FAO SPECIFICATIONS AND EVALUATIONS FOR AGRICULTURAL PESTICIDES

BIFENTHRIN

2-methylbiphenyl-3-ylmethyl (Z)-(1RS,3RS)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate



FOOD AND AGRICULTURE ORGANIZATION of THE UNITED NATIONS

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DISCLAIMER¹

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

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

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

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¹ This disclaimer applies to all specifications published by FAO.

INTRODUCTION

FAO establishes and publishes specifications* for technical material and related formulations of agricultural 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.

Since 1999 the development of FAO specifications follows 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, the procedure and evaluation applied by FAO and the Experts of the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS). [Note: prior to 2002, the Experts were of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent, which now forms part of the JMPS, rather than the JMPS.]

FAO Specifications now only apply to products for which the technical materials have been evaluated. Consequently from the year 2000 onwards the publication of FAO 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 plant protection product in accordance with chapter 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 JMPS. The data are to be provided by the manufacturer(s) according to the requirements of Appendix A, Annex 1 or 2 of the "Manual on the development and use of FAO specifications for plant protection products" 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.

FAO specifications under the **New Procedure** do <u>not</u> necessarily apply to nominally similar products of other manufacturer(s), nor to those where the active ingredient is produced by other routes of manufacture. FAO 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.

*NOTE: publications are available on the internet at *http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/en/* or in hardcopy from the Plant Protection Information Officer.

PART ONE

SPECIFICATIONS

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BIFENTHRIN

INFORMATION

ISO common name

Bifenthrin (ISO 1750 published)

Chemical name(s)

| IUPAC | 2-methylbiphenyl-3-ylmethyl (<i>Z</i>)-(<i>1RS</i> , <i>3RS</i>)-3-(2-chloro-3,3,3- |
|-------|---|
| | trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate |

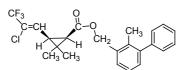
CA (2-methyl[1,1'-biphenyl]-3-yl)methyl 3-[(*1Z*)-2-chloro-3,3,3-trifluoro-1propenyl)-2,2-dimethylcyclopropanecarboxylate

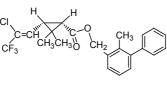
Synonyms

FMC 54800

Structural formulae

(Z)-(1R)-cis-





(Z)-(1S)-cis-

Molecular formula

 $C_{23}H_{22}CIF_{3}O_{2}$

Relative molecular mass

423.0

CAS Registry number

82657-04-3

CIPAC number

415

Identity tests

GC relative retention time, IR spectrum, electron ionization mass spectrum (from GC-MS), ¹H-NMR spectrum

BIFENTHRIN TECHNICAL MATERIAL

FAO specification 415/TC (January 2012*)

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 (415/2009 & 415/2010). It should be applicable to TC produced by 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 TC produced by other manufacturers. The evaluation reports (415/2009 & 415/2010), as PART TWO, form an integral part of this publication.

1. **Description**

The material shall consist of bifenthrin together with related manufacturing impurities, in a form of a light brown to amber viscous liquid, crystalline solid, or waxy solid with a faint slightly sweet odour, free from visible extraneous matter and added modifying agents.

2. Active Ingredient

2.1 **Identity test** (AOAC INTERNATIONAL: Bifenthrin Analysis in Technical Material and Formulations by Capillary Gas Chromatography, Note 1)

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

2.2 **Bifenthrin content** (AOAC INTERNATIONAL: Bifenthrin Analysis in Technical Material and Formulations by Capillary Gas Chromatography, Note 1)

The bifenthrin content shall be declared (not less than 930 g/kg) and, when determined, the mean measured content shall not be lower than the declared minimum content.

Note 1 Gas Chromatographic Determination of Bifenthrin in Technical and Selected Formulated Products: Collaborative Study. Edward J. Kikta *et al*, Journal of AOAC INTERNATIONAL, Volume: 94, Issue: 2 (2011), pages 453 to 458 or through the AOAC International Official Method of Analysis website (www.aoac.org).

^{*} Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: <u>http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/en</u>

BIFENTHRIN WETTABLE POWDER

FAO specification 415/WP (January 2012*)

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 (415/2009 & 415/2010). It should be applicable to relevant products produced by 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 relevant products produced by other manufacturers. The evaluation reports (415/2009 & 415/2010), as PART TWO, form an integral part of this publication.

1. **Description**

The material shall consist of an homogeneous mixture of technical bifenthrin, complying with the requirements of WHO specification 415/TC (January 2012), in the form of an off-white to tan powder, together with fillers 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** (AOAC INTERNATIONAL: Bifenthrin Analysis in Technical Material and Formulations by Capillary Gas Chromatography, Note 1)

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

2.2 **Bifenthrin content** (AOAC INTERNATIONAL: Bifenthrin Analysis in Technical Material and Formulations by Capillary Gas Chromatography, Note 1)

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

3. Relevant impurities

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

Maximum: 30.0 g/kg.

4 **Physical properties**

- 4.1 Wet sieve test (MT 185, CIPAC Handbook K, p. 149, 2003)Maximum: 2 % retained on a 75 µm test sieve.
- 4.2 **Suspensibility** (MT 184, CIPAC Handbook K, p. 142, 2003) (Notes 2 & 3)

^{*} Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: <u>http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/en</u>

A minimum of 60% of the bifenthrin content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at $30 \pm 2^{\circ}C$ (Note 4).

- 4.3 **Persistent foam** (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 5) Maximum 15 mL after 1 min.
- 4.4 **Wettability** (MT 53.3.1, CIPAC Handbook F, p.164, 1995)

The formulation shall be completely wetted in 3 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 \pm 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:

- wet sieve test (4.1),
- suspensibility (4.2)
- wettability (4.4).
- Note 1 Gas Chromatographic Determination of Bifenthrin in Technical and Selected Formulated Products: Collaborative Study. Edward J. Kikta *et al*, Journal of AOAC INTERNATIONAL, Volume: 94, Issue: 2 (2011), pages 453 to 458 or through the AOAC International Official Method of Analysis website (www.aoac.org).
- <u>Note 2</u> 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 184.
- Note 3 This test will normally only be carried out after the heat stability test 5.1.
- <u>Note 4</u> Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric and solvent extraction determination may be used on a routine basis provided that these methods have been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".

The AOAC method does not provide a method for chemical assay. The following procedure can be used to determine the remaining 10 % in the cylinder. For calculation, use the formula provided in MT 184. After removing the 9/10 top layer of the water/WP suspension, carefully remove the remaining bottom 1/10 residue and concentrate the solids either by filtration or centrifugation. Make sure to rinse the tube, lower 1/10 section only, at least twice with a small amount of water, to remove any of the remaining bottom material. Add the rinse to the filter or centrifuge tube for isolation. Dry the isolated WP to a constant weight under 50°C in a vacuum oven. After drying analyze the WP according to the method referenced in Note 1 for the WP. If the WP quantity is less than that specified in the procedure, the actual extraction volume should be proportionally adjusted.

- <u>Note 5</u> The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D at $30 \pm 2^{\circ}$ C.
- <u>Note 6</u> Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

PART TWO

EVALUATION REPORTS

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BIFENTHRIN

FAO/WHO EVALUATION REPORT 415/2010

Recommendations

The Meeting recommended that:

(i) The specifications proposed by FMC for bifenthrin TC and WP as amended should be adopted by WHO and FAO, taking into account that the collaboratively tested analytical method is now published and a method for the chemical assay of the active ingredient in the suspensibility assay has been provided.

Appraisal

The analytical method for determination of bifenthrin in TC and WP was published in the Journal of AOAC INTERNATIONAL, Volume 94 and is also available on the AOAC INTERNATIONAL website. Furthermore, the company provided an addendum to the analytical method for the determination of the remaining 10% in the cylinder in the CIPAC MT 184, suspensibility method.

The draft specifications were essentially in accordance with the requirements of the FAO and WHO Specification Manual, March 2006 revision. A few issues relating to the WP were identified by the Meeting.

WP only

The necessity of limiting water content was discussed by the Meeting. The Meeting accepted that water should be limited in the WP, to minimize to potential for clumping of the powder particles during storage of the formulation. The proposed limit of 30 g/kg was accepted. The Meeting noted the exceptionally long wetting time of 3 minutes, which was explained by the proposer to be due to the hydrophobic nature of the active ingredient.

BIFENTHRIN

FAO/WHO EVALUATION REPORT 415/2009

Recommendations

The Meeting recommended the following:

- (i) The specifications proposed by FMC for bifenthrin TC and WP, as amended, should be adopted by WHO subject to the publication of the analytical method for bifenthrin TC and WP and amendment of the analytical method for WP for determination of the suspensibility. In the meantime, the evaluation report can be published.
- (ii) The specifications for bifenthrin TC and WP, as amended, should be adopted by FAO, subject to the publication of the analytical method for bifenthrin TC and WP and amendment of the analytical method for WP for determination of the suspensibility. In the meantime, the evaluation report can be published.

Appraisal

The Meeting considered data and supporting information submitted by FMC for the development of new FAO and WHO specifications for bifenthrin TC and WP. The data submitted were broadly in accordance with the requirements of the FAO/WHO Manual (March 2006 revision of the first edition) and supported the draft specifications for new FAO and WHO specifications.

Bifenthrin is a pyrethroid insecticide, which had been the subject of a time-limited WHO interim specification withdrawn in April 2008. A WHOPES recommendation for the use of a 10 % bifenthrin WP in public health for indoor residual spraying for malaria vector control was published in 2001. The toxicology of bifenthrin was evaluated by the FAO/WHO JMPR in 2009. The WHO/IPCS (International Programme on Chemical Safety) has also evaluated bifenthrin in 2002.

The ISO common name, bifenthrin, denotes a compound consisting of the Z 1 R/S *cis* enantiomers of the trifluorochloromethylchrysanthemic acid esterified with the 2-methylbiphenylalcohol, together with small amounts of the respective E and *trans* forms (see below). Bifenthrin has two chiral centres, but as the configuration of the *cis*-trifluorochloromethylchrysanthemic acid is carried forward to the final product, bifenthrin contains predominantly the two *cis* stereoisomers at the cyclopropane moiety, providing the highest insecticidal activity (1). The *cis/trans* ratio in technical bifenthrin is higher than 97:3 and the Z/E ratio is higher than 99:1.

Confidential information on the manufacturing process and limits for all impurities occurring at or above 1 g/kg in the TC were provided to the Meeting. The manufacturing specification for minimum bifenthrin content of the TC was 930 g/kg. The limits for content of bifenthrin and impurities were supported by 5 batch analysis data. The manufacturing specification and their data on 5 batches have evolved over time, in the way that, among other, the minimum purity was increased (from initially 890 g/kg to 930 g/kg) and additional manufacturing sites were introduced.

The first impurity profile and specification were elaborated in 1986 for the TC produced in US. In recent years, two more production sites were introduced and the material produced characterized by analysis of 5 typical batches.

Mass balances were in the range of 98.6 to 99.1 and 97.9 to 98.8 % respectively in the batches of the two actual production sites.

The bifenthrin TC produced at the different sites were considered to meet a common manufacturing specification, even though some impurities show a considerable variability in their concentrations in the batches from the two sites analyzed. The questions of equivalence of the TC produced in the different sites was discussed and the Meeting agreed that based on the rules of the Manual on equivalence the TC produced at the different sites can be considered broadly equivalent. The methods to analyze the batches were the same for all samples and full validation was provided.

The information on the manufacturing process and impurities present in the TC was identical to that submitted in support of registration of bifenthrin in Switzerland.

The manufacturer provided information on the materials used in the hazard tests and the Meeting agreed that the hazard data were acceptable. The Meeting noted that the TC with a content of 901 g/kg, tested in the majority of toxicological and ecotoxicological studies (Annex 1, Tables 3-6), was lower than the current manufacturing specification (\geq 930 g/kg).

The proposer stated that no relevant impurities are present in the technical material, either > 1 g/kg or less than 1 g/kg. The question of the relevance of certain impurities was discussed by the Meeting. The stereoisomers having *trans*- and E configuration at the cyclopropane moiety or the vinyl bond, respectively, being present in technical bifenthrin were considered non-relevant as there was no indication that these stereoisomers would adversely influence the hazard when present at higher concentrations. The Meeting discussed the question of some residual solvents present in the TC – among them toluene – which had been considered relevant in other cases. In bifenthrin TC the amounts detected are so low that they can be considered as non-relevant.

However, based on the rules of the Specifications Manual, one impurity, the anhydride of the 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-cyclopropane carboxylic acid, for brevity called the TFP anhydride², was identified as a potentially relevant impurity. Considering the end points of the hazard data provided in Table 3 on acute dermal toxicity in the Buehler and Magnusson-Kligman tests on dermal sensitization and the composition of the technical materials used in these studies, the negative end point in the Buehler test and the positive end point in the Magnusson-Kligmann test were tentatively associated with a low content of TFP anhydride in the material used for the Buehler test and a higher content of TFP anhydride in the material used in the maximization test. The meeting noted, that the latter test is more challenging and tends to show more positive results with the same material used. It remained however unclear whether bifenthrin itself as a pure compound would elicit such a response in the tested animals. In order to elucidate how the residual TFP anhydride was contributing to the dermal sensitization, an additional study was recently undertaken with a low content (0.2 g/kg) of TFP anhydride. The overall result clearly showed that technical bifenthrin with such a low content of anhydride is a sensitizer too.

² The IUPAC chemical name of the TFP anhydride is 3-[(*1Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2- dimethylcyclopropanecarboxylic anhydride.

In conclusion, bifenthrin is a sensitizer by itself, which renders the TFP anhydride nonrelevant, and hence the Meeting agreed that no limit for this impurity needs to be set.

The method developed by the proposer and collaboratively validated by AOAC International to determine the content of bifenthrin in TC and in formulations (WP, EC, SC) utilizes megabore column gas chromatography with internal standard. This method allows the separation of the *cis* and *trans* isomers of bifenthrin and to the determination of the total bifenthrin content (expressed as sum of *cis* and *trans*-bifenthrin) as well as to the measurement of the ratio of *cis/trans* isomers present. However, the method for the WP does not yet provide a submethod for the determination of the suspensibility (MT 184, CIPAC Handbook K, p. 142). The suspensibility is an important clause in the specification for solid formulations forming suspensions upon dilution with water as a WP. The assay is preferably done by chemical analysis similar to that for the total content of TC or WP. This submethod which is normally a part of the method for total content in a solid formulation is not yet available.

In addition, the ratio of *cis/trans* isomers can be determined by non-enantioselective HPLC using an octadecyl-substituted silica (ODS) column (2). As the *cis/trans* isomers have diastereomeric relationship, they can easily be separated by this technique. The ratio of Z and E isomers at the vinyl bond together with the respective *cis/trans* isomers is determined using a non-enantioselective HPLC normal phase system (3), which provides full resolution of all *cis-trans* and Z/E isomers present in the technical bifenthrin. A validated method for determination of the TFP anhydride based on reversed phase HPLC-UV detection is available. The validation data show that the TFP anhydride can be determined in bifenthrin TC and show acceptable accuracy, reproducibility, and recovery and is capable to determine the impurity in a concentration range of 0.5 g/kg to 50 g/kg. The method is not validated for bifenthrin formulations.

As the AOAC method is not yet publicly available, an essential prerequisite for the publication of the specifications is missing and therefore the evaluation report only is published.

Bifenthrin is almost insoluble in water but moderately to highly soluble in organic solvents, such as hexane, ethanol, acetone, toluene, etc. It has a low volatility. It is stable under normal storage conditions and is only slowly hydrolyzed in water under neutral, acidic and basic pH conditions. The process of direct photolysis in water is slow, but in natural freshwater systems indirect photolysis may contribute significantly to the dissipation of the compound (cited after 4). Bifenthrin is strongly adsorbed on soil particles and is degraded with half-lives of typically 65 to 125 days (cited after Ref. 9). Despite this somewhat higher stability of bifenthrin in soil and water as compared to other pyrethroids, residues of bifenthrin are not expected to accumulate in soil and sediment, taking into consideration the low amounts applied and the moderate degradation rates in soil and water.

The toxicology data were elaborated using the technical active ingredient complying with the criteria given above (e.g. with a bifenthrin content of 901 g/kg, *cis/trans* ratio > 97.3, and Z/E 99: 1). Exceptions are data on skin sensitization (batch from 2004 with purity indicated) and in aquatic ecotoxicology testing, where biphenyl U-¹⁴C-labelled material having a comparable *cis/trans* ratio as the unlabelled material was used.

Bifenthrin generally shows moderate acute mammalian toxicity. The European Union, in the conclusion document on bifenthrin, also concluded that this compound is a sensitizer in the maximization test according to Magnusson and Kligman. The JMPR concluded that

the results of the long-term studies in rats and mice and a series of studies designed to evaluate genotoxicity indicated that bifenthrin is unlikely to pose a mutagenic and teratogenic hazard to humans. An ADI of 0–0.01 mg/kg bw was set based on a NOAEL of 1.0 mg/kg bw per day in a study of developmental toxicity in rats and using a safety factor of 100. The JMPR Meeting also established an ARfD of 0.01 mg/kg bw based on a threshold dose of 1.3 mg/kg bw for motor activity in a study of acute toxicity in male rats treated by gavage and using a safety factor of 100.

The test battery for the assessment of mutagenicity yielded again mixed results. Whereas some tests were clearly negative (such as the Ames test on different strains of *Salmonella typhimurium* with and without activation, respectively), other tests showed weak positive response or yielded inconclusive results with technical bifenthrin, such as the Mouse Lymphoma Mutagenesis Assay or the unscheduled DNA synthesis test with rat hepatocytes. The overall conclusion, as shared with the JMPR evaluation (2), was that bifenthrin does not pose a significant hazard to humans with respect to mutagenicity.

A considerable data package on ecotoxicological effects of bifenthrin was presented. Aquatic organisms like Daphnia magna, mysid shrimp and several fish species were found to be very sensitive to low levels of the compound. These levels, often in the sub-ng/l range, were determined using ¹⁴C-labelled bifenthrin (*cis/trans* ratio 98:2). The compound has been shown to bioaccumulate in fish (BCF 1060 at a concentration of less than 0.1 ng/l in a flowthrough system). Bifenthrin is therefore highly toxic to aquatic organisms except algae, where no effect concentrations in the ppm-range clearly above water solubilility were observed.

Non-target predatory insects and mites such as *Chrysoperla carnea* or *Typhlodromus pyri* showed a high mortality at the somewhat exaggerated field rates corresponding to 60 g a.i. per ha (recommended field rate in Switzerland in agriculture: 20 - 40 g/ha). The same holds for the honey bee, *Apis mellifera*. The spray deposits being dried up, the risk for honey bees is clearly reduced. In contrast, birds are not sensitive to the intake of bifenthrin, with acute toxicity (8 day feeding study) in the range of 1250 to 4450 mg/kg (LC₅₀).

Bifenthrin is used both in agriculture to control sucking and biting insects like aphids, white fly, colorado beetle in various crops and in public health applications (mainly as emulsifiable concentrates or wettable powder), against mosquitoes, houseflies, cockroaches.

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

The Meeting considered the proposed specifications were broadly in accordance with the requirements of the specification manual (FAO/WHO 2006) and thus certain clauses in the existing specifications, e.g. melting point and flash point, had been omitted and did not require further consideration.

References for the appraisal

| Ref. Nr. | Authors | Year | Title |
|----------|---|------------|--|
| 1 | Chamberlain K, Matsuo N, Kanoko H and Khambay B P S | 1998 | Pyrethroids, in "Chirality in Agrochemicals", Ed. Norio Kurihara and Juhshi Miyamoto, Wiley, p. 32 |
| 2 | Anon. | 1987 | FMC Test Method ACG 88, High Performance Liquid Chromatographic Analysis of FMC 54800 ("Reversed Phase") |
| 3 | Anon. | no date | FMC Corporation, Test Method ACG 89, High Performance Liquid Chromatographic Analysis of FMC 54800 ("Normal Phase") |
| 4 | Roberts T and Hutson D | 1988 | Metabolic Pathways of Agrochemicals, Part Two, Insecticides and Fungicides, "Bifenthrin", p. 594 to 596. The Royal Society of Chemistry |

SUPPORTING INFORMATION FOR EVALUATION REPORT 415/2009

EXPLANATION

The data for bifenthrin were evaluated in support of new FAO/WHO specifications.

Bifenthrin is not under patent.

Bifenthrin was first registered in the US and Europe in 1985. Bifenthrin was evaluated by the FAO/WHO JMPR in 1992 and 2009 and there are currently 27 approved CODEX maximum residue limits (MRLs) for bifenthrin. The WHO/IPCS (International Programme on Chemical Safety) has also evaluated bifenthrin (WHO Recommended Classification of Pesticides by Hazard, 2000-2002). The bifenthrin dossier was submitted to the European Commission in November 2003 in compliance with the EC Directive 91/414. Recently, EFSA published its conclusion on bifenthrin (available through http://www.efsa.europa.eu).

The draft specification and the supporting data were provided by FMC Corporation in 2001.

USES

Bifenthrin is a fourth generation pyrethroid insecticide and acaricide that affects the nervous systems of target pests. It is used in horticulture and public health against (including but not limited to) caterpillars, grasshoppers, fleas, ants, cockroaches, moths, beetles, mites, aphids, thrips, scales, termites, mosquitoes, scorpions, wasps, and spiders.

IDENTITY OF THE ACTIVE INGREDIENT

ISO common name

Bifenthrin (ISO 1750 published)

Chemical name(s)

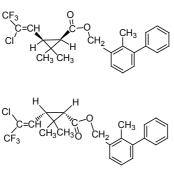
- IUPAC 2-methylbiphenyl-3-ylmethyl (*Z*)-(*1RS,3RS*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate
- CA (2-methyl[1,1'-biphenyl]-3-yl)methyl 3-[(*1Z*)-2-chloro-3,3,3-trifluoro-1propenyl)-2,2-dimethylcyclopropanecarboxylate

Synonyms

FMC 54800

Structural formulae

(Z)-(1R)-cis-



(Z)-(1S)-cis-

Molecular formula

 $C_{23}H_{22}CIF_{3}O_{2}$

Relative molecular mass

423.0

CAS Registry number

82657-04-3

CIPAC number

415

Identity tests

GC relative retention time, IR spectrum, electron ionization mass spectrum (from GC-MS)

Physico-chemical properties of bifenthrin

| Parameter | Value(s) and conditions | Purity % | Method reference (and technique if the reference gives more than one) | Reference |
|---|--|---|---|----------------|
| Vapour pressure | 2.4 x 10 ⁻⁵ Pa at 25°C | 98.9 | Gas Saturation Method | CGP-83-1 |
| Melting point, boiling point | Melting point: 65-70°C | 98.5 | DSC | P-2544 |
| and/or temperature of decomposition | Bifenthrin vaporizes intact in the 215-225°C temperature range | | TGA-IR | |
| Solubility in water | Less than 0.1 micrograms per litre at pH = 2, 7, and 11 (approximately 14 ppt) | 96.6 | Column generator method | P-17-99-45 |
| Octanol/water partition coefficient | Log $P_{OW} > 6$ The extremely low water solubility of bifenthrin makes a more precise measurement of the partition coefficient nearly impossible and unnecessary. | 96.5 | Shake flask partitioning with HPLC analysis | P-0698 |
| Hydrolysis characteristics | No hydrolysis was detected over a study period of 22 days at pH = 5, 7, and 9 | 96.5 | Hydrolysis solutions stored in glass at 25°C. Analysis by HPLC | P-0701 |
| Photolysis characteristics | This study estimates a DT50 of 24.4 to 24.8 days in the summer at 40° N and 50° N, respectively, and demonstrates that there is a pathway for the degradation of bifenthrin in water. Major transformation product-biphenyl alcohol. Quantum yield: 7.00 x 10^{-6} . | Radiolabe led bifenthrin (98.3%) | Acetonitrile (30%) in water was used as a co-solvent due to low solubility of bifenthnin. Analyses were carried out by HPLC. | P-3837 |
| Dissociation characteristics | Bifenthrin contains no functionalities subject to reversible dissociation. | Not applicable | Not applicable | Not applicable |

Table 1. Physico-chemical properties of pure bifenthrin

Table 2. Chemical composition and properties of bifenthrin technical material

| Manufacturing process, maximum limits for impurities \geq 1 g/kg, 5 batch analysis data | Confidential information supplied and held on file by FAO and WHO. Mass balances were 95.79 –98.54 % and percentages of unknowns were 4.21 – 1.46 %. |
|---|--|
| Declared minimum bifenthrin content | 930 g/kg |
| Relevant impurities ≥ 1 g/kg and maximum limits for them | None |
| Relevant impurities < 1 g/kg and maximum limits for them | None |
| Stabilisers or other additives and maximum limits for them | None |
| Melting temperature range | 65-70 °C, bifenthrin vaporizes intact at temperatures between 215-225°C |

HAZARD SUMMARY

Bifenthrin has been evaluated by the WHO IPCS [2000-2002, Report No. WHO/PCS/01.5] and by the FAO/WHO JMPR in 1992 and 2009. The JMPR concluded that the results of the long-term studies in rats and mice and a series of studies designed to evaluate genotoxicity indicated that bifenthrin is unlikely to pose a carcinogenic hazard to humans. An ADI was allocated on the basis of the NOAEL of 0 to 0.01 mg/kg/bw/day using a 100-fold safety factor. This result was supported by the same NOEL in the rat teratology study, although in the latter study gavage, rather than dietary administration, was used.

The IPCS hazard classification of bifenthrin is moderately hazardous, class II.

FORMULATIONS

The main formulation types available are WP (wettable powder), EC (emulsifiable concentrate), GR (granules), UL (ultra-low volume liquid), SC (suspension concentrate) and ME (micro emulsion).

These formulations are registered and sold in many countries throughout the world.

METHODS OF ANALYSIS AND TESTING

The analytical method for the active ingredient (including identity tests) is a AOAC collaboratively validated analytical method. The bifenthrin content is determined by capillary GC with FID and internal standardisation with octacosane. Validation includes TC and WP, whereas EC and SC were tested but the validation results did not meet the acceptance criteria. The method was published in the Journal of AOAC INTERNATIONAL, Volume: 94, beginning of 2011. Furthermore, an addendum to CIPAC MT 184 (suspensibility) for the chemical assay of the remaining 10 % in the cylinder was provided by the company (see Note 5, WP specification). Test methods for determination of physico-chemical properties of the technical active ingredient were based on accepted procedures during the time period bifenthrin was under development, while those for the formulations were based on CIPAC methods as indicated in the specifications.

PHYSICAL PROPERTIES

The physical properties, the methods for testing them and the limits proposed for the WP formulation, comply with the requirements of the FAO/WHO Manual (March 2006 version of the first edition). One exception is that the material was subjected to 3 minutes wetting time instead of the 1 minute specified. The wetting time specification reported as part of the "Bifenthrin Wettable Powder" report for the FAO/WHO Specification was determined by the CIPAC method MT 53.3 (CIPAC Handbook F, p. 164). Bifenthrin 10 WP shall be completely wetted in 3 minutes without swirling. This value reflected the actual production values obtained from the Bifenthrin 10 WP 2003 campaign in Middleport, NY. The longer wetting time is probably due to the hydrophobic nature of the active ingredient, bifenthrin. Even though this value is higher than 1 minute, no adverse impact during application is expected. This product has been in commercial use for a decade without any significant performance issues.

CONTAINERS AND PACKAGING

No special requirements for containers and packaging have been identified.

EXPRESSION OF THE ACTIVE INGREDIENT

The bifenthrin is expressed as bifenthrin.

ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

Notes.

- (i) The proposer confirmed that the toxicological and ecotoxicological data included in the summary below were derived from bifenthrin having impurity profiles similar to those referred to in the table above.
- (ii) The conclusions expressed in the summary below are those of the proposer, unless otherwise specified.

| | | | | • | | 3 7 | |
|----------------|------|--|------------------|--|---------------------|------------|--|
| Species | Test | Duration and conditions or guideline adopted | Resul | t | Batch/Purity | Reference | |
| Rat (M/F) | Oral | EPA 81-1 10% Corn oil. Single dose / 14 day observation 67, 55, 48, 44, 40 and 34 mg/kg b.w | LD ₅₀ | 55.5 mg/kg male 54.5 mg/kg combined 53.4 mg/kg female | E1276-140/ 92% | A82-756 | |
| Mouse (M/F) | Oral | EPA 81-1 10% Corn oil. Single dose / 14 day observations 50.0, 42.0, 35.0 and 25.0 mg/kg b.w | LD ₅₀ | 43.5 mg/kg male 42.5 mg/kg female | E2425-145/ 91.4% | A83-837 | |
| Rat (M/F) | Oral | EPA 81-1 10% Corn oil. Single dose / 14 day observation males : 20, 40, 60, 80, 90 or 100 mg/kg b.w females : 40, 60, 80 or 100 mg/kg b.w | LD ₅₀ | 70.1 mg/kg male 56.7 mg/kg combined 53.8 mg/kg female | 151A/ 91.4% | A83-859 | |
| Rat (M/F) | Oral | EPA 81-1, OECD 401 and EC method, part B1.14 day, undiluted, single dose, 14-day observation. males : 100, 150, 200 and 300 mg/kg b.w females : 75, 100, 200 or 300 mg/kg b.w | LD ₅₀ | 168.4 mg/kg male 186.1 mg/kg combined 210.4 mg/kg female | PL97-592/ 93.7% | A97-4681 | |

Table 3. Toxicology profile of bifenthrin technical material, based on acute toxicity, irritation and sensitization

| Species | Test | Duration and conditions or guideline adopted | Result | Batch/Purity | Reference |
|-------------------|-------------------------------|---|--|--|------------|
| Rabbit (M/F) | Dermal | EPA 81-2 14 day observations 24 hour exposure 2000 mg/kg | LD50 > 2000 mg/kg | E2392-105/ 88.35% | A83-1032 |
| Rat (M/F) | Dermal | EPA 81-2 24 hour exposure 2000 mg/kg | LD ₅₀ > 2000 mg/kg Practically non-toxic | E2392-105/ 88.35% | A85-1924 |
| Rat (M/F) | Inha- lation | OPPTS 870-1300, OECD 403, EC B2 Nose-only. 14 day observations 4 hour exposure 0.56, 0.99, and 2.3 mg/l. | LC ₅₀ 1.10 mg/L males 1.01 mg/L combined 0.8 mg/L females | PL02-0477/ 94.8% | A2003-5589 |
| Rabbit (M/F) | Primary Eye Irritation | EPA 81-4 48 hour observations; 0.1 mL administered | Unwashed / Washed – Practically non- irritating | E2392-105/ 88.35% | A83-1034 |
| Rabbit (M/F) | Primary Skin Irritation | EPA 81-5 4 hour exposure 0.5 ml (undiluted) | Non-irritating (PII = 0.0) | E2392-105/ 88.35% | A83-1033 |
| Guinea Pig (M) | Skin Sensitiz ation | Buehler method EPA 81-6 | Non-sensitizing | E2392-105/ 88.35% | A83-1035 |
| Guinea Pig (F) | Skin Sensitiz ation | Maximization method OECD 406 and Method B6 (Directive 96/54/EEC) | Positive | PL02-0477/ 94.8% TFP anhydride content 35 g/kg | A2002-5588 |
| Guinea Pig (F) | Skin Sensitiz ation | Maximization method OECD 406 and Method B6 (Directive 96/54/EEC) | Positive | G3042:140/ 96.2% TFP anhydride content 0.2 g/kg | A2009-6770 |

| Species | Test | Duration and conditions or guideline adopted | Result | Batch/purity | Reference |
|--------------|--|---|--|----------------------|------------|
| Dog (M/F) | 13-week feeding – Repeated dose | Dir. 87/302/EEC, Part B Gelatine capsules 0, 2.5, 5.0, 10.0 and 20.0 mg/kg bodyweight/day | NOEL = 2.5 mg/kg/day | E2392-105/ 88.35% | A83-820 |
| Rat (M/F) | 28-day feeding – Repeated dose | Dietary Range-finding 0, 50, 100, 200, 300 and 400 ppm | Death at ≥ 300 ppm Tremors at 200 ppm NOEL = 100 ppm | E2425-145/ 91.4% | A83-817 |
| Mouse (M/F) | 28-day feeding – Repeated dose | Dietary Range-finding study A83-839 : 50 (500), 100, 200, 300 ppm study A83-839A : 500, 600, 750 and 1000 ppm | NOEL = 300 ppm LOEL = 500 ppm | E2392-105/ 88.35% | A83-839 |
| Rat (M/F) | 90-day Feeding - Repeated dose | Dietary Range-finding 0, 12, 50, 100 and 200 ppm | NOEL = 100 ppm | E2425-145/ 91.4% | A83-818 |
| Dog (M/F) | 1-year Feeding – Chronic | Dir. 87/302/EEC, Part B – chronic toxicity test Gelatin capsule 0, 0.75, 1.50, 3.00 and 5.00 mg/kg/day | NOEL = 1.50 mg/kg day LOEL = 3.0 mg/kg/day | E2392-105/ 88.35% | A83-821 |
| Rat (M/F) | Chronic – Oncogenicity | EPA 83-5 2 year dietary 0, 12, 50, 100 and 200 ppm | NOEL = 50 ppm LOEL = 100 ppm Not carcinogenic | E2392-105/ 88.35% | A83-952 |
| Mouse (M/F) | Chronic – Oncogenicity | EPA 83-2 18-month dietary 0 , 50, 200, 500 and 600 ppm | NOEL = 50 ppm male 200 ppm female Increased incidence of submucosal tumours (hemangiomas) of marginal statistical significance. | E2392-105/ 88.35% | A83-974 |
| Rabbit (M/F) | 21-day Dermal Toxicity (Repeated dose) | EPA 82-2 (1984) 6 hours / day 0, 25, 50, 100 or 500 mg/kg/day | NOEL = 100 mg/kg/day | E2392-105/ 88.35% | A83-1041 |
| Rat (M/F) | 21-day Dermal Tox | EPA 82-2 (1984) 6 hours / day | NOEL = 50 mg/kg/day | G1295-15B/ 93.2% | A2000-5162 |

Table 4. Toxicology profile of technical bifenthrin based on repeated administration (subacute to chronic)

| Species | Test | Duration and conditions or guideline adopted | Result | Batch/purity | Reference |
|-------------|--------------------------------|--|--|---|------------|
| | (Repeated dose) | 5 days / week 0, 25, 50, 100, or 1000 mg/kg b.w./day | | | |
| Rat (M) | Dermal Absorption | No guideline. Applied as a dilution of a liquid formulation Achieved average dose (mg/kg b.w.) Group I: 0.18; Group II: 1.96; Group III: 19.38 | Dermal absorption 10-hours after administration of test material was 55.4% of the applied dose in animals dosed w/49.2 ug/10.8 sq. cm (4.6 ug/sq. cm) | ^{1₄} C-Study Lot 83022/ 95.49% | PC-0059 |
| Rat (F) | Teratology | EPA - OPPTS 870.3700 Dietary 0, 30, 60, 90, or 200 ppm (equivalent to 0, 2.5, 5.0, 7.4, and 16.3 mg/kg b.w./day) | Maternal NOEL = 90 ppm (7.4 mg/kg/d) | PL99-0108/ 95.3% | A2000-5263 |
| Rat (F) | Teratology | EPA 83.3 (1984) Days 6-15 of gestation 0 (vehicle), 0.50, 1.0 and 2.0 mg/kg/day Vehicle: corn oil | Not teratogenic at levels up to and including 2.0 mg/kg/day NOEL = 1 mg/kg/day | E2392-105/ 88.35% | A83-1091 |
| Rabbit (F) | Teratology | EPA 83.3 (1984) Days 7-19 of gestation 0 (vehicle), 2.67, 4.0 and 8.0 mg/kg/day. Individual doses were adjusted daily in order to compensate for changes in maternal body weights Vehicle: corn oil | Not teratogenic at levels up to and including 8.0 mg/kg/day NOEL = 2.67 mg/kg/day | E2392-105/ 88.35% | A83-1092 |
| Rat (M/F) | 2-Generation Reproduction | Dietary 0, 30, 60, or 100 ppm (approximately equivalent to 0, 1.5, 3.0 and 5.0 mg/kg/day) | NOEL toxicity = 60 ppm (3 mg/kg/day); NOEL reproduction 100 ppm (5mg/kg/day) | E2392-105/ 88.35% | A83-977 |
| Chicken (F) | Acute Delayed Neurotoxicity | 21 day observation | Negative | E2392-105 88.35% | A83-1081 |
| Rat (M/F) | Acute Neurotox | Undiluted (gavage), 14 day observation | NOEL = 35 mg/kg | PL97-592/ 93.7% | A97-4643 |

| Species | Test | Duration and conditions or guideline adopted | Result | Batch/purity | Reference |
|-----------|-----------------------------------|--|--|--------------------|-----------|
| | | Single oral dose : 0, 10, 35 or 75 mg/kg | FOB and motor activity effects noted in animals receiving 75 mg/kg | | |
| Rat (M/F) | 28-day Feeding – Repeated dose | Neurotoxicity study rangefinding 0 or 50 ppm (10 animals/sex/group) or 100, 200, or 300 ppm (5 animals/sex/group) | NOEL = 100 ppm LOEL = 200 ppm | PL97-592/ 93.7% | A97-4699 |
| Rat (M/F) | Subchronic Neurotoxicity | 13 weeks, dietary 0 or 50 ppm (10 animals/sex/group)or 100, 200, or 300 ppm (5 animals/sex/group) | NOEL = 50 ppm (2.9 mg/kg/day males; 3.7 mg/kg/day females) | PL97-592/ 93.7% | A97-4700 |

| Species | Test | Conditions | Result | Batch | Reference |
|--|--|---|--|----------------------|------------|
| Salmonella typhimurium | Ames Assay 0, 10, 33, 67, 100, 33, 667, 1000, 3.333, 6.667, 10.000 μg/plate in mutation test 1 0, 375, 1.875, 3.750 and 7.500 μg/plate in mutation test 2 (in both the presence and absence of S-9 mix) | 5 Strains with and without metabolic activation. Microsomes from male and female Swiss Webster mice and male Sprague Dawley rats | Not mutagenic | E2425-145/ 91.4% | A83-838 |
| Mouse Lymphoma Cells | Mouse Lymphoma Mutagenesis Assay 0.24, 0.18, 0.13, 0.10, 0.075, 0.056, 0.042, 0.032, 0.024, 0.018 μg/ml without metabolic activation. 0.10, 0.075, 0.056, 0.042, 0.032, 0.024, 0.018, 0.03, 0.010, 0.0075 μg/ml with metabolic activation | L5178Y TK+/- Rat liver S-9 | Weak positive results with and without metabolic activation | E2392-105/ 88.35% | A83-978 |
| Rat (M) | In vivo Cytogenetics 30, 10 and 3 mg/kg/day for five consecutive days | 5 day exposure oral by gavage | Negative | E2392-105 88.35% | A83-979 |
| Chinese Hamster Ovary (CHO) (F) | In vitro Chromosome Aberration 10.00, 30.00, 60.00 and 100.00 µg/mL in DMSO | Tested to 10,000 ug/mL with and without activation | Negative | E2392-105 88.35% | A1989-3099 |
| CHO (F) | HGPRT Assay Test 1 : 2.5, 5.0, 10, 25, 50, 100, 250, 500, 1000 µg/mL Test 2 : 250, 500, 750, 1000 µg/mL (without S9), 20, 30, 40, 50µg/mL (with S9) | With and without metabolic activation | Inconclusive w/metabolic activation | E2392-105/ 88.35% | A83-1144 |
| CHO (F) | In vitro Gene Mutation Preliminary cytotoxicity test : range of 0.10 to 10.000 μg/ml Main study : 100, 500, 1.000, 2.500, 5.000, 10.000 μg/ml in acetone | Tested to 10,000 ug/mL with and without activation | Not mutagenic | E2392-105/ 88.35% | A83-1105 |

Table 5. Mutagenicity profile of technical bifenthrin based on in vitro and in vivo tests

| Species | Test | Conditions | Result | Batch | Reference |
|--|---|--|--|----------------------|---------------------------------|
| Mouse Lymphoma Cells | HGPRT Gene Mutation Preliminary cytotoxicity test : 1, 5, 10, 30, 100 µg/ml Main study : 1.0, 30.0, and 60.00 µg/mL in acetone | L5178Y Dosed to the limit of solubility (500 ug/mL) | Not mutagenic | E2392-105/ 88.35% | A86-2059 |
| Rat Hepatocytes | Unscheduled DNA Synthesis Initial cytotoxicity test: ten treatments ranging from 100 to 0.005 µg/ml UDS assay: 0.01, 0.05, 0.1, 0.5, 1.0, 2.0 µg/ml in acetone | Tested at levels up to 100 ug/mL in DMSO | Marginally positive at one highly toxic dose. Two repeat assays yielded negative responses | E2392-105/ 88.35% | A83-985, A83-1043, 175408 |
| Mouse Embryo Cells (BALB/3T3) | Cell Transformation | No metabolic activation 3 - 100 µg/mL in DMSO | Negative | E2392-105/ 88.35% | A83-980 |
| Drosophila | Sex Linked Recessive Lethal – Genotox | Concentrations of 50 & 100 ug/mL | Negative | E2392-105/ 88.35% | A83-1104 |
| Chinese Hamster (F) Ovary (CHO) | In vitro Sister Chromatid Exchange | With and without metabolic activation up to 60 ug/mL in DMSO | Negative | E2392-105/ 88.35% | A1989-3016 |

Table 6. Ecotoxicology profile of technical bifenthrin

| Species | Test | Duration and conditions | Result [(isomer/form)] (purity) | Batch | Reference |
|--|---|--|--|--|------------------|
| (water flea) | OECD 202 Acute toxicity flow- through | 48 hrs exposure in a flow-through system, to five concentrations of bifenthrin (10, 5.0, 2.5, 1.2 and 0.6 μ g/L), control dilution water and solvent control dilution water (dimethyl formamide). | | E-2392-105/ | BW-83- 8-1444 |
| (water flee) | OECD 202 Acute toxicity flow-through | 48 hrs exposure in a flow-through system, to five concentrations of bifenthrin (0.025, 0.064, 0.12, 0.2 and 0.48 μ g/L), control dilution water and solvent control dilution water (dimethyl formamide). | LC ₅₀ (24hrs) >0.48μg/L (48hrs) - 0.11μg/L NOEC < 0.025 μg/L purity - 88.35%, composition - 98 % cis/2% trans isomer) | Path 830222-142 (¹⁴ C-) | BW-85- 2-1731 |
| Daphnia magna, Cerodaphnia dubia, Thamnocephale s platyurus, Hexagenia sp. (larvae), Caddis fly sp. (larvae), and Gammarus pulex. | OECD 202 Static acute toxicity tests | Daphnia: 48hrs exposure, concentrations: 0.018; 0.056; 0.18; 0.56, 1.8 & 5.6 mg/L Cerodaphnia dubia: 24hrs exposure, concentrations: 0.056; 0.18; 0.56, 1.8 & 5.6 mg/L Thamnocephales platyurus: 24hrs exposure, concentrations: 0.032; 0.056; 0.18; 0.56; 1.8 and 5.6 mg/L Hexagenia sp: 48hrs exposure, concentrations: 0.056; 0.18; 0.56, 1.8 and 5.6 mg/L Caddis fly sp: 48hrs exposure, concentrations: 0.056; 0.18; 0.56, 1.8 & 5.6 mg/L Gammarus pulex: 48hrs exposure, concentrations: 0.0032; 0.01; 0.032; 0.1; 0.32 & 1.0 mg/L | Daphnia: | PL00-0082, Batch B00-07 | 01-2424 /01 |

| Species | Test | Duration and conditions | Result [(isomer/form)] (purity) | Batch | Reference |
|---|------------------------------------|---|---|--------------------------------------|------------|
| | | | Bifenthrin technical (purity 93.8%) | | |
| Daphnia magna (water flea) | OECD 202 Chronic toxicity | Flow-through, 21-day life cycle toxicity test Groups of 40 daphnids (10 per replicate beaker) exposed to one of five nominal concentrations (0.6, 1.2, 2.5, 5.0 and 10 ng/L in water, to 50 μ L/L acetone (solvent control) or to water alone. Mean measured concentrations determined by liquid scintillation counting were 0.30, 0.76, 1.3, 2.9 and 7.6 ng/L. | MATC > 0.0013 < 0.0029 μg/L NOEC - 0.0013 μg/L ¹⁴ C-labelled bifenthrin (purity 96.2 %) | E2823-2 (¹⁴ C) | ABC36980 |
| <i>Mysidopsis bahia</i> (mysid) | OECD 202 Life cycle toxicity | Flow-through, 28-day life cycle toxicity Groups of 40 mysids (5 per replicate test chamber) in 20% seawater, to 0.1 mL/L acetone (solvent control) or to seawater alone (control). Nominal concentrations of bifenthrin were: 0.00, 0.79, 1.4, 2.8, 5.6 and 11.3 ng/L. Mean measured concentrations were: 0.98 (control and solvent control), 1.2, 1.3, 1.6, 2.5 and 4.7 ng/L. | MATC - 0.00125µg/L NOEC - 0.0012µg/L ¹⁴ C-labelled bifenthrin technical (Phenyl- ¹⁴ C, purity 96.5 %) | Path 83022-142 (¹⁴ C) | A90-3318 |
| Chlorella pyrenoidosa (green algae) Scenedesmus acutus (fresh water algae) | Acute toxicity | Two test species exposed to five concentrations of bifenthrin, ranging from 0.05 ppb to 50 ppm in 0.1% acetone. Culture medium according to guideline protocol, 25°C, continuous light, 100 µE/m ² /s, 50 mL of medium in 125 mL. | <i>Chlorella pyrenoidosa</i> NOEC > 50 ppm <i>Scenedesmus acutus</i> NOEC> 10 ppm Bifenthrin (purity not specified) | Not recorded | A2010-6981 |
| <i>Chironomus riparius</i> (midge) | Acute toxicity | ¹⁴ C bifenthrin applied just below the surface of an artificial water/sediment systems at the nominal concentration of 0, 0.1, 1, 10 and 100 μ g/l in the rage finding test and 0, 0.1, 0.32, 1.0, 3.2 and 10 μ g/l in the definitive test. | <u>Mortality:</u> EC ₅₀ - 3.96 μg/L NOEL - 0.32 μg/L <u>Emergence ratio</u> : EC ₅₀ - 3.96 μg/L NOEL - 1.06 μg/L | PL98-0360 | 19781 |

| Species | Test | Duration and conditions | Result [(isomer/form)] (purity) | Batch | Reference |
|--|-------------------------------|---|--|--------------|--------------------|
| | | the concentrations and 4 containing 20 | <u>Development rate:</u> EC ₅₀ >10.3 μg/L NOEL - 1.06 μg/L Bifenthrin technical (purity 94.4%) | | |
| <i>Eisenia foetida</i> (Earthworm) | Acute toxicity | Four replicates of 10 worms per treatment; total of 240 worms. Doses: 0.12 kg a.i./ha and100x (12 kg a i /ha | LC ₅₀ - 18.9 ppm a.i. NOEC - 5.7 ppm Bifenthrin technical (purity 88.35%) | E2392-105 | FCC82/85693 |
| <i>Apis mellifera</i> (honey bee) | Acute contact & oral toxicity | Acute contact toxicity: sprayed 20 mL solution containing bifenthrin at 50 ppm on a lot of caged bees. Two lots were tested for the product and two lots served as control. Mortality was noted after 24 hrs. | Acute oral toxicity: | Not recorded | Ph.L. SD-519-84 |
| <i>Poecilus cupreus (</i> carabid beetle) | Assessment of impact | (PEREKTHION (0.85 l/ha) and the control | Bifenthrin - 90% mortality at the application dose of 60 g/ha. Bifenthrin technical (purity 94.4%) | PL-98-0360 | 19547 |
| <i>,</i> | Assessment of impact | | Bifenthrin -100% mortality at the application dose of 60 g/ha | PL-98-0360 | 19141 |

| Species | Test | Duration and conditions | Result [(isomer/form)] (purity) | Batch | Reference |
|---|-------------------------|---|---|------------|-----------|
| mite) | | (water and acetone) were applied on glass plates (volume 200 l/ha) and were allow to dry. Twenty 2 to 3-day old mites (protonymph stage) were placed in each arenas per treatment. Mortality was assessed 24 hrs and 7 days after introduction. Seven day after application, female and male mites were transferred and the fecundity was assessed by counting the number of eggs laid after a further 7-day period. | Bifenthrin technical (purity 94.4%) | | |
| Chrysoperla carnea (green lacewing) | Assessment of impact | Bifenthrin: 60 g/ha, the reference (PERFECTKION (212.5 ml/ha) and the control (water and acetone) were applied on glass plates (volume 200 l/ha) and were allowed to dry. One larvae of <i>Chrysoperla carnea</i> was then placed on each glass plate and fed with lepidopteran eggs. The mortality was assessed daily. When pupation had occurred pupae were removed and placed in perspex oviposition cages. Adult emergence was measured daily until no adult had emerged for 7 consecutive days. | Bifenthrin - 100% at the application dose of 60 g/ha Bifenthrin technical; (purity 94.4%) | PL-98-0360 | 19572 |
| <i>Aphidius rhopalosiphi (</i> aphid parasitoid) | Assessment of impact | Bifenthrin: 60 g/ha, the reference (PERFEKTHION (425 ml/ha) and the control (water and acetone) were applied to 8 glass plates (volume 200 l/ha) and were allow to dry. Ten <i>Aphidius rhopalosiphi</i> (5 males and 5 females) were introduced into each test arena. | Bifenthrin -100% mortality. Bifenthrin technical; (purity 94.4%) | PL-98-0360 | 19545 |

| Species | Test | Duration and conditions | Result [(isomer/form)] (purity) | Batch | Reference |
|--|-------------------------|--|--|-----------|----------------|
| Sewage sludge | Assessment of impact | Determined the effect of the test item to the respiration rate of activated sludge. The respiration was measured after a contact time of 3 hrs. Two controls without test item were included in the test design. Due to the low water solubility, bifenthrin was added in the mg range. | EC ₅₀ - >1900 mg/L. Bifenthrin (purity 97.8%) | | E-17-99- 47 |
| | EEC Method C1 | Rainbow trout exposed in duplicate test | LC ₅₀ | E2392-105 | BW-83-8- |
| (Rainbow trout) | Acute toxicity | chambers in a flow-through system to five concentrations for 96 hrs. | (24 hrs) - 6.2 μg/L | | 1446 |
| | flow-through | Test nominal concentrations of 1.5, 0.75, (4 | (48 hrs) - 0.34 μg/L | | |
| | | 0.38, 0.19 and 0.094 µg/L bifenthrin maintained by introducing approx. 7 | (72 hrs) - 0.20 μg/L | | |
| | | aquarium volumes/day of fresh test solution | (96 hrs) - 0.15 μg/L | | |
| | | alkalinity as CaCO ₃ of 24 mg/L, pH 7.2-7.4, specific conductance range of 130-140 µmhos/cm. | (120 hrs) ~0.1 μg/L | | |
| | | | NOEC - 0.094 µg/L | | |
| | | | Bifenthrin technical (purity 88.35% composition 98% cis/ 2% trans isomers) | | |
| ' | EEC Method C1 | Bluegill exposed in duplicate test chambers | LC ₅₀ | E2392-105 | BW-83-8 |
| <i>macrochirus</i> (Bluegill sunfish) | Acute toxicity | in a flow-through system to five concentrations for 96 hrs. | (24 hrs) >1.0μg/L | | 1445 |
| | flow-through | Test nominal concentrations of 1.0, 0.65, | (48 hrs) - 0.65µg/L | | |
| | | 0.42, 0.27 and 0,18µg/L bifenthrin maintained by introducing approx. 8.6 | (72 hrs) - 0.44µg/L | | |
| | | aquarium volumes/day of fresh test solution. | (96 hrs) - 0.35µg/L | | |
| | | Test dilution water conditions were representative of a soft water quality. Total | (120 hrs) - 0.32µg/L | | |
| | | hardness: CaCO ₃ of 28-31 mg/L, alkalinity | (144 hrs) - 0.30 μg/L | | |
| | | as CaCO ₃ of 24-26 mg/L, pH 7.2-7.4, specific conductance range of 120-140 | NOEC< 0.18 μg/L | | |
| | | µmhos/cm. | Bifenthrin technical (purity 88.35%, | | |

| Species | Test | Duration and conditions | Result [(isomer/form)] (purity) | Batch | Reference |
|---|--|--|--|----------------------------|------------------|
| | | | composition - 98 % cis/2 % trans isomer) | | |
| Salmo gairdneri (Rainbow trout) | OECD 210 Toxicity to embryos and larvae | Flow-through with nominal test concentrations were 0.070, 0.035, 0.018, 0.0088 and 0.0044 µg/l. Unfertilised rainbow trout eggs and sperm were received individually and mixed for fertilization. 50 embryos were distributed to each of 28 incubation cups. Embryos development was observed daily. Percentage hatch calculations were based on the number of live larvae per cup after hatching compared to the number of viable embryos per cup on test day 20. To initiate the 48-hrs larvae exposure, incubation cups within each aquarium were combined on day 28, and the larvae were placed into their respective aquaria. Behaviour and appearance of larvae were observed daily and larvae were counted twice weekly. At 48 days post hatch (30 days post swim- up), the larvae were anaesthetised, and percentage survival, mean total length, and average wet weight were determined. | NOEC 0.012 μg/L ¹⁴ C-bifenthrin (52 mCi/mM phenyl ring label, Hexane solution 10.36% a.i.) | | BW-85-4- 1766 |
| Pimephales promela) (Fathead minnow) | EPA 72.5 Full life cycle toxicity | Flow –through full life cycle study with nominal water concentrations of 0.0050, 0.0090, 0.019, 0.038, 0.075 μg/l. 140 healthy embryos per test concentration used at the start of the test, and place in incubation cups. Number of embryos hatched in each cup recorded daily until hatching completed. Daily observations taken on eggs, embryos, | LC_{50} (96hr) - 0.21 µg/l (static) NOEC - 0.04 µg/l (parent survival) NOEC > 0.09 µg/l (reproduction) | ¹⁴ C E2823-2 | A86-2100 |

| Species | Test | Duration and conditions | Result [(isomer/form)] (purity) | Batch | Reference |
|---------|------|--|---|-------|-----------|
| | | and fry. Day 30, survival and standard length of live fish determined. Day 77, fish reduced to 15 fish per replicate. At 92 and 120 days post hatch fry anesthetised, measure weighted and revived in their respective test chambers. At 121 days post hatching, 20 fish randomly selected and placed in duplicate spawning chambers of each aquarium along with 5 spawning tiles. All other fish were retained in growth chamber or frozen for residue analysis. At 150 and 151 days post hatching, fish were sexed and reduced to 5 males and 12 females in all spawning chambers. On day 198 post hatching (study day 204), fish were reduced to 4 males and 6 females. Tiles were checked for the presence of eggs. Eggs were then placed in a separate container of the appropriate test solution. Spawns of < 50 eggs were placed into a growth chamber. Daily observations were done on eggs, embryos and fry. On day 56 post-hatching, the fish were measured and weighted. A part was frozen. | ¹⁴ C-FMC bifenthrin (96.2% purity) | | |

| Species | Test | Duration and conditions | Result [(isomer/form)] (purity) | Batch | Reference |
|--|--|--|--|-----------------|------------------|
| Lepomis macrochirus (Bluegill sunfish) | OECD 305 E Bio- accumulation | concentrations (0.007 µg/L and 0.085 µg/L) of 14C-radiolabeled bifenthrin for 60 days to aqueous solutions of bifenthrin under semi- static conditions with a 2-day renewal interval. The depuration phase was performed for 60 days under flow-through conditions, resulting in a total in-life | The concentrations in whole fish increased relatively fast at both treatment levels during the first 28 days of exposure. Thereafter, steady state was reached. 7.9 and 168.8 \pm 25.5 µg TRR/kg. During the depuration period, the concentrations of the total radioactive residue in whole fish declined with time. | 14C QFC14435 | 1084.008. 135 |
| | | Semi-static, two day renewal interval, four replicates per test group, twenty fish per replicate, aeration to prevent oxygen depletion, addition of application solution between renewal days in order to compensate for uptake by fish and adsorption to test vessel walls, daily feeding. Depuration period: Flow-through, started with 4 replicates per test group, with 13 fish per replicate, 50 L stainless steel vessels, 10 volume exchanges per day. Sampling: Water samples were taken twice daily in order to determine the total | The whole fish BCF based on the total radioactive residue at steady state, i.e., the BCFSS, was $1,494 \pm 229$ at 0.007 µg a.i./L and $1,622 \pm 218$ at 0.085 µg a.i./L. The bifenthrin BCFSS of whole fish was $1,362 \pm 219$ at 0.007 µg a.i./L and $1,414 \pm 204$ at 0.085 µg a.i./L whole fish. The depuration rate constants for whole fish were 0.024 day-1 for both treatment levels The elimination DT50 for bifenthrin was 28 and 22 days for the 0.007 and 0.085 | | |
| | radioactive residue in the test solutions by LSC during the uptake phase and the first 8 days of the depuration phase. The samples were quantified for 14C-residues, extracted with becape and analysed for bifenthrin and | μg a.i./L treatment levels, respectively. Phenyl-ring labelled 14C- bifenthrin radiochemical purity 97.8 %). | | | |

| Species | Test | | Result [(isomer/form)] (purity) | Batch | Reference |
|---------------------------|------------------------------------|---|--|--------------------|-----------|
| | | after start of the exposure. Water conditions: temperature ranged 19.9-24.0 °C, total hardness of 0-56 mg/L as CaCO3, total alkalinity of 327-700 mg/L as CaCO3, TOC <2 mg/L, pH of 7.37-8.46, specific conductivity of 420-800 μ S/cm, and dissolved oxygen concentration of 7.92-9.97 mg/L. | | | |
| Cyprinus carpio (carp) | OECD 305 C Bio- accumulation | nominal concentrations (high exposure level: 0.085 ng/mL, low exposure level: 0.0085 ng/mL) of the test substance. Flow-through system which introduced about 400L of fresh test solution per day. On week 10, the addition of the test substance was terminated and only dilution water was supplied during the next two weeks (depuration phase). | Bioconcentration factor Exposure - 0.085ng/mL: 1330x Exposure- 0.0085ng/mL:1030x Elimination Exposure -0.085ng/mL: 11 days (50%) Exposure -0.0085ng/mL: 6 days (50%) 14C- bifenthrin (FMC (FMC-U14C labeled) radiochemical purity 97 %) | 14C Isotope 195 | 2B479G |

| Species | Test | Duration and conditions | Result [(isomer/form)] (purity) | Batch | Reference |
|----------------|---------------------------------------|--|------------------------------------|-----------|-------------------|
| Bobwhite quail | Acute oral toxicity | 60 quails, divided (5/sex) into a control group + 5 treatment groups: 464, 681, 1000, 1470 and 2150 mg/kg. Orally administered via a syringe on test day 0. The control group received only corn oil. Body weight and food consumption were recorded at days 0, 3, 7, 14 and 21. Observations made daily. All birds found dead + 4 arbitrarily selected birds sacrificed from each group on test days 21 were subjected to a gross necropsy. | (purity 88.35%) | E2392-105 | BLAL83- QD 30 |
| Mallard duck | None stated Acute oral toxicity | 30 ducks, divided (5/sex) into a control group and 2 treatment groups: 1470 and 2150 mg/kg. Orally administered via a syringe on test day 0. The control group received only corn oil. BW and food consumption were recorded at days 0 (only body weight), 3, 7,14 and 21. Observations made daily. Four arbitrarily selected birds sacrificed on test day 21 were subjected to a gross necropsy. | (purity 89.25%) | E2392-105 | BLAL 83- DD 23 |

| Species | Test | | Result [(isomer/form)] (purity) | Batch | Reference | |
|----------------|---|--|---|----------------------------|-----------------|--|
| Bobwhite quail | OECD 205 Short-term (8- day) dietary study | 150 quails, divided into 5 vehicle control groups (10/group; corn oil), 5 positive control groups (10/group, using 10, 21.5, 46.4 68.1 and 100 ppm of dieldrin) and 5 treatment groups (10/group; using 312, 625, 1250, 2500 and 5000 ppm of bifenthrin). | LC50 - 4450 ppm for bifenthrin technical (purity 88.35%) | E2392-105 | BLAL83- QC34 | |
| | | | Test material incorporated into the diet with corn oil and fed to the birds for 5 days. | LC50 - 23 ppm for dieldrin | | |
| | | Following the 5-day test period birds were maintained on plain feed for a 3-day recovery period. | | | | |
| | | Food consumption recorded through-out the study | | | | |
| | | Birds weighed at 0 hr on day 1 and again on day 8. | | | | |
| | | Observations made daily. | | | | |
| | | All birds found dead and 4 arbitrarily selected birds from each group sacrificed at the termination of the study were subjected to a gross necropsy. | | | | |

| Species | Test | | Result [(isomer/form)] (purity) | Batch | Reference |
|---------------|---|--|------------------------------------|-----------|-----------------|
| Mallard ducks | Short-term (8- day) dietary study | 150 ducks, divided into 5 vehicle control groups (10/group; corn oil), 5 positive control groups (10/group, using 46.4, 68.1, 100, 147 and 215 ppm of dieldrin) and 5 treatment groups (10/group; using 312, 625, 1250, 2500 and 5000 ppm of bifenthrin technical). Test material incorporated into the diet with corn oil and fed to the birds for 5 days. Following the 5-day test period birds were maintained on plain feed for a 3-day recovery period. Food consumption recorded throughout the study Birds weighed at 0 hr on day 1 and again on day 8. Observations made daily. All birds found dead and 4 arbitrarily selected birds from each group sacrificed at the termination of the study were subjected to a gross necropsy. | | E2392-105 | BLAL83- DC34 |

| Species | Test | Duration and conditions | Result [(isomer/form)] (purity) | Batch | Reference |
|----------------|--------------------------|---|---|-------|-------------------|
| Bobwhite quail | OECD 206 Reproduction | Dietary effects quail, 3 groups of 20 replicates (1 male and 1 female per replicate) Dose levels of 25, 50 and 75 ppm. Diet given over a 24-week period – 12 weeks prior to the start of egg production and 12 weeks during egg production. All eggs laid were collected over a 12-week period from the beginning of week 13 until the end of week 24. | No evidence of any adverse effects on the reproduction. Bifenthrin (purity 88.35%) | | FCC57A/ 851423 |
| Mallard duck | OECD 206 Reproduction | Dietary effects quail, 3 groups of 6 replicates (2 male and 5 females per replicate Dose levels of 25, 50 and 75 ppm. Diet given over a 24-week period – 12 weeks prior to the start of egg production and 12 weeks during egg production. All eggs laid were collected over a 12-week period from the beginning of week 13 until the end of week 24. | No evidence of any adverse effects on the reproduction. Bifenthrin (purity 88.35%) | | FCC58A/ 851430 |

ANNEX 2

REFERENCES

| FMC or other | Year | Title |
|-----------------|------|--|
| document number | | |
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| 19545 | 2001 | Technical bifenthrin: an extended laboratory evaluation of the side effects of technical bifenthrin on the aphid parasitoid <i>Aphidius rhopalosiphi</i> |
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| 1084.008.135 | 2006 | Bifenthrin:Bioconcentration study with bluegill sunfish (Lepomis macrochirus) under semi-static conditions |
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| A1989-3016 | 1989 | Sister Chromatid Exchange Assay in Chinese Hamster Ovary (CHO) cells <i>in vitro</i> with bifenthrin |
| A1989-3099 | 1989 | Gene Mutation Assay in Chinese Hamster Ovary (CHO) cells <i>in vitro</i> with bifenthrin |
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| A2003-5589 | 2003 | Acute nose-only inhalation toxicity study of bifenthrin technical in albino rats |
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| A83-1032 | 1983 | Acute Dermal Toxicity of FMC 54800 Technical in Rabbits. |
| A83-1033 | 1983 | Primary Skin Irritation of FMC 54800 Technical in Rabbits. |
| A83-1034 | 1983 | Primary Eye Irritation of FMC 54800 Technical in Rabbits. |
| A83-1035 | 1983 | Skin Sensitization of FMC 54800, Technical in Guinea Pigs. |
| A83-1041 | 1983 | (Bifenthrin) Guinea Pig Sensitization - Maximization Test |
| A83-1043 | 1983 | Unscheduled DNA Synthesis in Rat Primary Hepatocytes |
| A83-1081 | 1984 | The Acute Oral Toxicity (LD50) and Neurotoxic Effects of FMC 54800 Technical to the Domestic Hen |
| A83-1091 | 1984 | Teratology Study in Rats with FMC 54800 Technical |
| A83-1092 | 1984 | Multi-Generation Reproduction Study with FMC 54800 Technical in Rats. |
| A83-1104 | 1984 | Mutagenicity Evaluation of FMC 54800 Technical, Notebook No. E- 3292-105, FMC Study No. A83/1104 in the Sex-Linked Recessive Lethal Test in <i>Drosophila Melanogaster</i> |

| FMC or other document number | Year | Title |
|------------------------------|------|---|
| A83-1105 | 1984 | Chromosome Aberrations in Chinese Hamster (CHO) Cells |
| A83-1144 | 1984 | CHO/HGPRT Mutation Assay in the Presence and Absence of |
| A00-1144 | 130- | Exogenous Metabolic Activation |
| A83-817 | 1983 | Twenty Eight Day Range Finding in Rats with FMC 54800 Technical |
| A83-818 | 1983 | Ninety Day Range Finding in Rats with FMC 54800 Technical |
| A83-820 | 1984 | 13-Week Sub-chronic Oral Toxicity Study in Dogs with FMC 54800 |
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| A83-837 | 1983 | Acute Oral Toxicity of FMC 54800 in Mice |
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| A83-978 | 1983 | L5178Y TH+/- Mouse Lymphoma Mutagenisis Assay |
| A83-979 | 1983 | Activity of FMC 54800 technical in the sub-chronic <i>in vivo</i> |
| 4.00,000 | 4000 | cytogenetics assay in Sprague-Dawley rats |
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| A97-4643 | 1998 | FMC 54800 Technical-Acute Neurotoxicity in Rats |
| A97-4681 | 1997 | FMC 54800 technical: Acute Oral Toxicity Study in Rats |
| A97-4699 | 1998 | FMC 54800 Technical-Twenty-Eight Day Neurotoxicity Range- Finding Study in Rats |
| A97-4700 | 1998 | FMC 54800 Technical – Subchronic Neurotoxicity Screen in Rats |
| ABC 34846 | 1998 | Full life cycle toxicity of ¹⁴ C FMC 54800 to fathead minnow |
| | 1300 | (<i>Pimephales promelas</i>) in a flow-through system |
| ABC 36980 | 1989 | Chronic Toxicity of ¹⁴ C-FMC 54800 to <i>Daphnia magna</i> under flow- |
| | | through test conditions |
| BLAL83DC34 | 1983 | 8-day dietary LC50 study with FMC 54800 technical in mallard ducklings |
| BLAL83DD23 | 1983 | Acute oral toxicity study with FMC 54800 technical in mallard ducklings |
| BLAL83QC34 | 1983 | 8-day dietary LC50 study with FMC 54800 technical in bobwhite quail |
| BLAL83QD30 | 1983 | Acute oral toxicity study with FMC 54800 technical in bobwhite quail |
| BW-83-8-1444 | 1983 | Acute Toxicity of FMC 54800 technical to <i>Daphnia magna</i> |
| | | |

| FMC or other | Year | Title |
|-----------------|------|---|
| document number | | |
| BW-83-8-1445 | 1983 | Acute Toxicity of FMC 54800 technical to bluegill (Lepomis |
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