Table A7.5.6-1. Talstar 8 SC (1000 mL/ha) – pitfall traps

Sample dates	DBT	DAT							
	7-5	7-9	21-23	35-37	55-57	63-65	84-86	104-106	126-128
Carabidae									
Bembidion obtusum	n.s.	*	n.s.	n.s.	n.s.	n.s.	-	-	-
Nebria brevicollis	-	n.s.	n.s.	-	-	-	-	-	-
Pterostichus melanarius	-	-	-	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Trechus qudristriatus	-	-	-	n.s.	n.s.	-	-	-	-
Carabid larvae	n.s.	n.s.	n.s.	-	-	-	-	-	-
Total Carabidae	n.s.	*	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Staphylinidae									
Xantholininae	-	-	-	-	n.s.	n.s.	-	-	-
Total Staphylinidae	n.s.	n.s.	**	n.s.	n.s.	n.s.	-	-	-
Chrysomelidae									
Chrysomelid adults	n.s.	-	n.s.	n.s.	n.s.	-	-	-	-
Linyphiidae									
Oedothorax apicatus	n.s.	-	*	n.s.	n.s.	n.s.	-	n.s.	-
Total linyphiids	n.s.	n.s.	n.s.	**	n.s.	n.s.	n.s.	n.s.	-

[+] Numbers were significantly higher in the treatment than the control plots. However, the designation 'ns' has been given to clarify that there was not a significant reduction compared to the control.

- indicates insufficient number in samples for analysis.

ns indicates no significant difference from control.

* numbers in treatment significantly reduced relative to control (* = $P < 0.05$, ** = $P < 0.01$, **** = $P < 0.001$).

Table A7.5.6-2. Talstar 8 SC (750 mL/ha) – pitfall traps

Sample dates	DBT	DAT							
	7-5	7-9	21-23	35-37	55-57	63-65	84-86	104-106	126-128
Carabidae									
Bembidion obtusum	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	-	-	-
Nebria brevicollis	-	n.s.	n.s.	-	-	-	-	-	-
Pterostichus melanarius	-	-	-	n.s.	n.s.	n.s.	n.s.	n.s.+	n.s.
Trechus quadristriatus	-	-	-	n.s.	n.s.	-	-	-	-
Carabid larvae	n.s.	n.s.	n.s.	-	-	-	-	-	-
Total Carabidae	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Staphylinidae									
Xantholininae	-	-	-	-	n.s.	n.s.	-	-	-
Total Staphylinidae	n.s.	n.s.	**	n.s.	n.s.	n.s.	-	-	-
Chrysomelidae									
Chrysomelid adults	n.s.	-	n.s.	n.s.	n.s.	-	-	-	-
Linyphiidae									
Oedothorax apicatus	n.s.	-	n.s.	n.s.	n.s.	n.s.	-	n.s.	-
Total linyphiids	n.s.	n.s.	n.s.	*	n.s.	n.s.	n.s.	n.s.	-

Table A7.5.6-3. Chlorpyrifos toxic reference – pitfall traps

Sample dates	DBT	DAT							
	7-5	7-9	21-23	35-37	55-57	63-65	84-86	104-106	126-128
Carabidae									
Bembidion obtusum	n.s.	***	***	***	**	**	-	-	-
Nebria brevicollis	-	n.s.	**	-	-	-	-	-	-
Pterostichus melanarius	-	-	-	n.s.	*	***	***	n.s.	n.s.
Trechus qudristriatus	-	-	-	***	n.s.	-	-	-	-
Carabid larvae	n.s.	***	**	-	-	-	-	-	-
Total Carabidae	n.s.	***	***	***	*	***	**	*	n.s.
Staphylinidae									
Xantholininae	-	-	-	-	***	***	-	-	-
Total Staphylinidae	n.s.	*	**	**	***	**	-	-	-
Chrysomelidae									
Chrysomelid adults	n.s.	-	n.s.	n.s.	n.s.	-	-	-	-
Linyphiidae									
Oedothorax apicatus	n.s.	-	n.s.	n.s.	n.s.+	n.s.	-	n.s.	-
Total linyphiids	n.s.	n.s.	n.s.	n.s.	n.s.+	n.s.	n.s.	n.s.+	-

Table A7.5.6-4. Talstar 8 SC (1000 mL/ha) – soil-core samples

Sample dates	DBT	DAT							
	12	8	23	37	51	68	90	106	131
Acari									
Total soil mites	n.s.	n.s.	n.s.	n.s.	n.s.	*	n.s.	n.s.	n.s.
Juvenile soil mites	-	-	-	n.s.	-	-	n.s.	n.s.	-
Mesostigmata	-	-	n.s.	n.s.	*	-	**	-	-
Oribatida	-	-	-	-	-	-	-	n.s.	n.s.
Prostigmata	-	-	-	n.s.	n.s.	*	n.s.	n.s.	-
Collembola									
Total Collembola	n.s.	n.s.	n.s.	n.s.	n.s.	-	-	n.s.	-

Table A7.5.6-5. Talstar 8 SC (750 mL/ha) – soil-core samples

Sample dates	DBT	DAT							
	12	8	23	37	51	68	90	106	131
Acari									
Total soil mites	n.s.	n.s.	n.s.	n.s.	n.s.	*	n.s.	n.s.	n.s.
Juvenile soil mites	-	-	-	**	-	-	n.s.	n.s.	-
Mesostigmata	-	-	*	*	n.s.	-	**	-	-
Oribatida	-	-	-	-	-	-	-	n.s.	n.s.
Prostigmata	-	-	-	n.s.	n.s.	**	*	n.s.	-
Collembola									
Total Collembola	n.s.	n.s.	n.s.	n.s.	n.s.	-	-	n.s.	-

Table A7.5.6-6. Chlorpyrifos toxic reference – soil-core samples.

Sample dates	DBT	DAT							
	12	8	23	37	51	68	90	106	131
Acari									
Total soil mites	n.s.	n.s.	n.s.	**	n.s.	**	n.s.	n.s.	n.s.
Juvenile soil mites	-	-	-	*	-	-	n.s.	n.s.	-
Mesostigmata	-	-	n.s.	n.s.	n.s.	-	**	-	-
Oribatida	-	-	-	-	-	-	-	n.s.	n.s.
Prostigmata	-	-	-	*	n.s.	***	**	n.s.	-
Collembola									
Total Collembola	n.s.	*	n.s.	n.s.	n.s.	-	-	n.s.	-

Table A7.5.6-7. Talstar 8 SC (1000 mL/ha) – suction samples

Sample dates	DBT	DAT							
	1	5	20	33	48	65	82	103	124
Collembola									
Entomobryomorpha	n.s.	n.s.	n.s.	-	n.s.+	-	-	n.s.	-
Symphypleona	-	n.s.	-	-	-	-	n.s.	n.s.	n.s.
Total Isotomidae	n.s.	n.s.	n.s.	-	n.s.	-	-	n.s.	-
Total Collembola	n.s.	n.s.	n.s.	-	n.s.+	-	n.s.	n.s.	n.s.

Table Table A7.5.6-8. Talstar 8 SC (750 mL/ha) – suction samples

Sample dates	DBT	DAT							
	1	5	20	33	48	65	82	103	124
Collembola									
Entomobryomorpha	n.s.	n.s.	n.s.	-	n.s.	-	-	n.s.	-
Symphypleona	-	n.s.	-	-	-	-	n.s.	n.s.	n.s.
Total Isotomidae	n.s.	n.s.	n.s.	-	n.s.	-	-	n.s.	-
Total Collembola	n.s.	n.s.	n.s.	-	n.s.	-	n.s.	n.s.	n.s.

Table A7.5.6-9. Chlorpyrifos toxic reference – suction samples

Sample dates	DBT	DAT							
	1	5	20	33	48	65	82	103	124
Collembola									
Entomobryomorpha	n.s.	**	n.s.	-	n.s.	-	-	n.s.	-
Symphypleona	-	**	-	-	-	-	*	***	*
Total Isotomidae	n.s.	**	n.s.	-	n.s.	-	-	n.s.	-
Total Collembola	n.s.	**	*	-	n.s.	-	**	**	*

Section 7.5.6(02) Annex Point IIIA XIII.3	Effects on other terrestrial non-target organisms	
	1 REFERENCE	Official use only
1.1 Reference	Walker, H. M. (2005). Talstar 80 FLO: A field evaluation of the effects of an 80 g/L formulation of bifenthrin on the degradation of buried straw in litter bags. Ecotox Ltd, unpublished report no. ER-05-KCB206 28 September 2005 (unpublished)	
1.2 Data protection	Yes	
1.2.1 Data owner	FMC Chemical sprl	
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I.	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	No The study is field trial performed in accordance with the EPFES workshop, Lisbon, 24 -26 April 2002	
2.2 GLP *(only where required)*	Yes	
2.3 Deviations	No	
	3 MATERIALS AND METHODS	
3.1 Test material	Talstar 80 Flo (synonymous with Talstar 8SC, suspension concentrate)	
3.1.1 Lot/Batch number	Sample reference: PL04-0226	
3.1.2 Specification	Nominal content of bifenthrin = 8% w/v (80 g bifenthrin/L)	
3.1.3 Description	Not stated	
3.1.4 Purity	See specification above	
3.1.5 Stability	Expiry date on the product is April 2006, test material applied on May 2004	
3.3 Methods		

Section 7.5.6(02) Annex Point IIIA XIII.3	Effects on other terrestrial non-target organisms	
3.3.1 Study site	'Gymkhana field', Kersbrook Cross, Bray Shop, Cornwall, UK (OS grid reference: SX 308 748). Test initiated on a bare plot (79 m x 13 m) along the northeast edge of the field, bounded by a hedge. Maize grown on site in three preceding years. Soil was a loam with particle size distribution of 35% w/w sand (2.00 – 0.05 mm), 48% silt (0.05 – 0.002 mm) and 17% clay (< 0.002 mm). Soil pH was 5.8, OM 7.1% w/w and WHC 32.8% w/w.	X
3.3.2 Application of test substances	For the two test treatments, bifenthrin was first applied to each experimental plot at the long-term plateau concentration of either 7.5 or 300 g a.s./ha in 400 L water/ha. Control plots were treated with 400 L water/ha. The treatments were incorporated into the soil to a depth of 10 cm. Each treatment was replicated six times giving a total of 18 experimental plots (3 treatments x 6 replicates for each treatment). The experimental litter bags were buried 11 days after the long-term plateau concentration treatments to a depth of approximately 5 cm. Four days later cumulative annual application rate applications of 32 or 80 g a.s./ha were applied to each experimental plot in 400 L water/ha. Control plots were again treated with water at 400 L water/ha.	X
3.3.3 Sampling	The soil concentration of bifenthrin was determined by taking five soil cores (5 x 10 cm) from each plot after each application. The litter bags were exhumed approximately one, three, six, nine and twelve months after the second application (cumulative annual application). The samples were washed, dried and then weighed before combustion at a minimum temperature of 600°C for at least 30 minutes. Calculations of the ash-free dry weight were made and used to determine the percentage degradation.	
3.3.4 Statistical analyses	All results were transformed to arcsin square root before statistical analysis by ANOVA and Dunnett's test.	
	4. RESULTS	
4.1 Litter bags	Degradation at the lowest application rate was not significantly lower than the control on any sampling occasion. Degradation in the highest application treatment was only significantly lower than the control three months after treatment. This difference was greater than 10%.	
4.2 Residues in soil cores	Mean residues of bifenthrin in the soil cores collected from the treated plots were between 87 and 139% of the nominal concentrations and were thus within the 50 – 150% guideline recommendations.	X
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The objective was to evaluate the effect of bifenthrin (applied as an 80 g a.s/L SC formulation) on biological function in soil as determined by the degree of degradation of buried straw. The study was conducted in an agricultural field in SW England, UK and comprised of a water treated control and two test treatments. For the two test treatments, bifenthrin was first applied to each experimental plot at the long-term plateau concentration of either 7.5 or 300 g a.s./ha in 400 L water/ha. Control plots were treated with 400 L water/ha. The treatments were incorporated into the soil to a depth of 10 cm. Each treatment was replicated six times giving a total of 18 experimental plots (3 treatments x 6 replicates for each treatment). The experimental litter bags were buried 11 days after the long-term	

Section 7.5.6(02) **Annex Point IIIA XIII.3**	**Effects on other terrestrial non-target organisms**	
	plateau concentration treatments to a depth of approximately 5 cm. Four days later cumulative annual application rate applications of 32 or 80 g a.s./ha were applied to each experimental plot in 400 L water/ha. Control plots were again treated with water at 400 L water/ha. The soil concentration of bifenthrin was determined by taking five soil cores (5 x 10 cm) from each plot after each application. The litter bags were exhumed approximately one, three, six, nine and twelve months after the second application (cumulative annual application). The samples were washed, dried and then weighed before combustion at a minimum temperature of 600°C for at least 30 minutes. Calculations of the ash-free dry weight were made and used to determine the percentage degradation. All results were transformed to arcsin square root before statistical analysis by ANOVA and Dunnett's test.	
5.2 Results and discussion	Degradation at the lowest application rate was not significantly lower than the control on any sampling occasion. Degradation in the highest application treatment was only significantly lower than the control three months after treatment. This difference was greater than 10%. Mean residues of bifenthrin in the soil cores collected from the treated plots were between 87 and 139% of the nominal concentrations and were thus within the 50 – 150% guideline recommendations.	
5.3 Conclusion	Under the conditions of the study, six months after treatment there were no significant effects on straw degradation in litter bags following the application of bifenthrin at either 7.5 + 32 g a.s./ha or 300 + 80 g a.s./ha.	
5.3.1 Reliability	1	
5.3.2 Deficiencies	No	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		

Section 7.5.6(02) Annex Point IIIA XIII.3	Effects on other terrestrial non-target organisms	
Materials and Methods	Agree with the applicant's version. **Revisions/amendments:** **3.3.1 Study site** *:... 48% silt (0.05 – 0.002 mm) and 17% clay (< 0.002 mm). Soil pH was 5.8, ~~OM~~* organic matter *7.1% w/w and ~~WHC~~* water holding capacity *32.8% w/w.* **3.3.2 Application of the test substance :** *~~For the two test treatments,~~* The study comprised a water control and two test item treatments. Each test item treatment represented a model crop system: a low crop use rate and a higher rate that represents possible future use. The test item was applied on two occasions for each model crop system, once to represent the long-term plateau concentration and the second to represent total accumulated annual concentration. B*~~b~~ifenthrin was first applied to each experimental plot at the long-term plateau concentration of either 7.5 or 300 g a.s./ha* (low crop use rate and future use respectively) *in 400 L water/ha. Control plots were treated with 400 L water/ha. The treatments were incorporated into the soil to a depth of 10 cm. Each treatment was replicated six times giving a total of 18 experimental plots (3 treatments x 6 replicates for each treatment).* *The experimental litter bags were buried 11 days after the long-term plateau concentration treatments to a depth of approximately 5 cm. Four days later cumulative annual application rate applications of 32 or 80 g a.s./ha were applied to each experimental plot* (low crop use rate and future use respectively) *in 400 L water/ha. Control plots were again treated with water at 400 L water/ha.*	
Results and discussion	Agree with the applicant's version. **Revisions/amendments:** **4.2 Residues in soil cores:** *Mean residues of bifenthrin in the soil cores collected from the treated plots were between 87 and 139% of the nominal concentrations and were thus within the 50 – 150% guideline recommendations.* Therefore, initial concentrations after the second application can be considered to be 0.026 mg/kg$_{dwt}$ (low crop use model) and 0.25 mg/kg$_{dwt}$ (future use model).	
Conclusion	Agree with the applicant's version.	
Reliability	1	
Acceptability	Acceptable	
Remarks	The study met with the following validity criteria (according to the OECD draft guideline 'Breakdown of organic matter in litterbags'): - At least 60% breakdown had occurred in the control plots by the end of the study. - The maximum coefficient of variation was less than 40% for breakdown in control plots during the first six months of the study. - The concentration of Bifenthrin in the soil cores collected for soil residue analysis was within 50-150% of the nominal concentration.	
	COMMENTS FROM	
Date		
Materials and Methods		
Results and discussion		
Conclusion		

Section 7.5.6(02) Annex Point IIIA XIII.3	Effects on other terrestrial non-target organisms	
Reliability		
Acceptability		

Table A7.5.6-10. Mean percentage degradation of buried straw litter bags following application of Talstar 80 SC to soil

Mean percentage degradation			
Exhumation	**Water control**	**7.5 + 32 g a.s./ha**	**300 + 80 g a.s./ha**
1 MAT	11.68	16.87*	18.80*
3 MAT	43.42	43.36	36.90**
6 MAT	55.42	55.12	53.36
9 MAT	59.62	58.33	56.68
12 MAT	69.25	73.82	69.74

MAT = Months after Treatment
** significantly higher degradation ($p < 0.05$) compared to the control*
*** significantly lower degradation ($p < 0.05$) compared to the control*

Section A7.5.7 Annex Point IIA7.5.7	Effects on mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	According to the 'Technical Guidance Document on data requirements', this is an additional data requirement. Tests may be required if direct and/or indirect exposure for mammals is possible. This is not the case for bifenthrin and its intended uses.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	01/03/2005	
Evaluation of applicant's justification	The lack of contamination of mammals is insufficiently justified. Exposure of mammals may arise from consumption of earthworm contaminated in soil, or plants in contact with soil, or aquatic organisms in contact with contaminated water, or even directly for rodents.	
Conclusion	Results are available in the toxicological section of the dossier. No further test are required.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.6 Summary of ecotoxicological effects and fate and behaviour in the environment

Annex Point IIA7.6

Official use only

1 REFERENCE

1.1 Reference Cross reference to Document II-A

RMS comment Document IIA as submitted by the notifier is reproduced below.

4 ENVIRONMENTAL EFFECTS ASSESSMENT

4.1 Fate and distribution in the environment

4.1.1 Degradation

4.1.1.1 Biodegradation (ready)

Guideline / Test method	Test type*	Test para-meter	Inoculum			Additional substrate	Test substance concentr.	Degradation		Reference
			Type	Concentration	Adap-tation			Incubation period	Degree [%]	
OECD 301B	Ready	CO_2 evolution	Activated sludge	1%	No	No	10 mg/L 20 mg/L	28 days	11 4	A7.1.1.2.1 (01)

*Test on *inherent* or *ready* biodegradability according to OECD criteria

A ready biodegradability (CO_2 evolution) test (not under GLP) clearly showed that bifenthrin in concentrations of 10 and 20 mg/L is not readily biodegradable. An inherent biodegradability test has not been carried out. In view of its relative stability in simulation tests, bifenthrin is considered to be not inherently biodegradable.

4.1.1.2 Biodegradation in water/sediment systems

A study under GLP was carried out (A7.1.2.2.2 (02)) to investigate the degradation of phenyl- and cyclopropyl-^{14}C labelled bifenthrin in two types of sediment. Bifenthrin rapidly disappeared from the water phase and was transported to the sediment phase. Bifenthrin was slowly degraded in the water/sediment systems. DT_{50} values were as follows: Calwich Abby Lake: DT_{50} system 266 d; DT_{90} system 881 d; DT_{50} water 2.7 d; DT_{90} water 8.7 d; Swiss Lake: DT_{50} system 95 d; DT_{90} system 316 d; DT_{50} water 2.6 d; DT_{90} water 10.3 d.
No metabolites ≥ 10% were found in the water phase. 4'-Hydroxybifenthrin was the only metabolite in the sediment ≥ 10% (11.1% on day 99 in the Swiss Lake system). The amount of bifenthrin in the sediment after 14 days was 87-95%. The mineralization ranged from 3.5% to 27% after 99 days and the maximum amount of bound residue was 14.2% after 99 days.
Based on several water/sediment studies, including the one mentioned above, Verhaar (2003, included as A7.1.2.2.2(03)) derived a dissipation half life from water for bifenthrin of 0.8 days, (k = 0.87 d^{-1}). This dissipation half life combines the degradation of bifenthrin in the aqueous compartment (DT_{50} = 1.4–74.6 days) and the adsorption of bifenthrin to sediment (log K_{OM} = 3.22–5.03).

4.1.1.3 Biodegradation in soil

Several reliable studies (ref. A7.2.1 (01), A7.2.2.1 (01), A7.2.2.1 (02)), all carried out under GLP, were performed on the rate and route of degradation of cyclopropyl- and phenyl-^{14}C labelled bifenthrin in 4 soil types. Bifenthrin was slowly degraded in these soils. DT_{50} values normalized to 20 °C were generally > 90 days but < 180 days. The average DT_{50} was 161 d (4 soils, 2 labels). No reliable calculations of DT_{90} values could be given. The formation of CO_2 within approx. 120 days was up to 50%, showing that bifenthrin is well mineralized in soil. Bound residues remained below 25% after approx. 120 days and were thus much below the threshold value of 70%. No single metabolite ever exceeded an amount of 10%. 4'-Hydroxybifenthrin, 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane carboxylate (TFP acid), 2-methyl-3-phenylbenzyl alcohol (BP

alcohol) and 2-methyl-3-phenylbenzoic acid could be identified as metabolites (maximum 8.2% for 4'-hydroxy-bifenthrin).
Several tests were carried out under field conditions. Following the review of the EU-Dossier under Council Directive 91/414/EEC for bifenthrin by the RMS (France), a recalculation of the DT_{50} values for the available field dissipation studies has been undertaken, including the determination of goodness of fit parameters according to the procedure outlined in FOCUS (2005); the derived DT_{50} values have been normalised to 20°C and field capacity at 10 kPa (pF2). The normalised (20°C and pF2) geometric mean DT50 was calculated to be 86.97 days.

4.1.1.4 Abiotic degradation

Hydrolysis

Guideline / Test method	pH	Tempe-rature [°C]	Initial TS concentration, C_0 [mol/L]	Reaction rate constant, K_h [d^{-1}]	Half-life, DT_{50} [day]	Coefficient of correlation, r_2	Reference
Method follows generally OECD 111	5.05	25	1.23×10^{-6}; 12.3×10^{-6} *	< 0.03	> 22	Not applicable	A7.1.1.1.1 (01)
	7.08	25	1.23×10^{-6}; 12.3×10^{-6}	< 0.03	> 22	Not applicable	
	8.97	25	1.23×10^{-6}; 12.3×10^{-6}	< 0.03	> 22	Not applicable	

* 0.52 and 5.22 mg/L

A hydrolysis experiment (not under GLP) carried out in buffers with pH 5, pH 7 and pH 9 at 25 °C showed that bifenthrin is hydrolytically stable in water. At initial test concentrations of 0.52 and 5.22 mg/L the DT50 value was >22 d at each pH tested. This is confirmed by its relative stability in simulation tests (soil, water/sediment).

Photolysis in water

Guideline / Test method	Initial molar TS concen-tration	Total recovery of test substance [% of appl.a.s.]	Photolysis rate constant (k^c_p)	Direct photolysis sunlight rate constant (k_{pE})	Reaction quantum yield (ϕ^c_E)	Half-life ($t_{1/2E}$)	Reference
In-house method (1985)	2.36 µmol/L*	93-99	0.0023 - 0.0032 d^{-1}	0.0023 – 0.0032 d^{-1}	Not measured	209-300 days	A7.1.1.1.2 (01)
Draft OECD Guideline (August 2000)	49.6 µg/L	92.1±6.6%	0.0716 d-1	0.0294 d-1	7 x 10-6	24.4 days	A7.1.1.1.2 (02)

* 1 mg/L

The results of a photolysis experiment (not under GLP) demonstrated that under late summer outdoor sunlight irradiation at 41° N (U.S.A.) photolysis of bifenthrin was slow with a half-life of about 255 days. No photoproduct accounted for more than 3%. However, this study was flawed in that it used borosilicate glass (not quartz glass) as the test vessel. Borosilicate glass does not allow uv light to penetrate. Thus, the photodegradation kinetics from this experiment are inappropriate to use.

A recent GLP photolysis experiment under artificial lighting conditions showed that bifenthrin degrades in water under influence of light with a half life of ca 10 days. Metabolites formed are biphenyl alcohol, biphenyl acid, and 4'-OH-bifenthrin. This is clearly a detoxifying pathway. Under normal water/sediment conditions this photodegradation is not easily observed since it is masked by the movement of bifenthrin to sediment. It is however likely the major degradation pathway for any bifenthrin remaining in the aqueous layer or any bifenthrin that is released from sediment to the aqueous layer. The estimated half life at 40°N during summer ('Madrid' conditions) is 24.4 days.

4.1.1.5 Distribution

Adsorption/desorption to/from soils

Guideline / Test method	Adsorbed a.s. [%]	K_a [1] [L/kg]	K_{aOC} [2] [L/kg]	K_d [3] [L/kg]	K_{dOC} [4] [L/kg]	K_a / K_d [5]	Degradation products		Reference
							Name	[%] of a.s.	
Method follows generally OECD 106							None	-	A7.1.3 (01)
Soil 1: Sandy loam	98	4160	239080	11044	634713	0.38			
Soil 2: Silt loam	98	5429	301611	11610	645000	0.47			
Soil 3: Clay loam	97	3688	275224	10254	765224	0.36			
Soil 4 : Sand	91	992	130526	3342	439737	0.30			

[1] K_a = Adsorption coefficient
[2] K_{aOC} = Adsorption coefficient based on organic carbon content
[3] K_d = Desorption coefficient
[4] K_{dOC} = Desorption coefficient based on organic carbon content
[5] K_a / K_d = Adsorption - Desorption distribution coefficient ratio

A screening adsorption test with 4 soils showed that bifenthrin is very strongly adsorbed to soil. Bifenthrin has an average K_{oc} of 236610 L/kg, range 130526 – 301611 L/kg. Bifenthrin is essentially immobile in the soil and no leaching to groundwater will occur.

4.1.2 Accumulation

Measurements of aquatic bioconcentration

Guideline / Test method	Expo-sure	Species	Initial concentr. of a.s. [µg/L]	Steady-state whole body BCF [L/kg]	Uptake rate constant	Depuration rate constant	Reference
similar to OECD Guideline 305C	70 d	*Cyprinus carpio*	0.0085 (low) 0.085 (high)	666 (low) 1082 (high)	1.8e-1	3.1e-2	A7.4.3.3. 1 (02)
Special higher tier test with sediment in the test system	21 d	*Pimephales promelas* Asellus sp *Daphnia magna* *Corbicula fulminea*	0.24–1.86 0.33 0.24 0.33-2.58	63 146 423 140	ND ND ND ND	ND ND ND ND	A7.4.3.3. 1 (03)
OECD 305C	28 (60+28)	*Lepomis macrochirus*	0.007 0.085	1241 1414	26.92 37.80	0.024 0.032	A7.3.3.3. 1(05)

Based on its log K_{ow} of 6.6, bifenthrin is expected to have a high bioconcentration potential. A BCF study was done with common carp. The results from this study were fitted to determine the steady state concentration of bifenthrin in fish. The BCF value for uptake of bifenthrin in fish from clean water based on the fitted steady state concentration at the high exposure level, is 1082 L/kg (see table). However, experiments carried out in the

presence of soil sediment show that the bioconcentration is greatly diminished by the presence of sediment particles (see table), due to preferential adsorption to sediment.
A new study with bluegill sunfish was performed (2006) and the results obtained in this study confirmed the results found in the carp study; indeed the whole steady state BCF was found to 1414.

Calculation of terrestrial bioconcentration and estimations of aquatic and terrestrial biomagnification
See Doc II-B

4.2 Effects on environmental organisms

4.2.1 Aquatic compartment

Acute toxicity to fish

Guideline / Test method	Species	Endpoint / Type of test	Exposure		Results			Remarks	Reference
			design	duration	LC_0 (µg/L)	LC_{50} (µg/L)	LC_{100} (µg/L)		
EPA	*O. mykiss*	Mortality	Flow through	96 h	0.03	0.1	0.3	-	A7.4.1.1 (04)
Higher tier test with sediment	*O. mykiss*	Mortality	Static	96 h	1.3	6.26	>9.7	-	A7.4.1.1 (05)

Bifenthrin is acute highly toxic to fish. Several studies (all under GLP) were conducted with two species in standard tests. The 96-h LC_{50} values ranged from 0.0001 to 0.00035 mg/L. However in acute higher tier tests in the presence of sediment the toxicity was diminished. In this case the 96-h LC_{50} was 0.00626 mg/L. It is accepted that such tests represent a more realistic exposure scenario and the endpoint values for risk assessment may be based on these LC_{50} values (see Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001) and HARAP[1], used for risk assessment of plant protection products).

Acute toxicity to invertebrates

Guideline / Test method	Species/ Endpoint	Exposure		Results			Remarks	Reference
		design	duration	EC_0 [µg/L]	EC_{50} [µg/L]	EC_{100} [µg/L]		
EPA OPP 72-2	*Daphnia magna*/Mortality	Flow-through	48 h	<0.025	0.11	>0.48	-	A7.4.1.2 (02)
Higher tier test with sediment	*Daphnia magna*/Mortality	Static	48 h	0.49	2.3	10.3	-	A7.4.1.2 (03)

Bifenthrin is acute highly toxic to invertebrates. Several studies (all under GLP) were conducted with *Daphnia magna, Cerodaphnia dubia, Thamnocephalus, Gammarus pulex, Hexagenia* spec. and a Caddis fly species in standard tests. 48-h or 24-h EC_{50} values ranged from 0.00011 to 0.0057 mg/L. However in acute higher tier tests in the presence of sediment the toxicity to *Daphnia magna* was diminished to an EC_{50} of 0.0023 mg/L. It is accepted that tests with sediments represent a more realistic exposure scenario and the endpoint values for risk assessment may be based on these LC_{50} values (see Guidance Document on Aquatic Ecotoxicology (Sanco/3268/2001) and HARAP[1], used for risk assessment of plant protection products).

[1] Campbell, P.J., Arnold, D.J.S, Brock, T.C.M., Grandy, N.J., Heger, W., Heimbach, F., Maund, S.J. and Streloke, M. (1999) Guidance document on higher-tier aquatic risk assessment for pesticides (HARAP), SETAC-Europe Publication, Brussels.

Growth inhibition in algae

Guideline / Test method	Species	Endpoint / Type of test	Exposure		Results (mg/L)			Remarks	Reference
			design	duration	NOE_rC	E_bC_{50} [1]	E_rC_{50} [2]		
OECD 201	*C. pyrenoidosa*	Cell growth	Static	72 h	50	> 50	>50	-	A7.4.1.3 (01)
	S. acutus				10	>10	>10		

[1] calculated from the area under the growth curve; [2] calculated from growth rate

Bifenthrin has a low toxicity to algae. The 72-h EC_{50} values of bifenthrin for the algae *Chlorella pyrenoidosa* and *Scenedesmus acutus* were > 50 mg/L and > 10 mg/L, respectively.

Chronic toxicity to fish

Guideline / Test method	Species/ Endpoint	Exposure		Result NOEC	Remarks	Reference
		design	duration			
Agrees with OECD 210	*Oncorhynchus mykiss* / larval survival	Flow-through	76 days	0.012 µg/L	ELS test	A7.4.3.2 (01)

The chronic toxicity of bifenthrin to fish is very high. In an ELS test with *Oncorhynchus mykiss* the 76-d NOEC was 0.012 µg/L, whereas in a Full Life Cycle test the 120-d NOEC was 0.04 µg/L. The acute/chronic ratio based on the clean water 96 hour study with *O. mykiss* and the 76 day ELS test with *O. mykiss* is 0.12.

Chronic toxicity to invertebrates

Guideline / Test method	Species/ Endpoint	Exposure		Result NOEC	Remarks	Reference
		design	duration			
Agrees with OECD 202, Part II	*Daphnia magna*/ reproduction	Flow-through	21 d	0.00095 µg/L	-	A7.4.3.4 (02)

Reproduction studies (under GLP) with *Daphnia magna* showed a high chronic toxicity of bifenthrin, with a lowest NOEC of 0.00095 µg/L. The 28-d NOEC for *Mysidopsis bahia* was 0.0012 µg/L. The acute/chronic ratio based on the clean water 48 hour study with *D. magna* and the 21 day reproduction test with *D. magna* is 0.0086.

No chronic toxicity tests with aquatic organisms in sediment-augmented systems were performed. However, as was argued previously, it is generally accepted that the presence of sediment represent a more realistic exposure scenario for substances like bifenthrin, and end point values for risk assessment may preferentially be based on effect values determined in the presence of sediment (see Guidance Document on Aquatic Ecotoxicology (Sanco/3268/2001) and HARAP[1], used for risk assessment of plant protection products). Therefore we have estimated sediment-augmented chronic toxicity end points for fish and invertebrates based on the acute toxicity determined in sediment-agumented toxicity tests and the acute/chronic ratios determined from acute and chronic studies conducted under clean water conditions. The resultant chronic toxicity end points for fish and invertebrates are presented in the next table:

Chronic toxicity to aquatic organisms under sediment-augmented conditions

Guideline / Test method	Species/ Endpoint	Exposure		Result NOEC	Remarks	Reference
		design	duration			

Estimation	*Oncorhynchus mykiss* / larval survival	N.A.	>28 days	0.75 µg/L		
Estimation	*D. magna* / *reproduction*	N.A.	21 days	0.0198 µg/L		

Toxicity to sediment dwelling organisms

Guideline / Test method	Species/ Endpoint	Exposure design	Exposure duration	Result	Remarks	Reference
Draft OECD 219	*Chironomus riparius*/ Mortality	Spiked water	28 d	NOEC = 0.32 µg/L LC_{50} = 3.96 µg/L	-	A7.4.3.5.1 (01)
	Chironomus tentans/ growth	Spiked sediment	10 d	NOEC = 83 µg/kg		A7.4.3.5.1 (02)

A study under GLP revealed that bifenthrin has a high toxicity to *Chironomus riparius* larvae in a spiked water phase test. The 28-d LC_{50} was 3.96 µg/L and the 28-d NOEC was 0.32 µg/L. In a spiked sediment test the 10 day NOEC for growth was 83 µg/kg.

Inhibition of microbial activity (aquatic)

Guideline / Test method	Species / Inoculum	Endpoint / Type of test	Contact time	Results EC_{20}	Results EC_{50}	Results EC_{80}	Remarks	Reference
OECD 209	Activated sludge	Oxygen uptake	3 h	>1929 mg/L	>1929 mg/L	>1929 mg/L	Concentrations far exceeding the solubility	A7.4.1.4 (01)

A study under GLP showed little to no effect of bifenthrin on the respiration of activated sludge micro-organisms. No effect was detected of concentrations up to 1929 mg/L. Bifenthrin is not expected to have any influence on sewage treatment plants.

4.2.2 Terrestrial compartment

Effects on earthworms

Guideline / Test method	Species/ Endpoint	Exposure duration	Result	Remarks	Reference
OECD 207	*Eisenia fetida*/mortality	14 d	LC_{50} > 18.9 mg/kg	-	A7.5.1.2 (01)
ISO 11268-2	*Eisenia fetida*/reproduction	56 d	NOEC = 2.13 mg/kg	-	A7.5.2.1 (01)

Studies (under GLP) have been performed on the acute toxicity of bifenthrin to the earthworm *Eisenia fetida*. The results of these studies showed that bifenthrin has an acute 14-d LC_{50} higher than 18.9 mg/kg soil and a 56-d NOEC for reproduction equal to 2.13 mg/kg.

Effects on soil micro-organisms

Bifenthrin has little effect on soil micro-organisms. A study under GLP (ref. A7.5.1.1 (01)) was carried out on the effect of an agricultural formulation of bifenthrin on nitrogen conversions of lucerne meal in soil and on substrate induced soil respiration. The concentration in the soil was 0.13 mg a.s./kg soil. After 28 days formation of ammonium was low and similar to the control. The average final nitrate and total mineral-N concentrations were 20% lower in the treated samples than in the control after 28 d. The substrate induced oxygen consumption was 2.1% higher in the treated samples than in the control after 28 days. Thus no effects greater than 25% were observed, meaning that bifenthrin has no effect on soil micro-organisms at normal agricultural application rates (i.e. 0.39 kg/ha). Note that nitrate formation in soil nitrification tests is highly variable, and a difference of ± 25% compared to the control is considered to be within the normal variability. Given the nature of the test no NOEC can be derived other than to observe that at normal agricultural application rates, bifenthrin has no effect on soil nitrification.

Effects on plants

Bifenthrin has no effect on the emergence of seedlings of 4 dicotyledons and 2 monocotyledons, at a soil addition rate of 0.08 mg/kg dry soil weight.

4.2.3 Atmosphere

Bifenthrin has a low volatility: its saturated vapour pressure is 2.41 x 10^{-5} Pa. It has a moderate volatility from water because its estimated Henry's law constant is 101 Pa m^3 mol^{-1}, which is equivalent with an air-water partition coefficient of 0.04 L/L. However, emission from surface water to atmosphere will not occur because of the strong adsorption of bifenthrin to sediment.

The atmospheric oxidation by hydroxyl radicals and ozone was calculated using the Atmospheric Oxidation Program for Microsoft Windows (AOPWIN v. 4.01, in EPISUITE v 3.11). The estimation methods used by AOPWIN are based on the structure-activity relationship (SAR) methods developed by Atkinson.
The calculated overall OH rate constant is 29.6 x 10^{-12} cm^3 mol^{-1} sec^{-1}. Assuming a 12-h day and an OH concentration of 1.5 x 10^6 cm^{-1} this gives a half-life of 0.36 days.
For the ozone reaction the overall rate constant is 0.163 x 10^{-17} cm^3 mol^{-1} sec^{-1} and the half-life is 7.05 days (at 7 x 10^{11} mol ozone/cm^3).

Based on the atmospheric properties and fate of bifenthrin there is no need for special consideration. It is also not expected that bifenthrin will have an effect on:

- degrading air quality
- tropospheric ozone building
- acidification
- ozone layer depletion
- global warming

Section A8

Annex Point IIA8

Measures necessary to protect man, animals and the environment

8.1 Recommended methods and precautions concerning handling, use, storage, transport or fire

HANDLING
Technical measures : Vapour extraction at source
STORAGE
Recommended storage conditions:
- in a cool, well-ventilated area
- protected from humidity
- away from any source of ignition
- out of reach of children.
- away from food and drinks and animal foodstuffs

Recommended packaging materials:
- Original packaging

8.2 In case of fire, nature of reaction products, combustion gases, etc.

STABILITY AND REACTIVITY
Stability : Stable at ambient temperature and under normal conditions of use

Hazardous reactions :
- May decompose on heating
- Hazardous decomposition products :

On combustion or on thermal decomposition (pyrolysis) releases:
Carbon oxides (CO, CO2), Hydrogen fluoride, Hydrogen chloride

FIRE FIGHTING MEASURES
Suitable extinguishing media : Powders, Foam, Carbon dioxide (CO2)
Not suitable extinguishing media : Water (the product is hazardous for the environment - do not dilute it)
Specific fire fighting methods : Isolate fire area. Evacuate downwind
Contain the extinguishing fluids by bunding (the product is hazardous for the environment)
Do not attempt to fight the fire without suitable protective equipment
Do not breathe fumes
Protection of fire-fighters : Self-contained breathing apparatus
Complete protective clothing

8.3 Emergency measures in case of an accident

FIRST AID MEASURES
Inhalation : Move the affected person to the fresh air
If the person feels unwell: Call a doctor
Skin contact : Remove all contaminated clothing and footwear
Wash immediately with plenty of soap and water. In case of redness or irritation, call a doctor
Eye contact : Rinse immediately with plenty of water (for at least 15 minutes).
If irritation persists, consult an eye specialist
Ingestion : If the person is fully conscious, make him/her drink water.
Never give an unconscious person anything to drink
If the person is fully conscious, try to induce vomiting
Call a doctor immediately

8.4 Possibility of destruction or decontamination following release in or on the following: (a) air (b) water,

ACCIDENTAL RELEASE MEASURES
Personal precautions : In case of important spillage :
Only qualified personnel equipped with appropriate protective equipment may intervene
Environmental precautions : Do not allow product to spread into the environment

Section A8 Annex Point IIA8		Measures necessary to protect man, animals and the environment
	including drinking water (c) soil	Contain the spilled material by bunding (product is hazardous for the environment) Methods for cleaning up : - Recovery : Recover the product with absorbent material - Neutralization : Absorb spillage with: - earth or sand Neutralize non-recoverable product with : - a solution of caustic or soda ash, and an appropriate alcohol (methanol, ethanol or isopropanol) - Cleaning/decontamination : Wash with plenty of water and detergent. - Disposal : Dispose of contaminated material at an authorized site
8.5	**Procedures for waste management of the active substance for industry or professional users**	**DISPOSAL CONSIDERATIONS** WASTE FROM PRODUCT : Destruction/Disposal : Dispose of in accordance with relevant local regulations Incinerate at a licensed installation CONTAMINATED PACKAGING : Destruction/disposal : Recycle following cleaning or dispose of at an authorised site
8.6	**Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms**	No unintended side-effects reported
8.7	**Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of ground water against pollution caused by certain dangerous substances**	Not applicable: none of the substances included into the formulation is listed on directive 80/68/EEC

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	September2005
Materials and Methods	Applicants version is acceptable

Section A8

Annex Point IIA8

Measures necessary to protect man, animals and the environment

Results and discussion	Applicants version is acceptable except for the following: *8.7: the following text has to be added for bifenthrin* Organohalogen compounds are covered by List I of the Annex to Directive 80/68/EEC. Biocides and their derivatives are covered by List II of the Annex to Directive 80/68/EEC.
Conclusion	Applicants version is acceptable
Reliability	
Acceptability	acceptable
Remarks	

Section A9 Classification and labelling

Annex Point IIA9

9.1	**Symbols**	T, N
9.2	**Risk phrases**	R 20: Harmful by inhalation. R 25: Toxic if swallowed R 43: May cause sensitization by skin contact. R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
9.3	**Safety phrases**	S 1/2: Keep locked up and out of the reach of children S 23: Do not breathe vapour and spray S 24: Avoid contact with skin S 37: Wear suitable gloves. S 38: In case of insufficient ventilation, wear suitable respiratory equipment. S 45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible) S 29: Do not empty into drains.

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	September 2006

Section A9 Classification and labelling

Annex Point IIA9

RMS comments

Environmental classification:

Bifenthrin is currently not classified according to Annex I of Council Directive 67/548/EEC.

The proposition N, R50/53 is acceptable

As far as the substance is concerned, the sentence "S60-61 This material and its container must be disposed of as hazardous waste. Avoid release to the environment. Refer to special instructions/safety data sheets" is preferred.

Applicants version adopted

Human Health classification:

& 9.2 Risk Phrases should be amended as following:;

[R 23 Toxic by inhalation]
R 25: Toxic if swallowed
[R 38 Irritating to skin]
[R 40 Limited evidence of carcinogenic effect Category 3]
R 43: May cause sensitization by skin contact.
[R48/22 Danger of serious damage to health by prolonged exposure]

& 9.3 Safety phrases:
S 1/2: Keep locked up and out of the reach of children
S 23: Do not breathe vapour and spray

[S36/ S 37: Wear suitable protective clothing and gloves]

S 38: In case of insufficient ventilation, wear suitable respiratory equipment.
S 45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
S 29: Do not empty into drains.

Supprimé : R 20: Harmful by inhalation

Mis en forme

Supprimé : R 50/53: Very toxic to aquatic organisms, may cause long-term adverse¶ effects in the aquatic environment.¶

Supprimé : S 24: Avoid contact with skin

Supprimé : S 37

Supprimé : Wear suitable gloves

Supprimé : ¶