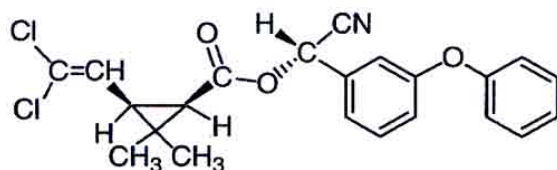
Chemical names

IUPAC: a racemic mixture of: (*S*)- α -cyano-3-phenoxybenzyl-(1*R*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*R*)- α -cyano-3-phenoxybenzyl-(1*S*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate

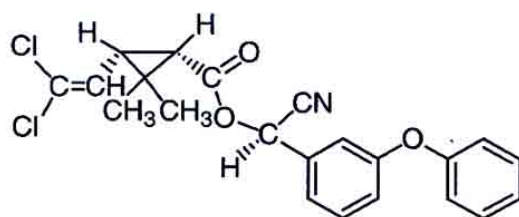
CA: [1 α (*S*^{*}), 3 α](\pm)-cyano(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate

Structural formula

(*S*) (1*R*)-*cis*-



+



(*R*) (1*S*)-*cis*-

Empirical formula



Relative molecular mass

416.3

CAS Registry number

67375-30-8

CIPAC number

454

Identity tests

GC retention time, IR spectrum.

Physico-chemical properties of alpha-cypermethrin

Table 1. Physico-chemical properties of pure alpha-cypermethrin

Parameter	Value	Purity %	Method	Reference
Vapour pressure	3.4 x 10 ⁻⁷ Pa at 25°C	97.3	EEC A4	PML 1992-C39
	1.9 x 10 ⁻⁵ Pa at 51°C (BASF)			
	2.3 X 10 ⁻⁵ Pa at 20°C (Tagros)	97.4	EEC A4	10802
Melting point	81.5°C (range 81.4-83.7°C) (BASF)	97.3	OECD 102	AL-303-001
	Melting point: 77.8-80.8°C (Tagros)	97.4	EEC A1, A2	10781
Boiling point	200°C at 0.07 mm Hg (BASF) Cannot be determined at atmospheric pressure as decomposition occurs before boiling	99.0	OECD 102	AL-303-001
	195.8-197.8°C at 9.3 Pa (Tagros)	97.4	EEC A1, A2	10781
Decomposition temperature	Decomposition temperature starts at ca 270°C (below boiling point at atmospheric pressure) (BASF)	97.3	-	AL-303-001
Solubility in water (all in µg/l at 25°C)	pH <i>cis</i> -1 <i>cis</i> -2 total 4.08 3.92 0.67 4.59 7.12 1.83 3.97 5.80 9.06 3.33 4.54 7.87 distilled water, unbuffered 0.81 1.25 2.06 (BASF)	98.0	EEC A.6	AL-311-002
	10 at 30°C (Tagros)	97.4	OECD 105	10778
Octanol/water partition coefficient	log P K _{OW} = 5.5 at ambient temperature (BASF)	95.4	OECD 117, HPLC method	AL-315-001
	log P _{OW} = 6.93 at 25°C, pH 7.0 (Tagros)	97.4	EEC A8 GC-ECD method	10805

Table 1. Physico-chemical properties of pure alpha-cypermethrin

Parameter	Value	Purity %	Method	Reference
Hydrolysis characteristics (half-life)	measured: pH 4, stable at 40°C pH 7, 27 days at 50°C pH 7, 5.3 days at 60°C pH 7, 2.0 days at 75°C pH 9, 3.5 days at 25°C pH 9, 3.0 hours at 50°C Calculated: pH 7, 101 days at 20°C pH 7, 67 days at 25°C pH 9, 7.3 days at 20°C pH 9, 3.5 days at 25°C (BASF)	radio-labelled purity 99.0, unlabelled purity 97.3	OECD 111	AL-322-002
	pH 4, stable at 50°C pH 7, stable at 50°C pH 9.0, 15.41 days at 40°C pH 9.0, 21.02 days at 30°C (Tagros)	97.4	OECD 111	12327
Photolysis characteristics	Conditions: pH 5 (sterile buffer, no hydrolytic decomposition), 22°C, artificial sunlight over 15 and 28 days, two radiolabelled test substances, dark control samples. benzene-label: DT ₅₀ = 2.2 days continuous irradiation DT ₅₀ = 6.3 days calculated for solar exposure cyclopropane-label: DT ₅₀ = 1.2 days continuous irradiation DT ₅₀ = 3.4 days calculated for solar exposure Environmental half-life, 2.9 days, calculated from quantum yield for latitude 40°N during spring (BASF)	each radio-labelled compound >99	SETAC Part 1: 10	AL-324-003
Dissociation characteristics	Does not dissociate	-	-	EU 2004

Alpha-cypermethrin is not flammable or auto-flammable and does not have explosive or oxidizing properties.

Table 2. Chemical composition and properties of alpha-cypermethrin technical material (TC)

Manufacturing process, maximum limits for impurities ≥ 1 g/kg, 5 batch analysis data	Confidential information supplied and held on file by FAO. Mass balances were 99.0-100.3% and percentages of unknowns were in the range of <0.05-0.14% for the sum of six impurities, each <0.1% (BASF). Mass balances were 99.70–99.94%, percentages of unknowns were in the range of <0.06-0.3% for their sum, each <0.1% (Tagros).
Declared minimum alpha-cypermethrin content	930 g/kg (BASF) 950 g/kg (Tagros)
Relevant impurities ≥ 1 g/kg and maximum limits for them	None.

Table 2. Chemical composition and properties of alpha-cypermethrin technical material (TC)

Relevant impurities < 1 g/kg and maximum limits for them:	None.
Stabilisers or other additives and maximum limits for them:	None.
Melting temperature range of the TC	81.4-83.7°C (BASF) 77.8-80.8°C (Tagros)

Pure alpha-cypermethrin consists of colourless crystals, the TC is a white to cream powder with a mild chemical odour.

Hazard summary

IPCS initially made a full evaluation of cypermethrin (IPCS 1989) and later a full evaluation of alpha-cypermethrin (IPCS 1992). IPCS concluded that, when applied according to good agricultural practice, exposure of the general population to alpha-cypermethrin is low and is unlikely to present a hazard. With good work practices, hygiene measures, and safety precautions, the use of alpha-cypermethrin is unlikely to present a hazard to those occupationally exposed to it. The occurrence of "facial sensations" is an indication of exposure and, if they occur, work practices should be reviewed. With recommended application rates, it is unlikely that alpha-cypermethrin will attain levels of environmental significance. It is highly toxic to aquatic arthropods, fish and honeybees under laboratory conditions. Significant toxic effects on non-target invertebrates and fish are only likely to occur in cases of spillage, over-spraying and misuse.

Evaluations of alpha-cypermethrin by the FAO/WHO JMPR and JECFA (JMPR 1980, 1982; JECFA 1996, 1998, 2000, 2002 and 2003) have produced conclusions which are in agreement with those of IPCS. The JECFA allocated an ADI of 0-0.02 mg/kg bw/d and no acute RfD for alpha-cypermethrin (JECFA 1996).

An EU review concluded that alpha-cypermethrin fulfils the safety requirements of Articles 5(1)(a) and (b) of Directive 91/414/EEC, and that residues arising from the proposed uses, with good plant protection practice, should have no harmful effects on human or animal health (EU 2004). The following toxicological reference doses were allocated: ADI = 0-0.015 mg/kg bw/d (1-year toxicity in dog, 100 safety factor); ARfD = 0.04 mg/kg bw (acute oral rat neurotoxicity, 100 safety factor); AOEL (systemic) = 0.01 mg/kg bw/d (90-d dog study, 100 safety factor); AOEL (dermal) = 0.2 mg/kg bw/d (15-d rabbit dermal study, 100 safety factor).

The WHO hazard classification of alpha-cypermethrin is: moderately hazardous, class II (WHO 2002).

Formulations and co-formulated active ingredients

The main formulation types available for use in public health applications (primarily indoor residual spraying) are WP and SC (SC is also used for bed net treatment). The main formulation types available for use in agriculture are EC, SC and UL. The EC formulation is also used to control ectoparasites on animals. These formulations are registered and sold in many countries in Europe, South America, Africa, Australasia and Asia.

Alpha-cypermethrin may be formulated alone or co-formulated with other insecticides, such as flufenoxuron or teflubenzuron.

Methods of analysis and testing

The analytical method for the active ingredient (including identity tests) is a full CIPAC method (CIPAC H, CIPAC K) for the analysis of TC, WP, EC, UL, SC and oil-enhanced SC. Alpha-cypermethrin is determined by capillary GC, with FID and internal standardization with dioctyl phthalate. Alpha-cypermethrin (a pair of enantiomers) produces a single GC peak.

Impurities in alpha-cypermethrin are determined by GC-FID and HPLC-UV methods.

Test methods for determination of physico-chemical properties of the technical active ingredient were OECD or EC, while those for the formulations are CIPAC, as indicated in the specifications.

Physical properties

The physical properties, the methods for testing them and the limits proposed for the formulations comply with the requirements of the FAO/WHO manual (FAO/WHO 2002), with the exception of determination of spontaneity of dispersion (SC specification) which is tested at the maximum application rate (0.5% instead of the usual 5%).

Containers and packaging

No special requirements for containers and packaging have been identified. The WP may be packaged in metallized film (“alupoly”) sachets but not water-soluble bags.

Expression of the active ingredient

The active ingredient is expressed as alpha-cypermethrin in g/kg or g/l at $20 \pm 2^\circ\text{C}$.

ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

Note: BASF and Tagros provided written confirmation that the toxicological and ecotoxicological data included in the following summary were derived from alpha-cypermethrin having impurity profiles similar to those referred to in Table 2, above.

Table A. Toxicology profile of technical alpha-cypermethrin, based on acute toxicity, irritation and sensitization

Species	Test	Purity %	Duration and conditions or guideline adopted	Result	Reference
Rat (m, f)	oral	95.6	Single exposure. Study conducted according to B.1 92/69/EEC	LD ₅₀ = 57 mg/kg bw (m) LD ₅₀ = 71 mg/kg bw (f) (BASF)	SBTR.92.033
Rat, Wistar (m,f)	oral MLD	98	OECD 401, 14 d. 0, 80, 120, 180 mg/kg bw (in peanut oil)	LD ₅₀ = 132 (104-168) mg/kg bw (Tagros)	1361
Rat (m, f)	dermal	96	Single exposure. Study conducted according to B.3 92/69/EEC	LD ₅₀ >2000 mg/kg bw (BASF)	SBTR.92.033
Rat, Wistar (m,f)	dermal MLD	98	OECD 402, 14 d, 0 & 2000 mg/kg bw	LD ₅₀ >2000 mg/kg bw (Tagros)	1363
Rat (m, f)	inhalation	95.6	Single 4-hour exposure. Study conducted according to B.2 92/69/EEC	LC ₅₀ >1.59 mg/l (BASF)	SLL 266/930770
Rat, Wistar (m,f)	inhalation MLC	98	OECD 403, 14 d, 0, 0.614, 0.451, 0.273 mg/l	LC ₅₀ = 0.313 (0.109-0.893) mg/l (Tagros)	1364
Rabbit (m, f)	skin irritation	95.6	Single exposure, Study conducted according to B.4 92/69/EEC	Non-irritant (BASF)	SBTR.92.033
Rabbit	skin irritation	98	OECD 404, 500 mg (4 h), observed 1, 24, 48 & 72 h after treatment	Mild irritant (Tagros)	1365
Rabbit (m, f)	eye irritation	95.6	Single exposure. Study conducted according to B.5 92/69/EEC	Non-irritant (BASF)	SBTR.92.033
Rabbit	eye irritation	98	OECD 405, 100 mg, observed 1, 24, 48 & 72 h after treatment	Mild irritant (Tagros)	1369
Guinea pig (m, f)	skin sensitization	95.6	Maximization test. Study conducted according to B.6 84/449/EEC	Non-sensitizing (BASF)	SBTR.92.033
Guinea pig, Hartley	skin sensitization	98	OECD 406, 250 mg, observed for 28 d.	Not a sensitizer	1366

ECB, Ispra, has classified alpha-cypermethrin as R37 (irritant for respiratory system).

Table B. Toxicology profile of technical alpha-cypermethrin, based on repeated administration (sub-acute to chronic)

Species	Test	Purity %	Duration and conditions or guideline adopted	Result	Reference
Rat (m, f)	5-week feeding	96.5	B.7 92/69/EEC, 35 d (normal duration is 28 d).	NOAEL = 20 mg/kg bw/d (m) (BASF)	SBGR.81.212
Rat (m, f)	Oral, 6-week	95.6	B.7 92/69/EEC, 35 d (normal duration is 28 d).	NOEL = 20 mg/kg bw/d (m) (BASF)	SBTR.93.002
Mouse (m, f)	Oral, 29-d	95.4	B.7 92/69/EEC, 29 d	NOAEL = 56 mg/kg bw/d (m, f) (BASF)	LSR 92/SHL008/0346

Table B. Toxicology profile of technical alpha-cypermethrin, based on repeated administration (sub-acute to chronic)

Species	Test	Purity %	Duration and conditions or guideline adopted	Result	Reference
Dog (m, f)	Oral, increasing dose feeding study (range-finding)	Batch F8300 47B	B.7 92/69/EEC (not fully compliant), 14 d	NOAEL = 5 mg/kg bw/d, based on clinical signs of toxicity in 1f (BASF)	3107
Rat (m, f)	Oral, 90 d	96.5	OECD 408 (1981)	NOAEL = 9 mg/kg bw/d (BASF)	SBGR.81.293
Rat	90 d	97.1	OECD 408	NOAEL = 25 mg/kg bw/d (Tagros)	10378
Dog (m, f)	Oral, 90 d	95.8	OECD 408 (1981)	NOAEL = 2.3 mg/kg bw/d (BASF)	3197
Mouse, CD-1 (m, f)	Oral feeding, 13-week	95.4	Study approximated OECD 408 (1981). Groups 12 m, 12 f, fed 13 weeks at 0, 50, 250, or 1000 ppm in diet.	NOAEL = 6.3 mg/kg bw/d (BASF)	92/SHL009/0849
Dog (m, f)	1 year feeding	95.4	US EPA Guideline No. 83-1	NOAEL = 1.5 mg/kg bw/d (based on clinical signs of skin irritation in 1 f) (BASF)	11110
Rat, Wistar (m, f)	Carcinogenicity, 2 year feeding	98	Directive 87/302/EEC, method B but 24 rats (not 50) included in 2 y sacrifice. Cypermethrin (WL 43467) (approx. 25% alpha-cypermethrin) fed to 48/sex/group at 1, 10, 100, 1000 ppm in diet (0.05, 0.5, 5, and 50 mg/kg/day). Observations after sacrifice at 6, 12, 18 & 24 months.	NOAEL = 5 mg/kg bw/d (chronic effects) No evidence of carcinogenicity at 50 mg/kg bw/d (highest concentration tested). (BASF)	TLGR 78.189
Mouse (m, f)	Carcinogenicity, 78-week feeding	95.4	Directive 87/302/EEC method B. Alpha-cypermethrin at 0, 30, 100, 300 ppm in diet (3, 10.6, 35.2 mg/kg/day males, 3.5, 11.5, and 37.7 mg/kg/day females)	NOAEL = 3 mg/kg bw/d = 30 ppm (based on reduced body weight gain in males at 100 ppm). No evidence of carcinogenicity at 300 ppm (highest dose tested). (BASF)	95/SHL010/0596

Table B. Toxicology profile of technical alpha-cypermethrin, based on repeated administration (sub-acute to chronic)

Species	Test	Purity %	Duration and conditions or guideline adopted	Result	Reference
Rats (m, f)	Reproductive toxicity 3-generation	99	Directive 87/302/EEC method B. Males up to 25 mg/kg/day, females up to 20 mg/kg/day.	No adverse reproductive effect up to 5 mg/kg bw/d. NOAEL = 5 mg/kg bw/d = 100 ppm (maternal) based on reduced pre-mating body weight and food consumption at 500 ppm. NOAEL = 5 mg/kg bw/d = 100 ppm (reproduction), based on reduced litter size at birth primarily in F1a generation, and reduced mean pup weights on day 21 for F1b females and F3b males at 500 ppm. (BASF)	TLGR.78.188
Rat (m, f)	Teratogenicity & developmental toxicity	95.6	OECD 414 (1981). Pregnant females received 0, 3, 9, or 15 mg/kg/day on gestation days 6-18.	No maternal or developmental toxicity at 3 or 9 mg/kg/day. NOAEL = 9 mg/kg bw/d (maternal) NOAEL = 9 mg/kg bw/d (fetal) (BASF)	SLN/3/92 & SLN/4/92
Rabbit (m, f)	Teratogenicity & developmental toxicity	95.6	OECD 414 (1981); US EPA 83-3 (1982); JMAFF (1985) Pregnant females received 0, 3, 15 or 30 mg/kg/day on gestation days 7-19.	No maternal or developmental toxicity at 3 or 15 mg/kg/day. NOAEL = 15 mg/kg bw/d (maternal) NOAEL = 30 mg/kg bw/d (fetal). (BASF)	SLN/3/92 & SLN/4/92
Rat (m, f)	Acute neurotoxicity	95.4	US EPA (40 CFR 160); UK DoH (London, 1989); OECD (Paris, 1982); JMAFF (59 Nohsan 3850) Single oral dose of 0, 4, 20, or 40 mg/kg	NOAEL = 4 mg/kg bw (BASF)	SBTR.93.002

In chronic toxicity studies (≥1 y), dietary administration of alpha-cypermethrin to mice, rats and dogs resulted in clinical signs of treatment that were limited to adverse effects on the skin and hair. Decreases in body weight gains were observed in mice treated with doses ≥100ppm (approximately

14.3 mg/kg bw/day). The dog appeared more sensitive than the mouse to the effects of alpha-cypermethrin, as indicated by NOAELs of 1.5 mg/kg bw/day and 3 mg/kg bw/day for dogs and mice, respectively.

Alpha-cypermethrin was not carcinogenic in long-term studies in mice after administration via the diet. Results from the carcinogenicity study with cypermethrin (the two alpha-cypermethrin isomers comprised approximately 25% of the total cypermethrin) have been used to fulfil data requirements for alpha-cypermethrin. Developmental toxicity tests conducted in rabbits and rats with alpha-cypermethrin revealed no teratogenic effects for either species.

Alpha-cypermethrin is neurotoxic to all species

Table C. Mutagenicity profile of technical alpha-cypermethrin, based on *in vitro* and *in vivo* tests

Species	Test	Purity %	Conditions	Result	Reference
<i>Salmonella typhimurium</i> TA98, TA100, TA1535, TA1537, TA1538 <i>E. coli</i> WP2 uvrA	Point mutation, Ames test, <i>in vitro</i>	95.6	92/69/EEC Dose range: 31.25, 62.5, 125, 250, 500, 1000 and 5000 µg/plate with and without S9.	Not mutagenic (BASF)	SBTR.93.007
<i>Salmonella typhimurium</i> TA98, TA100, TA1535, TA1537, TA1538	Point mutation, Ames test, <i>in vitro</i>	99	92/69/EEC method B14 50, 150, 500, 1500, and 5000 µg/plate with and without S9.	Not mutagenic (BASF)	SBTR.93.007
<i>Salmonella typhimurium</i> TA98, TA100, TA1535, TA1537	Bacterial reverse mutation assay	98	OECD 471 12.5-1000 µg/plate	Negative (Tagros)	1367
L5178Y mouse lymphoma cells	Gene Mutation Test <i>In vitro</i>	95.4	0, 0.03, 0.1, 0.3, 3.3, 10, 33, 50 µg/ml with and without S9. Study conducted following method B of 87/303/EEC	Not mutagenic (BASF)	087378
Chinese hamster ovary cell lines	Chromosomal aberration	98	OECD 473 5.5, 6.5 & 7.5 µM with S-9 4, 5 & 6 µM without S-9	Negative (Tagros)	10402
Human lymphocytes	Chromosome aberrations, cytogenic investigation, <i>in vitro</i>	95.6	92/69/EEC method B In culture for 24 or 48 h (S9 incubated 3 h) Dose range: trial #1: 125, 500, 1000 µg/ml trial #2: 93.75, 375, 500, 750 µg/ml, with and without S9 125, 500 and 1000 µg/ml in 2 trials with S9	Not genotoxic (BASF)	SBTR.93.007

Table C. Mutagenicity profile of technical alpha-cypermethrin, based on *in vitro* and *in vivo* tests

Species	Test	Purity %	Conditions	Result	Reference
TK6 human lymphoblastoid cells	Mammalian cell gene mutation test	97.1	OECD 476 0.005, 0.01, 0.04, 0.06 mM with S-9 0.005, 0.01, 0.02, 0.04 mM without S-9	Negative (Tagros)	10404
Bone marrow cells (Wistar rats, Charles River)	Chromosome aberration, cytogenic investigation, <i>in vivo</i>	95.8	Rat femoral bone marrow, 6 per sex per group 0, 2, 4, 8 mg/kg orally, single dose	Not genotoxic (BASF)	SBGR.84.120
Rat, hepatocytes (Albino Wistar)	UDS after partial hepatectomy, <i>in vivo</i>	96.5	0, 40 mg/kg, single oral dose, 6 h exposure	Not genotoxic (BASF)	SBGR.81.225
Mouse, Swiss, femoral bone marrow	Micronucleus assay <i>in vivo</i>	95.4	0, 1, 5, 10 mg/kg orally, single dose 24, 48, 72 h harvest	Not genotoxic (BASF)	087367
Mouse, Swiss albino (m, f)	Micronucleus assay <i>in vivo</i>	98	OECD 474 25, 50 & 75 mg/kg, vegetable oil vehicle	Negative (Tagros)	10403
Mouse (m, f)	Dominant lethal test, <i>in vivo</i> .	99	87/302/EEC, method B 0, 5, 10, or 15 mg/kg bw for 5 consecutive days	Not mutagenic (BASF)	TLGR.0042.77
Mouse	Mouse bone marrow chromosome study	98	OECD 475 0, 10, 20 & 40 mg/kg bw	Negative (Tagros)	1368
<i>Saccharomyces cerevisiae</i> XV 185-14C	Gene mutation	95.8	0, 31.25, 62.5, 125, 250, 500, 1000, 2000, or 4000 µg/plate, with or without S9	Not mutagenic (BASF)	SBGR.84.117

Table D. Ecotoxicology profile of technical alphacypermethrin

Species	Test	Purity %	Duration and conditions	Result	Reference
<i>Daphnia magna</i> (water flea)	Acute toxicity	93.4-95.7	48 h, semi-static test system with renewal after 24 h OECD 202 I	EC ₅₀ = 0.3 µg/l (BASF)	SBGR.81.277
<i>Daphnia magna</i> (water flea)	24 h acute immobilization	98	24 h. 0, 0.03, 0.06, 0.12, 0.24, 0.48 µg/l	EC ₅₀ = 0.14 (0.1-0.18) µg/l water (Tagros)	1360
<i>Daphnia magna</i> (water flea)	Chronic toxicity	98-98.5	21 d, semi-static test system with renewal after 24 h OECD 202 II	NOEC = 0.03 µg/l (BASF)	SBGR.81.277
<i>Salmo gairdneri</i> (rainbow trout)	Acute toxicity	98-98.5	96 h, semi-static with renewal every 12 h. OECD 203	LC ₅₀ = 2.8 µg/l NOEC = 1.5 µg/l (BASF)	SBGR.81.026

Table D. Ecotoxicology profile of technical alphacypermethrin

Species	Test	Purity %	Duration and conditions	Result	Reference
<i>Cyprinus carpio</i> (common carp)	Acute toxicity	98	OECD 203 96 h mortality 0, 0.0003, 0.0005, 0.0008, 0.001 & 0.002 mg/l	LC ₅₀ = 0.00084 (0.0007-0.0009) mg/l (Tagros)	1358
<i>Pimephales promelas</i> (fathead minnow)	Fish early life stage toxicity	91.5	60 embryos/concentration. The embryos were obtained within 48 hours after fertilization and were followed up to day 30	NOEC = 0.25 µg/l (BASF)	BW-80-9-723
<i>Pimephales promelas</i> (fathead minnow)	Fish early life stage toxicity	98.2-99.4	Embryos within 24 h after fertilization, observed 34 d 30 embryos/concentration	NOEC = 0.03 µg/l (BASF)	SBGR.82.298
Rainbow trout	Bioconcentration	96.1	73 d study. 0.2 µg/l 18 d exposure in flow-through system at 15°C. Study with cypermethrin	Bioaccumulation factor calculated as 1204, uptake rate constant of 0.11/L water/g fish, depuration rate constant 0.09 L water/g fish/day. Cypermethrin rapidly taken up and eliminated, alpha-cypermethrin expected to be similar. (BASF)	SBGR.81.026
<i>Selenastrum capricornutum</i> (green alga)	Acute toxicity	93.4-95.7	96 h, static water, OECD (201)	EC ₅₀ >100 µg/l (growth rate) EC ₅₀ >100 µg/l (biomass) no morphological effects observed under test conditions. (BASF)	SBGR.81.277
<i>Pseudo-kirchneriella subcapitata</i> (green alga)	Growth inhibition test	96	Static, 72 h; 5 concentrations, 3 replicates, plus control with 5 replicates; daily assessments of growth. EEC 92/69, OECD 201	Effect on biomass: EbC ₅₀ (0-72 h) >1 mg/l EbC ₁₀ (0-72 h) <0.05 mg/l Effect on growth rate: ErC ₅₀ (0-72 h) >1 mg/l ErC ₁₀ (0-72 h) >1 mg/l (BASF)	AL-520-002

Table D. Ecotoxicology profile of technical alphacypermethrin

Species	Test	Purity %	Duration and conditions	Result	Reference
<i>Chlorella vulgaris</i> (green alga)	Growth inhibition	97.1	OECD 201, 72h	EC ₅₀ = 15.26 µg/ml (Tagros)	11441
<i>Chironomus riparius</i> Meigen	Chronic toxicity sediment dwelling organisms	97	Static system containing standard sediment (according to OECD 207) and water (Elendt, M4-medium); two definitive tests conducted, each with test duration 28 days; 7 test concentrations, each with 4 replicates plus a control with 4 and a solvent control with 4 replicates; assessment of larval development and emergence.	NOEC = 0.024 µg a.s./l LOEC = 0.048 µg a.s./l EC ₅₀ = 0.227 µg a.s./l (95% confidence limits: 0.120 – 1.066 µg a.s./l) (BASF)	AL-523-002
Macro-invertebrates, zooplankton and algae	Effect on freshwater ecosystem	Min. 93%	Natural assemblages of freshwater macroinvertebrates, zooplankton and algae in ponds	overall Ecologically Acceptable Concentration (EAC) = 0.015 µg/, single and repeated applications (BASF)	AL-560-023
<i>Eisenia foetida</i> (earthworm)	Acute toxicity	98.2-99.4	14 d, OECD (207)	14-day LC ₅₀ >100 mg a.s./kg soil NOEC = 100 mg/kg soil (BASF)	SBGR.83.071
<i>Lampito mauritii</i> (earthworm)	Acute toxicity	98	OECD 207 0-80 mg/kg dry soil	EC ₅₀ = 57.4 (39.2-84) mg/kg artificial soil (Tagros)	1359
<i>Apis mellifera</i> (honey bee)	Acute oral toxicity	99.5	48 h, OECD (213), according to recommendations of ICPBR (1999)	LD ₅₀ >0.059 µg/bee (BASF)	SBGR.82.023
<i>Apis mellifera</i> (honey bee)	Contact toxicity	99.5	48 h, OECD (214), according to recommendations of ICPBR (1999)	LD ₅₀ >0.033 µg/bee (BASF)	SBGR.82.023
Northern bobwhite quail (<i>Colinus virginianus</i>)	Acute toxicity	96.1	EPA 71-1, SETAC	Highest dose (2025 mg a.s. /kg body weight) caused no compound-related mortality (BASF)	ETX-00-107

Table D. Ecotoxicology profile of technical alphacypermethrin

Species	Test	Purity %	Duration and conditions	Result	Reference
Northern bobwhite quail (<i>Colinus virginianus</i>)	Dietary toxicity	96.1	U.S. EPA. Guideline 71-2, OPPTS 850.2200; OECD 205	LC ₅₀ >5000 mg a.s./kg diet NOEC = 5000 mg a.s./kg diet (BASF)	ETX-00-182 / AL-534-003
Northern bobwhite quail (<i>Colinus virginianus</i>)	Sub-chronic toxicity and reproduction	96.1	U.S. EPA Guideline 71-4; USEPA OPPTS 850.2300; OECD 206.	NOEC = 150 mg a.s./kg diet (BASF)	AL-534-002

Based on lower tier data, alpha-cypermethrin appeared to be potentially hazardous to aquatic organisms. Therefore, a higher-tier evaluation of the potential risk to aquatic environments was conducted using results from pond ("mesocosm") studies. Based on these mesocosm results and data from a series of single-species laboratory toxicity tests with sensitive organisms, a conservative Ecologically Acceptable Concentration (EAC) of 0.015 µg alpha-cypermethrin/l (water solubility approximately 5 µg/l) was recommended for single and repeated applications.

Although alpha-cypermethrin was toxic in acute tests in which honey bees were directly exposed to fresh residue, the results from numerous field tests indicate that application of alpha-cypermethrin is of low risk to honey bees. This is because direct exposure to alpha-cypermethrin, through contact and ingestion, is very limited due to its repellent effect on foraging bees.

Alpha-cypermethrin poses negligible risks to birds through acute, short-term, and chronic (reproductive) exposure.

ANNEX 2. REFERENCES

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