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-dimethylcyclopropane carboxylate

Note. Evaluation report ONLY. The FAO specifications will be published subject to publication of the analytical methods for determination of the bifenthrin content in TC and WP

FOOD AND AGRICULTURE ORGANIZATION of THE UNITED NATIONS

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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.

(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.

Appraisal

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Bifenthrin is a pyrethroid insecticide, which had been the subject of a WHO interim specification withdrawn in April 2008.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 to control anophelines 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 minimum 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 A-D), was lower than the current manufacturing specification (≥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-dimethylcyclopropanecarboxylic acid, for brevity called the TFP anhydride[1], was identified as 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 test 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

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

overall result clearly showed that technical bifenthrin with such a low content of anhydride is a sensitizer too. In conclusion, bifenthrin is a sensitizer by itself, which renders the TFP anhydride non-relevant, and hence 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 determine the total bifenthrin content (expressed as sum of cis and trans-bifenthrin) as well as to measure the ratio of cis/trans isomers present. 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 shows acceptable accuracy, reproducibility, and recovery and is capable to determine the impurity in a concentration range of 0.5 g per kg to 50 g per kg level. 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 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-^{14}C-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 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 (Ref. 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 ^{14}C-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 (LC_{50}).

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 Appraisal

1 K. Chamberlain, Noritada Matsuo, Hideo Kanoko and Bhupinder P.S. Khambay, Pyrethroids, in Chirality in Agrochemicals, Ed. Norio Kurihara and Juhshi Miyamoto, Wiley, 1998, p. 32 .

2 Anonymous, FMC Corporation, Test Method ACG 88, High Performance Liquid Chromatographic Analysis of FMC 54800 (“Reversed Phase”) 1987.

3 Anonymous, FMC Corporation, Test Method ACG 89, High Performance Liquid Chromatographic Analysis of FMC 54800 (“Normal Phase”) without date.

4 Metabolic Pathways of Agrochemicals, Part Two, Insecticides and Fungicides, T. Roberts and D. Hutson, Bifenthrin, The Royal Society of Chemistry, p. 594 to 596.

SUPPORTING INFORMATION
FOR
EVALUATION REPORT 415/2009

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) 3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate

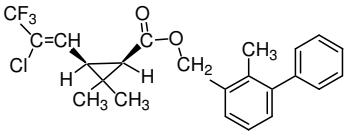
CA (2-methyl[1,1'-biphenyl]-3-yl)methyl 3-[(1Z)-2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate

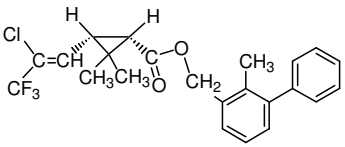
Synonyms

FMC 54800

Structural formulae

(*Z*)-(1*R*)-*cis*-





(*Z*)-(1*S*)-*cis*-

Molecular formula

$C_{23}H_{22}ClF_3O_2$

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

Table 1: Physico-chemical properties of pure 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 and/or temperature of decomposition	Melting point: 65-70 °C Bifenthrin vaporizes intact in the 215-225°C temperature range	98.5	DSC TGA-IR	P-2544
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 day 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}.	Radio-labeled 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 2: Chemical composition and properties of bifenthrin technical material

Manufacturing process, maximum limits for impurities ≥ 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, WP, EC and SC, but the method is not yet published by AOAC. In addition, an analytical method for determination of the suspensibility of certain bifenthrin formulations forming suspensions in water (WP, SC) is not yet available.

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 Manual (5th 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 WHO 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

Note: the proposer provided written confirmation that the toxicological data included in the following summary were derived from bifenthrin having impurity profiles similar to those referred to in Table 2, above.

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
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

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)	Inhalation	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 Sensitization	Buehler method EPA 81-6	Non-sensitizing	E2392-105/ 88.35%	A83-1035
Guinea Pig (F)	Skin Sensitization	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 Sensitization	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

Table 4: Toxicology profile of the technical material based on repeated administration (subacute to chronic)

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 Feed-ing – 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 Feed-ing – 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 Feed-ing - 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 Feed-ing – 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	NOEL = 50 ppm male 200 ppm female	E2392-105/ 88.35%	A83-974

Species	Test	Duration and conditions or guideline adopted	Result	Batch/purity	Reference
		0 , 50, 200, 500 and 600 ppm	Increased incidence of sub-mucosal tumours (hemangiomas) of marginal statistical significance.		
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 (Repeated dose)	EPA 82-2 (1984) 6 hours / day 5 days / week 0, 25, 50, 100, or 1000 mg/kg b.w./day	NOEL = 50 mg/kg/day	G1295-15B/ 93.2%	A2000-5162
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	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

Species	Test	Duration and conditions or guideline adopted	Result	Batch/purity	Reference
		Vehicle: corn oil			
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 Single oral dose : 0, 10, 35 or 75 mg/kg	NOEL = 35 mg/kg FOB and motor activity effects noted in animals receiving 75 mg/kg	PL97-592/ 93.7%	A97-4643
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

Table 5: Mutagenicity profile of the technical material based on in vitro and in vivo tests

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	Tested to 10,000 ug/mL with and without activation	Not mutagenic	E2392-105/ 88.35%	A83-1105

Species	Test	Conditions	Result	Batch	Reference
	Main study : 100, 500, 1.000, 2.500, 5.000, 10.000 µg/ml in acetone				
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
Daphnia magna (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 µg/L), control dilution water and solvent control dilution water (dimethyl formamide).	LC_{50}: (24hrs) - >10 µg/L (48hrs) - 1.6 µg/L NOEC < 0.60 µg/L Bifenthrin technical (purity - 88.35%, composition - 98 % cis/2% trans isomer)	E-2392-105/	BW-83-8-1444
Daphnia magna (water flea)	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 µg/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*, *Thamnocephales 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	<u>*Daphnia*</u>: EC_{50}(48hrs) - 0.37 µg/L NOEC - 0.056 µg/L <u>*Cerodaphnia dubia*</u> EC_{50}(24hrs) - 0.31 µg/L NOEC- 0.043 µg/L <u>*Thamnocephales platyurus*</u> EC_{50}(24hrs) - 5.7 µg/L NOEC - 0.032 µg/L <u>*Hexagenia sp*</u> EC_{50}(48hrs) - 0.39 µg/L NOEC - 0.039 µg/L <u>*Caddis fly sp*</u> EC_{50}(48hrs) - 0.12 µg/L NOEC - 0.031 µg/L <u>*Gammarus pulex*</u> EC_{50}(48hrs) - 0.11 µg/L	PL00-0082, Batch B00-07	01-2424/01

Species	Test	Duration and conditions	Result [(isomer/form)] (purity)	Batch	Reference
			NOEC - 0.032 µg/L 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 µL/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
Mysidopsis bahia (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.	*Chlorella pyrenoidosa* NOEC > 50 ppm *Scenedesmus acutus* NOEC> 10 ppm Bifenthrin (purity not specified)	Not recorded	A2010-6981
Chironomus riparius (midge)	Acute toxicity	^{14}C bifenthrin applied just below the surface of artificial water/sediment systems at the nominal concentration of 0, 0.1, 1, 10 and 100 µg/l in the rage finding test and 0, 0.1,	Mortality: EC_{50} - 3.96 µg/L NOEL - 0.32 µg/L Emergence ratio:	PL98-0360	19781

Species	Test	Duration and conditions	Result [(isomer/form)] (purity)	Batch	Reference
		0.32, 1.0, 3.2 and 10 µg/l in the definitive test. Six vessels per concentration prepared, appropriate controls - 2 for the measure of the concentrations and 4 containing 20 chironomid larvae.	EC_{50} - 3.96 µg/L NOEL - 1.06 µg/L Development rate: EC_{50} >10.3 µg/L NOEL - 1.06 µg/L Bifenthrin technical (purity 94.4%.)		
Eisenia foetida (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 On days 7 and 14, worms removed for counting.	LC_{50} - 18.9 ppm a.i. NOEC - 5.7 ppm Bifenthrin technical (purity 88.35%)	E2392-105	FCC82/85693
Apis mellifera (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: ingestion was tested by nourishment of lots of bees by means of a micropipette at a constant volume (20µL). The bees were presented a drop of sweet water containing fixed quantities of bifenthrin. One hr after treatment the bees received honey and pure water. Three doses (0.04 µg, 0.1 µg and 0.4 µg) and one control have been tested and mortality was noted after 24 hrs.	Acute contact toxicity: 100% mortality. Acute oral toxicity: LD_{50}(24hrs)-0.1 µg/bee. Bifenthrin (purity not stated)	Not recorded	Ph.L. SD-519-84
*Poecilus cupreus (*carabid beetle)	Assessment of impact	Six adults per container. 60 g/ha dose of bifenthrin, the reference (PERFEKTHION (0.85 l/ha) and the control (water and acetone) were applied to 5 replicate test arenas (volume 400 l/ha).	Bifenthrin - 90% mortality at the application dose of 60 g/ha. Bifenthrin technical (purity 94.4%)	PL-98-0360	19547

Species	Test	Duration and conditions	Result [(isomer/form)] (purity)	Batch	Reference
		Mortality and food consumption were assessed.			
*Thyphlodromus pyri (*predatory mite)	Assessment of impact	Bifenthrin: 60 g/ha, the reference (PERFEKTHION (212.5 ml/ha) and the control (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 -100% mortality at the application dose of 60 g/ha Bifenthrin technical (purity 94.4%)	PL-98-0360	19141
*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 *Chrysoperla carnea* 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
*Aphidius rhopalosiphi (*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 *Aphidius rhopalosiphi* (5 males and 5 females) were introduced into each test	Bifenthrin -100% mortality. Bifenthrin technical; (purity 94.4%)	PL-98-0360	19545

Species	Test	Duration and conditions	Result [(isomer/form)] (purity)	Batch	Reference
		arena.			
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%)	E6788:143	E-17-99-47
Salmo gairdneri (Rainbow trout)	EEC Method C1 Acute toxicity flow-through	Rainbow trout exposed in duplicate test chambers in a flow-through system to five concentrations for 96 hrs. Test nominal concentrations of 1.5, 0.75, 0.38, 0.19 and 0.094 µg/L bifenthrin maintained by introducing approx. 7 aquarium volumes/day of fresh test solution via modified, proportional diluter apparatus. Total hardness: $CaCO_3$ of 28-30 mg/L, alkalinity as $CaCO_3$ of 24 mg/L, pH 7.2-7.4, specific conductance range of 130-140 µmhos/cm.	LC_{50} (24 hrs) - 6.2 µg/L (48 hrs) - 0.34 µg/L (72 hrs) - 0.20 µg/L (96 hrs) - 0.15 µg/L (120 hrs) ~0.1 µg/L NOEC - 0.094 µg/L Bifenthrin technical (purity 88.35% composition 98% cis/ 2% trans isomers)	E2392-105	BW-83-8-1446
Lepomis macrochirus (Bluegill sunfish)	EEC Method C1 Acute toxicity flow-through	Bluegill exposed in duplicate test chambers in a flow-through system to five concentrations for 96 hrs. Test nominal concentrations of 1.0, 0.65, 0.42, 0.27 and 0,18µg/L bifenthrin maintained by introducing approx. 8.6 aquarium volumes/day of fresh test solution. Test dilution water conditions were representative of a soft water quality. Total hardness: $CaCO_3$ of 28-31 mg/L, alkalinity as	LC_{50} (24 hrs) >1.0µg/L (48 hrs) - 0.65µg/L (72 hrs) - 0.44µg/L (96 hrs) - 0.35µg/L (120 hrs) - 0.32µg/L	E2392-105	BW-83-8 1445

Species	Test	Duration and conditions	Result [(isomer/form)] (purity)	Batch	Reference
		$CaCO_3$ of 24-26 mg/L, pH 7.2-7.4, specific conductance range of 120-140 µmhos/cm.	(144 hrs) - 0.30 µg/L NOEC< 0.18 µg/L Bifenthrin technical (purity 88.35%, 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.)	^{14}C Path 830222-142	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	LC_{50} (96hr) - 0.21 µg/l (static)	^{14}C E2823-2	A86-2100

Species	Test	Duration and conditions	Result [(isomer/form)] (purity)	Batch	Reference
		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, 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 removed from the tiles and frozen for residue analysis. Spawn 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.	NOEC - 0.04 µg/l (parent survival) NOEC > 0.09 µg/l (reproduction) ^{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	Lepomis macrochirus were exposed to 2 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 assessment phase of 120 days. 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 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 hexane and analysed for bifenthrin and degradation products. Fish samples were taken on days 7, 15, 28, 39, 48, and 60 after start of the exposure. During the depuration phase, fish samples were taken on days 1, 2, 4, 8, 14, 30, 42 and 60 after start of the depuration phase, i.e. on days 61, 62, 64, 68, 74, 90, 102, and 120 after start of the exposure. Water conditions; Temperature ranged 19.9-24.0 °C, total	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 ± 25.5 µg TRR/kg. During the depuration period, the concentrations of the total radioactive residue in whole fish declined with time. The whole fish BCF based on the total radioactive residue at steady state, i.e., the BCF_{SS}, was 1,494 ± 229 at 0.007 µg a.i./L and 1,622 ± 218 at 0.085 µg a.i./L. The bifenthrin BCF_{SS} of whole fish was 1,362 ± 219 at 0.007 µg a.i./L and 1,414 ± 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 DT_{50} for bifenthrin was 28 and 22 days for the 0.007 and 0.085 µg a.i./L treatment levels, respectively. Phenyl-ring labelled ^{14}C- bifenthrin radiochemical purity 97.8 %).	^{14}C QFC14435	1084.008. 135

Species	Test	Duration and conditions	Result [(isomer/form)] (purity)	Batch	Reference
Cyprinus carpio (carp)	OECD 305 C Bio-accumulation	Two groups of fish, continuously exposed to 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). Concentrations of the test substance in water and whole fish were measured periodically.	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%) ^{14}C- bifenthrin (FMC (FMC-u-ring-^{14}C) radiochemical purity 97 %)	^{14}C Isotope 195	2B479G
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.	LD50 - 1800 mg/kg bw Bifenthrin (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. BWand food consumption were recorded at days 0 (only body weight), 3, 7,14 and 21. Observations made daily. Four arbitrarily selected birds sacrificed on	LD_{50} >2150 mg/kg bw Bifenthrin (purity 88.35%)	E2392-105	BLAL 83- DD 23

Species	Test	Duration and conditions	Result [(isomer/form)] (purity)	Batch	Reference
		test day 21 were subjected to a gross necropsy.			
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). 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 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.	LC_{50} - 4450 ppm for bifenthrin technical (purity 88.35%) LC_{50} - 23 ppm for Dieldrin	E2392-105	BLAL83-QC34
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	LC_{50} - 1280 ppm for bifenthrin technical (purity 88.35%) LC_{50} - 64 ppm for dieldrin	E2392-105	BLAL83-DC34

Species	Test	Duration and conditions	Result [(isomer/form)] (purity)	Batch	Reference
		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.			
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%)	E2392-105	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%)	E2392-105	FCC58A/ 851430

Annex 2 Reference List

FMC or other document number	Year	Title
19141	2001	Technical bifenthrin: an extended laboratory evaluation of the side effects of technical bifenthrin on the predatory mite *Thyphlodromus pyrii*
19545	2001	Technical bifenthrin: an extended laboratory evaluation of the side effects of technical bifenthrin on the aphid parasitoid *Aphidius rhopalosiphi*
19547	2001	Technical bifenthrin: an extended laboratory evaluation of the side effects of technical bifenthrin on the carabid beetle *Poecilius cupreus*
19572	2001	Technical bifenthrin: an extended laboratory evaluation of the side effects of technical bifenthrin on the green lacewing *Chrysoperla carnea*
19781	2002	^{14}C-bifenthrin:determination of acute toxicity (EC50) to *Chironomus riparius* (28 days, static)
175408	1990	Unscheduled DNA Synthesis in Primary Hepatocytes of Male Rats *in vitro* with bifenthrin
01-2424/01	2002	Static acute toxicity tests with the insecticide bifenthrin technical and 6 arthropod species
1084.008.135	2006	Bifenthrin:Bioconcentration study with bluegill sunfish (Lepomis macrochirus) under semi-static conditions
2B479G	1993	Bioaccumulation study of FMC 54800 with carp (*Cyprinus carpio)*
A1989-3016	1989	Sister Chromatid Exchange Assay in Chinese Hamster Ovary (CHO) cells *in vitro* with bifenthrin
A1989-3099	1989	Gene Mutation Assay in Chinese Hamster Ovary (CHO) cells *in vitro* with bifenthrin
A2000-5162	2000	Bifenthrin technical: 21 day repeated dose dermal toxicity study in rat
A2000-5263	2000	Bifenthrin technical: Prenatal Developmental Toxicity Study in Rat
A2002-5588	2003	Bifenthrin Technical: Contact Hypersensitivity in Albino Guinea-Pigs, Maximisation Test
A2003-5589	2003	Acute nose-only inhalation toxicity study of bifenthrin technical in albino rats
A2009-6770	2009	(Bifenthrin) Guinea Pig Sensitization - Maximization Test
A2010-6981	1985	Bifenthrin toxicity to algae
A82-756	1982	Acute Oral Toxicity Study in Rats, FMC 54800
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 *Drosophila Melanogaster*
A83-1105	1984	Chromosome Aberrations in Chinese Hamster (CHO) Cells
A83-1144	1984	CHO/HGPRT Mutation Assay in the Presence and Absence of 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 Technical
A83-821	1985	52-Week Chronic Oral Toxicity in Dogs
A83-837	1983	Acute Oral Toxicity of FMC 54800 in Mice
A83-838	1983	*Salmonella*/Mammalian-Microsome Plate Incorporation Mutagenicity Assay (AMES Test)
A83-839	1983	Twenty Eight Day Range Finding in Mice with FMC 54800 Technical
A83-952	1986	Combined chronic oral toxicity and oncogenicity study of FMC 54800: 2-year feeding study in albino rats
A83-959	1983	Acute Oral Toxicity of FMC 54800 in Rat
A83-974	1991	FMC 54800 Technical – Oncogenicity Lifetime Feeding Study in Albino Mice Histopathological Review of Selected Sections of Liver, Lung and Urinary Bladder
A83-977	1986	Multi-Generation Reproduction Study with FMC 54800 Technical in Rats.
A83-978	1983	L5178Y TH+/- Mouse Lymphoma Mutagenisis Assay
A83-979	1983	Activity of FMC 54800 technical in the sub-chronic *in vivo* cytogenetics assay in Sprague-Dawley rats
A83-980	1983	Activity of FMC 54800 technical in the Morphological Transformation of BALB/3T3 Mouse Embryo Cells in the Absence of Metabolic Activation
A83-985	1983	Unscheduled DNA Synthesis in Rat Primary Hepatocytes
A85-1923	1986	Acute Intraperitoneal Toxicity of FMC 54800 Technical in Rats
A85-1924	1985	Acute Dermal Toxicity of FMC 54800 Technical in Rats.
A86-2059	1986	Study to Determine the Ability of FMC 54800 to Induce Mutations to 6-Thioguanine Resistance in Mouse Lymphoma L5178Y Cells Using a Fluctuation Assay
A86-2100	1988	Full life cycle toxicity of ^{14}C-FMC 54800 to fathead minnow (*Pimephales promelas*) in a flow-through system
A90-3318	1991	Life cycle toxicity of bifenthrin (FMC 54800) to the mysid, *Mysidopsis bahia*
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

FMC or other document number	Year	Title
A97-4700	1998	FMC 54800 Technical – Subchronic Neurotoxicity Screen in Rats
ABC 34846	1988	Full life cycle toxicity of ^{14}C FMC 54800 to fathead minnow (*Pimephales promelas*) in a flow-through system
ABC 36980	1989	Chronic Toxicity of ^{14}C-FMC 54800 to *Daphnia magna* 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 bobw-hite 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 *Daphnia magna*
BW-83-8-1445	1983	Acute Toxicity of FMC 54800 technical to bluegill (*Lepomis macrochirus*)
BW-83-8-1446	1983	Acute Toxicity of FMC 54800 technical to rainbow trout (*Salmo gairdneri*)
BW-85-2-1731	1985	Acute toxicity of ^{14}C-FMC 54800 to *Daphnia magna* under flow-through conditions
BW-85-3-1747	1985	The chronic toxicity of ^{14}C-FMC 54800 to *Daphnia magna* under flow through conditions
BW-85-4-1766	1985	The toxicity of ^{14}C-FMC 54800 to rainbow trout (*Salmo gaird-neri*) embryos and larvae
CGP-83-1	1983	Vapor Pressure of FMC 54800
E-17-99-47	1999	Effect of bifenthrin to sewage sludge
FCC57A/851423	1986	The effects of dietary inclusion of FMC 54800 on the repro-duction in the bobwhite quail
FCC58A/851430	1986	The effects of dietary inclusion of FMC 54800 on the repro-duction in the mallard duck
FCC82/85693	1985	The acute toxicity (LC50) of FMC 54800 to the earthworm *Eisenia foetida*
na	1985	Bifenthrin toxicity to algae
P-0698	1983	Octanol water partition coefficient of FMC 54800
P-0701	1983	Hydrolysis of bifenthrin
P-17-99-45	1999	Water solubility of bifenthrin
P-2544	1991	Bifenthrin: physical and chemical characteristics
P-3837	2006	Photodegradation of Bifenthrin in Buffered Aqueous Solution at pH 7 by Simulated Sunlight
PC-0059	1986	A Dermal Absorption Study in Rats with ^{14}C-FMC 54800.
Ph.L-SD-519-84	1984	Preliminary ecotoxicological tests of FMC 54800 on *Apis melli-fera*